IN THE CIRCUIT COURT OF THE SIXTH JUDICIAL CIRCUIT
IN AND FOR PASCO COUNTY, FLORIDA

STATE OF FLORIDA, OFFICE OF THE ATTORNEY GENERAL, DEPARTMENT OF LEGAL AFFAIRS,

Plaintiff,

v. Case No. 2018-CA-001438

PURDUE PHARMA L.P., *et al.*, **FILED UNDER SEAL**

Defendants.

_____/

CVS HEALTH CORPORATION AND CVS PHARMACY INC.'S
MOTION TO EXCLUDE OPINIONS OF DR. ANDREW KOLODNY

CVS Health Corporation and CVS Pharmacy, Inc. (together, "CVS") move to exclude the opinions of Plaintiff's expert Dr. Andrew Kolodny. Kolodny's opinions lack a sufficient factual basis and are devoid of any connection to his experience. As to CVS, Kolodny's entire opinion relies on a handful of documents to claim that CVS published deceptive messages that caused the opioid crisis beginning in the late 1990s. In an attempt to support this speculative opinion, Kolodny has cited fewer than ten CVS-related documents—some of which are not written by CVS, others Kolodny does not claim contain deceptive statements, and all but one are from a time period when opioid sales were *decreasing* in Florida. Indeed, the primary document he relies on (and mischaracterizes) is from 2016—twenty years after Kolodny asserts that opioid sales first started inappropriately increasing, and five years after their sales in Florida peaked. And although Kolodny tries to attribute to CVS a few documents written by trade associations, he has no basis for doing so. At no point has Kolodny described how his experience allows him to conclude that the limited documents Plaintiff's counsel has cherry picked for him resulted in a "dramatic increase

in supply" of opioids. Ex. 1, A. Kolodny Rebuttal Rep. 25. Accordingly, his opinions as to CVS should be excluded.[1]

ARGUMENT

Under Florida law, an expert's opinion must be based on "sufficient facts or data." Fla. Stat. § 90.702(1). Each step of an expert's analysis must be "supported by good grounds," which "means that any step that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible." *McClain v. Metabolife, Int'l, Inc.*, 401 F.3d 1233, 1245 (11th Cir. 2005). In addition, where "the witness is relying solely or primarily on experience, then the witness must explain *how* that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *United States v. Frazier*, 387 F.3d 1244, 1261 (11th Cir. 2004) (quoting Fed. R. Evid. 702 advisory committee's note to 2000 amendments). Kolodny's opinions do not satisfy these threshold requirements.

A. Kolodny's CVS Opinions Are Not Based on Sufficient Facts or Data.

Kolodny's broad opinion—that CVS used "[d]eceptive messages" to "promot[e] use of prescription opioids," which "led to an increase in opioid sales and consumption," Ex. 1, Kolodny Rebuttal Rep. 4 ¶ 11—rests on a narrow set of documents spanning a fifteen year period. These anecdotal documents fail to prop up the extraordinary conclusion that CVS's alleged "marketing"

[1] CVS adopts and incorporates by reference the arguments in Defendants' Motion to Exclude the Expert Opinions of Dr. Andrew Kolodny and Incorporated Memorandum of Law. As Defendants explain, Kolodny is not qualified to opine about marketing causation because he has no specialized training, knowledge, or experience in marketing. In addition, his causation opinions are speculative and unreliable as he has not undertaken any statistical or similar analysis, he has failed to consider alternative causes, and he has not tied the effects of particular marketing efforts to specific Defendants, among other flaws. And Kolodny's abatement opinions should be excluded as unreliable and not tied to the facts of the case.

caused an increase in opioid use. *See McClain*, 401 F.3d at 1250 ("Uncontrolled anecdotal information offers one of the least reliable sources to justify opinions about both general and individual causation."). Indeed, Kolodny's opinions are nothing more than an improper narration of those documents. *See City of Huntington v. AmerisourceBergen Drug Corp.*, No. 3:17-01362, 2021 WL 1320716, at *2–3 (S.D.W. Va. Apr. 8, 2021) (precluding Kolodny from providing factual narratives because "[e]xpert testimony which 'merely regurgitates factual information that is better presented directly to the jury rather than through the testimony of an expert witness' is properly excluded" (citation omitted)).

The absence of sufficient facts underlying Kolodny's opinions is shown in his Opening Report, in which he relies exclusively on a single CVS document, which does not support his claim, as the source for all of CVS's purported "[d]eceptive and false messages." *See* Ex. 2, Kolodny Expert Rep. 29 n.107, 30 n.111, 31 n.114, 32 n.119 (all citing Ex. 3, CVS-MDLT3-000001481).[2] That document—a CVS "Opioid Prescriber Toolkit"—is from *2016*, *see* Ex. 3, CVS-MDLT3-000001481, well after Kolodny believes that opioid prescriptions began to inappropriately increase around 1997, *see* Ex. 2, Kolodny Expert Rep. 1 ("The growth in opioids after that year [1997] was not medically justifiable."). Indeed, the data cited in Kolodny's report show that, from 2011 to 2020, opioid sales *decreased* in Florida. *See id.* at 24 & fig. 10. There is no basis to find that the 2016 "Opioid Prescriber Toolkit" "increase[d] sales of opioids," *id.* at 28, when such sales were decreasing following its creation. And that single document, made almost 20 years after Kolodny believes opioid prescriptions started inappropriately increasing, cannot support the claim that CVS's alleged "marketing" had anything to do with that increase.

[2] The only other document cited in the Opening Report as to CVS is not identified as a source of any deceptive statements. *See* Ex. 2, Kolodny Expert Rep. 36 ¶ 14 & n.144.

Moreover, Kolodny mischaracterizes the Toolkit in a failed effort to force CVS into his misguided opinions. For instance, Kolodny attributes to CVS the statement "[f]ear of addiction is an inappropriate barrier to treatment of chronic pain and results in undertreatment of pain." *See* Ex. 2, Kolodny Expert Rep. 29 n.107 (citing Ex. 3, CVS-MDLT3-000001481, at CVS-MDLT3-000001529). But the Toolkit makes no such claim. It emphasizes that "opioids still should only be taken for the time that they are needed and at the lowest dose needed," while acknowledging that "[m]any patients fear becoming addicted to opioids." Ex. 3, CVS-MDLT3-000001481, at CVS-MDLT3-000001529. There is nothing deceptive about those claims.

Likewise, Kolodny asserts that CVS stated that "Veterans and the Elderly are appropriate targets for opioids." *See* Ex. 2, Kolodny Expert Rep. 32 n.119 (citing Ex. 3, CVS-MDLT3-000001481, at CVS-MDLT3-000001493). The Toolkit made no such statement, instead listing "current guidelines for treatment of selected types of pain," and including citations to two studies regarding "persistent pain in older persons." *See* Ex. 3, CVS-MDLT3-000001481, at CVS-MDLT3-000001493. Another statement attributed to CVS is that "[p]atients who appear to be suffering from opioid addiction may have 'pseudoaddiction' defined as drug seeking behavior caused by 'undertreatment of pain.' These patients should have their opioid dose increased." Ex. 2, Kolodny Expert Rep. 30 n.111 (citing Ex. 3, CVS-MDLT3-000001481, at CVS-MDLT3-000001513). But the Toolkit only relays the definition of "pseudoaddiction" found in the literature at the time. *See* Ex. 3, CVS-MDLT3-000001481, at CVS-MDLT3-000001513 (relying on "APS position statement, *Definitions Related to the Use of Opioids for the Treatment of Pain*"). Indeed, the Florida Board of Medicine's own standards of practice for the prescribing of controlled substance medications in effect from 2010 *defined* "pseudoaddiction" in this way:

(g) Pseudoaddiction. For the purpose of this rule, "pseudoaddiction" is defined as a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

See Ex. 4, Fla. Admin. Code § 64B8-9.013 (2010) (Standards of Practice for the Use of Controlled Substances for the Treatment of Pain).[3]

The last alleged "deceptive" message Kolodny attributes to CVS is that "[d]octors can prevent addiction in patients on opioids by using 'risk assessment tools' and by close monitoring." *See* Ex. 2, Kolodny Expert Rep. 31 n.112 (citing Ex. 3, CVS-MDLT3-000001481 at 1489, CVS-MDLT3-000001501). The cited portions of the Toolkit made no such unconditional statement. They provided "highlights" of "clinical guidelines" from the American Pain Society and American Academy of Pain Medicine, while explaining that "[i]dentifying patients who misuse opioids . . . is complex" and the screening tools have "limitations" and "cannot be applied universally." Ex. 3, CVS-MDLT3-000001481 at CVS-MDLT3-000001489, CVS-MDLT3-000001501.

Other scattered documents marshalled in Kolodny's Rebuttal Report do not support an opinion that CVS made deceptive messages or that such messages—even if made—contributed to an inappropriate increase in opioid use. For instance, Kolodny points to a 2001 letter from CVS that purportedly "promot[ed]" a website by Purdue. Ex. 1, Kolodny Rebuttal Rep. 12 (citing PDD1701189357); *see* Ex. 14, PDD1701189357. But Kolodny does not claim that the letter contains a deceptive statement by CVS. *See id.* Instead, the only allegedly deceptive statement connected to that website is an article—not written by CVS—from *2000*, a year before CVS allegedly "promoted" the website. *See* Ex. 6, PDD1701205785, at PDD1701205831 (cited Ex. 1,

[3] In 2019, the Board of Medicine amended its standards of practice for the use of controlled substances for the treatment of pain, and removed reference to the definition of "pseudoaddiction." *See* Ex. 5.

Kolodny Rebuttal Rep 12 & n.38). Kolodny does not state that the article was on the website when CVS promoted it, or that CVS knew of its existence.

Kolodny also misses the mark in seeking to attribute documents written by others to CVS. He cites three email chains from 2013 in which various groups opposed the rescheduling of certain prescription drugs. *See* Ex. 7, ENDO-FLAG-00367151 (Email chain including American Cancer Society (Mar. 18, 2013)) (cited Ex. 2, Kolodny Expert Rep. 36 ¶ 14); Ex. 8, CVS-MDLT1-000022717 (Email from National Association of Chain Drug Stores (Aug. 14, 2013)) (cited Ex. 1, Kolodny Rebuttal Rep. 14 ¶ 29 n.47); Ex. 9, CVS-MDLT1-0000025430 (Nov. 13, 2013) (similar) (cited Ex. 1, Kolodny Rebuttal Rep. 14 ¶ 29 n.47). Kolodny has no basis for opining that these documents should be ascribed to CVS (or indeed, any qualifications relevant to offering an expert opinion on questions of attribution or even about how members interact with trade groups).[4] Kolodny identifies no statement by CVS, let alone one that would be deceptive, in any of those three documents. *See* Ex. 2, Kolodny Expert Rep. 36 ¶ 14 (asserting only that "CVS and Walgreens were members" of "the National Association of Chain Pharmacies," which "attempted to block an effort by the DEA to up-schedule hydrocodone combination products"); Ex. 1, Kolodny Rebuttal Rep. 14 ¶ 29 & n.47 (similar). The only purportedly deceptive statements are from a *draft* letter, which Kolodny does not assert was ever sent or that CVS wrote or even saw the letter. *See* Ex. 1, Kolodny Rebuttal Rep. 14 ¶ 29 & n.48 (citing NACDS_MDL0003564); Ex. 10, NACDS_MDL0003564 ("attached is a draft letter"). Kolodny also cites a training document—

[4] Kolodny's reliance on documents petitioning government agencies for action on matters of public concerns would be inadmissible in any event because such comments are protected by the First Amendment petition clause and cannot be made a basis for liability. This issue will be the subject of a motion *in limine* to be filed by the deadline for such motions on February 7, 2022.

from 2015—authored by Therapeutic Research Center, not CVS. *See* Ex. 11, CVS-MDLT3-000015264; Ex. 1, Kolodny Rebuttal Rep. 13 ¶ 26 n.39.

In short, the entire foundation of Kolodny's opinion as to CVS relies on, at best, a handful of documents, some of which contain no statements by CVS, while others came years after opioid sales stopped increasing. Those limited documents are not sufficient for an expert opinion that CVS made deceptive statements that led to an increase in opioid use in Florida over two decades.

B. Kolodny Does Not Explain How His Experience Supports His Conclusion.

Not only do those documents fail to support Kolodny's unfounded opinion, but Kolodny never articulates how his experience connects those scattered documents to his conclusion. Courts do not admit opinions "merely by the *ipse dixit*" of an expert. *Frazier*, 387 F.3d at 1261; *see also id.* ("[T]he court's gatekeeping function requires more than simply 'taking the expert's word for it.'" (quoting Fed. R. Evid. 702 advisory committee's note to 2000 amendments)). But that is exactly what Kolodny asks this Court to do. Nowhere does he provide a link between his experience, the handful of CVS-related documents he identifies, and his broad conclusion that those documents led to an increase in opioid sales in Florida. *See Kemp v. State*, 280 So. 3d 81, 90 (Fla. 4th DCA 2019) (excluding opinion where "prosecution did not meet its burden to explain how [expert]'s experience led to the conclusion he reached"); *Quashen v. Carnival Corp.*, No. 1:20-cv-22299-KMM, 2021 WL 5978472, at *12 (S.D. Fla. Dec. 17, 2021) (excluding opinions where "[t]he opinions contained in [expert]'s report make no specific reference as to how any of his opinions are informed by his professional experience beyond a conclusory statement that his experience is the basis of his opinion").

Instead, Kolodny implicitly concedes that he has no experience in making such a connection. He defers to another expert, Matthew Perri, to explain "how the opioid Defendants, led by the manufacturers, dramatically expanded the overall market for opioids." Ex. 2, Kolodny

Expert Rep. 27. But Perri's expert report has *no opinions* as to CVS. *See* Ex. 12, Perri Expert Rep. 1 n.1 (defining "defendants" as "the manufacturing defendants, Teva, Endo and Allergan, and their related families of companies"); Ex. 13, Perri Dep. 271:20–21 ("[I]n my report, I -- I don't really address the pharmacy chains."). Accordingly, there is no basis in Kolodny's reports to conclude that his experience allows him to make the conclusion that the few documents concerning CVS have any relationship to an increase in opioid use.

CONCLUSION

The Court should exclude Dr. Andrew Kolodny's opinions as to CVS.

January 21, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on January 21, 2022, a true and correct copy of the foregoing was filed with the Clerk for Court using the Florida Courts e-Filing Portal, which will provide copies to all parties of record via electronic mail.

/s/ Marcos E. Hasbun
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Exhibit 1

IN THE CIRCUIT COURT OF THE SIXTH JUDICIAL CIRCUIT
IN AND FOR PASCO COUNTY, FLORIDA

STATE OF FLORIDA, OFFICE OF THE ATTORNEY GENERAL, DEPARTMENT OF LEGAL AFFAIRS,

Plaintiff,

v. Case No. 2018-CA-001438

PURDUE PHARMA L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS INC., JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, CEPHALON, INC., TEVA PHARMACEUTICALS USA, INC., ALLERGAN FINANCE, LLC, ACTAVIS PHARMA, INC., ACTAVIS LLC, INSYS THERAPEUTICS, INC., AMERISOURCEBERGEN DRUG CORPORATION, CARDINAL HEALTH, INC., MCKESSON CORPORATION, MALLINCKRODT LLC, WALGREEN CO., CVS HEALTH CORPORATION, and CVS PHARMACY, INC.,

Defendants.

Expert Rebuttal Report of Andrew Kolodny, M.D.

October 29, 2021

HIGHLY CONFIDENTIAL

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I. Introduction and Summary

I have been retained on behalf of the State of Florida to opine on the nature of opioid addiction, on the conduct of the Defendants in its case against Purdue Pharma L.P., et al, on the public health crisis caused by the oversupply of opioids in Florida, and on strategies to abate the opioid crisis.

In undertaking this assignment, I have applied my years of experience in public health, public policy, addiction medicine, and research on opioid prescribing, marketing of opioids, and on the root causes of the opioid crisis. On July 31, 2021, I submitted an affirmative expert report on behalf of the Florida Attorney General's Office. I refer to this report herein as "my report" or my "opening" or "affirmative" report.

Counsel for the Florida Attorney General's Office has asked me to respond to various opinions offered by Defendants' retained experts, including Drs. Warfield, Garthwaite, Michna, Grabowski, Yong, Fryzek, McCrary, Baker, Kyle, Rosenblatt, Chintagunta, Wailes, Nicholson, Choi and Ms. Bramer. I have also been asked to explain the importance of their views, if any, on the expert opinions set forth in my Affirmative Report. My qualifications are described in my Affirmative Report, including its Exhibit 1. I am being compensated for my work at the rate of $725 per hour, as noted in my initial report.

A list of documents I considered — in addition to those listed in Schedule 3 of my Affirmative Report — is attached as Schedule 1. An updated list of cases in which I have provided testimony is attached as Updated Schedule 2.

A summary of my opinions contained in this rebuttal report follows.

1. The increased prevalence of opioid use disorder (OUD) that led to an array of health and social problems referred to as the opioid crisis was primarily caused by overexposing the United States population, including people in the State of Florida, to prescription opioids. This overexposure of the population to prescription opioids was largely a consequence of the Defendants' multi-faceted campaign to increase sales of opioid analgesics in the United States, including Florida. The unbranded campaign and branded campaigns relied on deceptive statements about opioids. Defendants disseminated false and misleading statements and materials that downplayed the serious risks of opioids, particularly the risk of addiction, and exaggerated the benefits of long-term use. Despite overwhelming evidence that an oversupply of opioids was fueling a public health crisis, Defendants attempted to preserve the massive oversupply by using new regulatory requirements as a further opportunity to continue promoting their deceptive messages to prescribers and pharmacists.

2. While physicians consider many sources in determining which medications to prescribe, the Defendants, though their unbranded campaign, influenced all of those sources. Because the unbranded campaign successfully promoted prescribing of opioids as a class of drug, it is neither necessary nor feasible to apportion the resulting harms to individual

defendants based on their branded promotion. My conclusion that these actions caused a rise in prescriptions and that the rise in exposure of the population to opioids caused an epidemic of opioid addiction is based on accepted public health methods for determining causality.

3. Opioid analgesics should be avoided for long-term, round-the-clock use except when treating end-of-life pain. To justify their use, the defendants downplayed opioid risks, exaggerated benefits and promoted deceptive concepts such as pseudoaddiction, breakthrough pain, use of screening tools to prevent addiction and abuse, and opioid rotation. Defendants' experts defense of these concepts is invalid and is based on articles and studies that were influenced by Defendants and their paid KOLs. I explain the origins of these concepts and why they are misleading and why they do not justify the use of opioids for chronic pain outside the end-of-life setting.

4. In determining a level of inappropriate consumption, I use a conservative baseline of 1997, at which point Americans were already consuming too many opioids, more than people in other countries with advanced healthcare systems. The massive oversupply from that point on resulted in a sharp increase in the prevalence of OUD in Florida and nationwide. OUD results from repeated exposure to opioids, with dose and duration of exposure being the strongest risk factors. Defendants' experts criticisms of this conclusion are invalid. The studies show that neither "recreational" use nor use of marijuana nor any other factor is as strong a risk factor for addiction as repeated exposure to opioids. Defense' experts to dismiss the public health crisis as a general "substance abuse crisis" is not supported by adequate evidence, nor is the theory that the opioid crisis is caused by economic or other factors.

5. Many people who developed OUD from prescription opioids transitioned to heroin use, including the use of heroin contaminated with fentanyl, to avoid withdrawal. If not for the Defendants' actions, there would not have been a sharp increase in OUD prevalence and associated opioid-related morbidity and mortality. OUD – which developed from both medical and non-medical use of prescription opioids -- is essentially the cause of death in the vast majority of opioid-related deaths, regardless of whether the person also used another drug at the time of death.

6. My opinion about the prevalence of OUD in Florida is based on accepted methods in the field of public health, including looking at the number of people who initiated treatment and the number of people in the treatment gap. This method is superior to relying on a survey that only measured active symptoms of OUD. The measures suggested by Defendants' experts, including using the NSDUH, would undercount those suffering from OUD.

7. The opioid crisis can be abated. I recommend abating the opioid crisis by decreasing the incidence of OUD through primary prevention interventions, while increasing the treated

prevalence of OUD through secondary and tertiary interventions. I disagree with Defendants' experts who criticize the need for long-term medication for people with OUD. My recommendations account for the success of the interventions by decreasing the use of certain interventions at different time horizons.

II. Marketing Rebuttal

8. Opioid use disorder develops from repeated exposure to opioids, either medically or non-medically. Evidence shows that a longer duration of opioid use and higher dosages are the strongest risk factors for developing OUD.[1] Repeated exposure to opioids causes changes to the brain that may be irreversible.[2] Just as opioid use can cause OUD, tobacco smoking can cause lung cancer. Smoking is not sufficient for developing lung cancer (not all smokers will develop lung cancer) nor is it necessary for developing lung cancer (lung cancer can develop without exposure to smoking), however it is an established scientific fact that smoking is a cause of lung cancer. It is also a fact that populations with higher rates of tobacco smoking have higher rates of lung cancer.

9. The Surgeon General's report "The Health Consequences of Smoking—50 Years of Progress: A Report from the Surgeon General,"[3] describes a strategy of cigarette manufacturers and other stakeholders to deny that smoking caused lung cancer:

> " …the observational, as opposed to experimental, nature of epidemiologic approaches led some scientists to question whether such approaches could be used to determine causation scientifically. Others confused epidemiologic analyses with the statistical methods used to describe the data (Shimkin 1979). Cigarette manufacturers and their spokespersons capitalized on this confusion by claiming that only experimental approaches could lead to evidence establishing causation: the evidence used by public health authorities to conclude that smoking caused

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[1] Mark J. Edlund et al., "The Role of Opioid Prescription in Incident Opioid Abuse and Dependence among Individuals with Chronic Noncancer Pain: The Role of Opioid Prescription," *The Clinical Journal of Pain* 30, no. 7 (July 2014): 557–64, https://doi.org/10.1097/AJP.0000000000000021; Roger Chou et al., "The Effectiveness and Risks of Long-Term Opioid Therapy for Chronic Pain: A Systematic Review for a National Institutes of Health Pathways to Prevention Workshop," *Annals of Internal Medicine* 162, no. 4 (February 17, 2015): 276–86, https://doi.org/10.7326/M14-2559.

[2] Upadhyay J, et al. (2010). Alterations in brain structure and functional connectivity in prescription opioid-dependent patients. *Brain*, 133(Pt7), 2098–114 doi: 10.1093/brain/awq138; Younger JW, et al. (2011). Prescription opioid analgesics rapidly change the human brain. *Pain*, 152(8), 1803–10. doi: 10.1016/j.pain.2011.03.0280.

[3] US Department of Health and Human Services, *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General* (Atlanta, GA: US Department of Health and Human Services, Centers for Disease …, 2014), https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf.

lung cancer was only "statistical" and therefore not scientific (Brandt 2007; Proctor 2011) (pg. 51-52)."

10. The advisory committee tasked with determining whether smoking caused lung cancer put forth a stepwise process to evaluate causality. Many of these steps eventually were incorporated into a set of principles for determining causation.[4]

11. Several Defendants' experts, including Drs. Warfield, Garthwaite, Kyle, Nicholson, Chintagunta, Wailes, and McCrary criticize my report and others for not conducting a casual analysis proving that deceptive marketing caused the population of Florida to be overexposed to opioids and that this overexposure caused an increase in opioid-related harms. My opinion, based on my clinical experience, my public health experience, the body of evidence, epidemiological methods for determining causation, and deductive reasoning[5] is that:

    - Deceptive messages promoting use of prescription opioids led to an increase in opioid sales and consumption.

    - The increased consumption of prescription opioids led to an increase in the prevalence of OUD.

    - The increased prevalence of OUD resulted in an increase in opioid-related morbidity and mortality and other health and social problems.

    - Many individuals who developed OUD from prescription opioids switched to heroin and eventually used heroin contaminated with fentanyl.

12. Physicians consider a variety of sources in making clinical decisions about opioid prescribing. Many of these sources have been influenced by the unbranded campaign of the Defendants, which I described in my report and elaborate on below. A number of the Defendants' experts, including Grabowski (¶ 14), Yong (p. 43), Warfield (p. 109), Michna (p. 50), Chintagunta (p.7), and Nicholson (pp. 24-25) argue that I have failed to consider that prescribers do not only make decisions based on marketing, but based on journal articles, clinical studies, medical education, pharmacy benefits plans, guidelines, conference presentations, and other factors. As I explained in my opening report and elaborate on here, the Defendants worked on, and invested in, influencing precisely those factors through their unbranded multi-faceted campaign that promoted aggressive and inappropriate opioid prescribing practices. Through the Defendants' efforts, these other

[4] Austin Bradford Hill, "The Environment and Disease: Association or Causation?," *Journal of the Royal Society of Medicine* 108, no. 1 (January 2015): 32–37, https://doi.org/10.1177/0141076814562718.
[5] *Id.*

sources of information for prescribers exaggerated the benefits of opioids, downplayed the serious risks and promoted aggressive and inappropriate opioid prescribing.

13. Similarly, Defendants' expert McCrary attempts to limit the causal analysis to Endo's detailing of Opana ER. But, as explained in more detail below, looking only at detailing of branded opioids would severely understate each Defendants' role in causing the opioid crisis. Endo, for example, as shown in greater detail below, participated heavily in the *unbranded* campaign to promote more aggressive opioid prescribing. This campaign included investing heavily in medical education and unbranded publications, journal articles, and other forms of promotion that, along with its detailing of its branded opioid products, caused a rise in the levels of prescription opioids.

14. The unbranded promotion described below also rebuts the points made by defense experts such as Nicholson that causation must be assessed separately for branded opioids (Nicholson discusses Cephalon's branded opioids Actiq and Fentora) and generic opioids, like those sold by Teva and the Actavis generic Defendants. In fact, when Cephalon sponsored an unbranded publication that downplayed opioid risks and exaggerated benefits, like those described in the next paragraphs, this did not only help Cephalon sell its branded opioids, but also led to increased prescribing of all opioids and allayed prescribers concerns about addiction and abuse. This led to increased sales of generics as well.

15. Much of the deceptive promotion of opioid prescribing was unbranded, and much of it was developed and disseminated directly and indirectly by the manufacturer Defendants working together. A good example is the publication *Responsible Opioid Prescribing* that was underwritten by Endo, Cephalon, and Purdue and was co-sponsored by defendant-funded pain organizations and front groups, including the American Pain Foundation and the American Academy of Pain Medicine. I discussed this publication in my opening report at n.111.[6] It is authored by Dr. Scott Fishman, a prominent Key Opinion Leader (KOL).[7] In response to an investigation by the United States Senate Finance Committee, the Federation of State Medical Boards admitted that it distributed more than 9,000 copies of the book in the State of Florida.[8]

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[6] ENDO_OPIOID_DEPMAT-000040854.

[7] Endo documents show, for example, that Dr. Fishman received thousands of dollars in payments. ENDO_OPIOID_DEPMAT-000034526; Kitlinski Tr. ENDO_OPIOID_DEPMAT-000033205. To the extent Defendants' experts, such as Edward Michna, rely (Michna Report 15 n.42, citing an article by, among others, KOL Lynn Webster, and n.43, citing an article by KOL Russell Portneoy) upon the publications of KOLs who received thousands in payments from the Defendants over the years, their opinions are not based on unbiased and objective science, but on industry-influenced views of the Defendants' favored speakers.

[8] June 8, 2012 Letter from H. Chaudhry (FSMB) to Senators Baucus and Grassley re: Response to May 8, 2012 Letter.

- The publication contains false and misleading messages that promote aggressive and inappropriate opioid prescribing, including the implication that opioids are safe and effective for long-term use.[9] The book promotes the discredited "concept" of pseudoaddiction, as I discussed in my opening report at 30 & n.111. For example, the publication promotes the dangerous notion that patients who hoard opioid medication and obtain opioids from more than one doctor are in need of *more* opioids for pain.[10] The publication incorrectly claimed that signs of addiction in patients, such as "[r]equesting analgesics by name," "[d]emanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding opioid medication are signs of pseudoaddiction and not addiction.[11] This is a very dangerous message to communicate to prescribers, because increasing the opioid dose in a patient who has difficulty controlling their use can easily result in an overdose. Instead of suggesting that opioid doses be increased in patients with aberrant use of their medication, clinicians should be taught to immediately seek an assessment for OUD, which is a life-threatening condition.

- The publication also promotes the idea that doctors can use "screening tools" such as the Opioid Risk Tool invented by Dr. Lynn Webster, a prominent KOL. But screening tools that can reliably predict who will become addicted to opioids do not exist. And, as I explained in my opening report, opioids are inherently addictive. As noted by public health officials in the Journal of the American Medical Association, the problem with long-term opioid use is that these are "risky drugs, not risky patients."[12]

- Yet Defendants jointly funded and promoted this book. Moreover, the evidence in this case demonstrates that Endo made this book available to its sales staff in Florida as part of an "Objection Handler," to deal with objections that prescribers

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[9] *See* ENDO_OPIOID_DEPMAT-000040854, at 40862.
[10] *See* ENDO_OPIOID_DEPMAT-000040854, at 40889.
[11] *Id.* Endo also used this concepts in training modules for its sales representatives, see ENDO_FLAG_00343069 at 343069-70. CVS promoted the concept in its Prescriber toolkit, CVS-NYAG-000044689 at 447221.
[12] Dowell D, Kunins HV, Farley TA. Opioid analgesics--risky drugs, not risky patients. JAMA. 2013 Jun 5;309(21):2219-20. doi: 10.1001/jama.2013.5794. PMID: 23700072.
Many other manufacturer products likewise promote the use of screening tools, as discussed in my opening report. For example, an Endo sales training from 2010, purporting to be part of the REMS requirements, promoted the SOAPP test as being at least a weak predictor of opioid abuse and suggested that the rise in opioid abuse can be attributed to insufficient "monitoring" by physicians. END00305153, 165, 167. Pharmacy Defendants also promoted this concept. CVS trained healthcare providers on the same concept in documents like the Opioid Prescriber Toolkit, CVS-NYAG-000044685 at 44709, which promoted the ORT, the SOAPP and other screening tools.

may have had to prescribing opioids.[13] Alleged co-conspirators such as Mallinckrodt, who I understand are no longer active Defendants in this case, gave the book away via its front group, C.A.R.E.S. Alliance, as did co-sponsor and alleged co-conspirator Purdue.

16. The book *Responsible Opioid Prescribing* also promoted the Defendants' own web sites, such as Endo's painedu.com, Cephalon's emergingsolutionsinpain.com, Purdue's pain.com, Purdue's partners against pain, and the web sites of front groups like the National Pain Education Council (NPECweb.org), which themselves promoted misrepresentations that downplayed opioid risks and exaggerated the benefits of use.[14]

17. Another good example of unbranded promotion, also cited in my opening report at n. 111, is the book *Avoiding Opioid Abuse While Managing Pain.*[15] This book is written by another well-known KOL, Dr. Lynn Webster, who was president of the front group the American Academy of Pain Medicine and author of CMEs (continuing medical education) sponsored by Defendants, including Cephalon and Endo, and who was a KOL for Teva, Janssen, and Mallinckrodt.[16] It makes the following medically deceptive claim that so-called "pseudoaddiction" should be seen as an explanation for aberrant patient behavior, including doctor-shopping, and that the patient's opioid dose should be increased to remedy the situation. The book was used by Endo as an approved material to be distributed to prescribers in Florida and assigned it a "dropped materials" number. According to materials produced by Endo in this case, Endo distributed this book to prescribers in Florida.[17]

18. Defendants' experts, including Chintagunta (pp.9-10) and Grabowski (p. 32) mention prescribing guidelines as a factor influencing prescribing decisions, but they fail to acknowledge the role the Defendants and their co-conspirators played in developing and disseminating these prescribing guidelines.

    - For example, in 1997 two defendant-funded front groups, the American Pain Society (APS) and the American Academy of Pain Medicine (AAPM) issued a

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[13] PXEND-106 (ENDO_OPIOID_DEPMAT-000087545) (Objection Handler).
[14] *See* ENDO_OPIOID_DEPMAT-000040916.
[15] ENDO_OPIOID_DEPMAT-000060572.
[16] For payments Teva/Cephalon made to Webster, see TEVA_MDL_A_13610632 (Actiq and Fentora, approximately $90K between 2002 and 2007). For payments to Webster from 2014 on, see https://openpaymentsdata.cms.gov/physician/1136720. For example, in 2014, Webster received payments from Defendants Insys, Mallinckrodt, and Teva. In 2016, Webster received payments from Teva and Endo.
[17] ENDO_FLAG-00644111; PXEND-106 (ENDO_OPIOID_DEPMAT-000087545) (Objection Handler).

consensus statement endorsing opioid use for chronic pain.[18] The widely cited and distributed consensus statement downplayed the risk of addiction, the risk of respiratory depression, and the role played by tolerance in limiting long-term effectiveness. Authors of the consensus statement included prominent KOLs with financial ties to Defendants, including Dr. Russell Portenoy. The chairman of the group issuing the statement was Dr. David Haddox, a KOL and paid speaker for Purdue Pharma, maker of OxyContin. Haddox became a Purdue Vice President three years later. In 2009, APS and AAPM issued a new prescribing guideline based on the consensus opinions of its 21 authors.[19] Although the guideline acknowledged the lack of evidence supporting long-term opioid use, it nevertheless encouraged opioid prescribing for chronic pain and falsely suggested that opioid addiction could be prevented through use of screening tools and close monitoring. Of the 21 people who served on the project, 14 had financial ties to opioid manufacturers. Of note, the financial ties between opioid manufacturers and the APS and AAPM have been the subject of multiple United States Senate investigations because of their promotion of aggressive and inappropriate opioid prescribing.

- In 2009, the American Geriatric Society issued new guidelines that recommended that over-the-counter pain relievers, such as ibuprofen and naproxen, be used rarely and that opioids should be used instead for all patients with moderate to severe pain. Among the 10 experts on the task force that wrote the new guidelines, at least five were paid speakers, consultants, or advisers for opioid manufacturers at the time the guidelines were issued, including Dr. Perry Fine, a former president of AAPM and a prominent KOL who was working for at least six opioid manufacturers at the time the guidelines came out.[20] A sixth guideline task force member, the chairman, was listed as a paid speaker for an opioid company a year later.

- Considering the extensive influence of opioid manufacturers on prescribing guidelines, it is not surprising that a recently published guideline analysis found "that the [13] guidelines for opioid prescribing chronic non-cancer pain from 2007 to 2013 were at risk of bias because of pervasive conflicts of interest with the pharmaceutical industry and a paucity of mechanisms to address bias (pg. 2)."[21]

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[18] Fauber J. 2012. Painkiller boom fueled by networking: doctors, researchers with financial ties to drug makers set stage for surge in prescriptions. Milwaukee-Wisconsin Journal Sentinel, Feb. 18, p. A1.
[19] *Id.*
[20] Fauber, J. & Gabler, E. 2012. Narcotic painkiller use booming among elderly. *Milwaukee Journal Sentinel/Medpage.*
[21] Spithoff S, Leece P, Sullivan F, Persaud N, Belesiotis P, Steiner L. Drivers of the opioid crisis: An appraisal of financial conflicts of interest in clinical practice guideline panels at the peak of

19. Defendants' experts including Grabowski argue that prescribers base decisions on clinical studies. But the Defendants paid for and promoted flawed studies, such as the enriched enrollment randomized withdrawal studies described in Dr. Clauw's report. Defendants then misleadingly promoted these studies to prescribers as evidence that opioids are effective for chronic pain.[22] Medical textbooks – which Grabowski mentions at 28 – were also influenced by Endo and other opioid manufacturers. Moreover, the fact that articles mentioned abuse and addiction does not contradict the claims about deceptive marketing and education, because the Defendants put out a great deal of marketing and "educational" material aimed at allaying concerns about addiction, claiming that opioid addiction rarely developed in patients treated with opioids and that signs of addiction were likely to be "pseudoaddiction" as described above. When regulatory and enforcement efforts threatened to disrupt the enormous supply of opioids flooding the United States and especially the state of Florida, the Defendants disseminated messages, directly and through front groups, that such efforts were hampering the access of legitimate pain patients to prescribed opioids.[23]

20. The Defendants invested in misleading medical education. This included continuing medical education, pharmacist education, and so-called peer-to-peer education using paid KOLs. These KOLs spoke to Florida prescribers thousands of times promoting Defendants' opioid products using deceptive messages. One of the Defendants' experts, Dr. Ed Michna, was himself a KOL for multiple opioid manufacturers including Teva, Insys Therapeutics and Purdue Pharma, three companies that were criminally convicted for illegally promoting use of their products.[24]

    Defendant expert Grabowski (p. 30) identified press coverage as an additional source of information for physicians, citing McGinty et al[25] as evidence that this information was widespread. However, this study found that the volume of press coverage increased over time, rising nearly 500% from 1998 to 2012, and that news stories appearing earlier in the study period were more likely to mention law enforcement solutions. This is consistent

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opioid prescribing. PLoS One. 2020;15(1):e0227045. Published 2020 Jan 24. doi:10.1371/journal.pone.0227045.

[22] PXEND-61 (ENDO-OPIOID_MDL-00681622) (coaching sales representatives to use the Hale and Katz studies in sales calls); ENDO_FLAG-00253781 (manager reminding Florida sales team to bring Hale "brochure" to a sales workshop for Opana ER).

[23] *E.g.* EPI002370800.

[24] *See* ENDO_OPIOID_MDL-00781631, at row 52 (Michna listed on list of Endo speakers along with well-known KOLS such as Charles Argoff); PDD1701018717 and PDD1701225811 (Warfield was a Purdue speaker). https://openpaymentsdata.cms.gov/physician/247077.

[25] Emma E. McGinty et al., "Criminal Activity or Treatable Health Condition? News Media Framing of Opioid Analgesic Abuse in the United States, 1998-2012," *Psychiatric Services (Washington, D.C.)* 67, no. 4 (April 1, 2016): 405–11, https://doi.org/10.1176/appi.ps.201500065.

with the narrative pushed by the opioid industry through the Pain Care Forum, front groups and public relations firms that opioid harms were limited to so-called "drug abusers" and that efforts to respond to the problem should not penalize pain patients for the bad behavior of "addicts" by limiting supply.[26] The American Pain Foundation, a front group that received most of its funding from Endo in its final years, even issued a deceptive guide for journalists called "A Reporter's Guide: Covering Pain and Its Management" and supported by Alpharma Pharmaceuticals. It noted in at least five places that the risk of opioid addiction is low, and it falsely claimed that fewer than 1 percent of children treated with opioids become addicted.[27]

21. Endo claimed in trainings and speaker programs that chronic opioid therapy is effective for patients with chronic non-cancer pain. Endo promoted the idea that patients on high doses of opioids who were continuing to experience pain because they had developed tolerance to opioids should be rotated to another opioid.[28] This practice, which KOLs referred to as "opioid rotation," was presented as if it were a sound, evidence-based clinical practice and based on a theory that cross-tolerance between opioid molecules is less than 100%. But this practice was harmful and likely resulted in greater rates of OUD and opioid overdoses. Instead of so-called "opioid rotation," patients on high doses of opioids who continued to experience pain because of tolerance should have been tapered off opioid analgesics instead of switching to a different opioid molecule.

22. Falsely promoting opioid rotation as if it were an evidence based clinical practice served the interests of the Defendants in two important ways. *First*, they were able to convince pharmacy benefit managers and insurance companies to add their newly approved opioids such as Opana ER, to prescription drug formularies that already included other extended-release opioids by arguing that new opioids were necessary because clinicians need to be able to rotate to other opioids. *Second*, it perpetuated the myth that tolerance from use of opioids (an important reason to avoid long-term opioid use) could be easily dealt with by rotating from one opioid drug to another. These presentations also promoted the idea of rescue medications for "breakthrough pain," a concept I address in my report, and promoted the Hale study and other flawed studies to claim opioids are effective, which I understand is discussed in the report of Dr. Clauw.[29]

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[26] David Armstrong, How Purdue planted its 'anti-story' and delayed the reckoning for its role in the opioid epidemic, ProPublica (Nov. 19, 2019), https://www.statTThe.com/2019/11/19/how-purdue-pharma-planted-its-anti-story/.

[27] Charles Ornstein, Tracy Weber, The Champion of Painkillers, Propublica (Dec. 23, 2011), https://www.propublica.org/article/the-champion-of-painkillers.

[28] Endo promoted the idea of opioid rotation in training modules. ENDO_FLAG_00343069, at 3380, where it claimed that "a new opioid can restore analgesia without problematic side effects."

[29] See slide deck for Opana ER Extended Release tablets, with INTAC technology, Treating Moderate to Severe Chronic Pain, ENDO-OPIOID_MDL-00418479.

23. The Pharmacy Defendants' experts suggest the pharmacies did not engage in marketing and promotion and that trainings for their pharmacists safeguarded against abuses. Defense expert Garthwaite argues that I have not adequately linked opioid-related harms to the misconduct of Defendants, particularly CVS. As shown below, the pharmacies were among those Defendants promoting misleading messages to prescribers. Walgreens expert Parrado (pp. 14-15) opines that Walgreens' policies and trainings were the "best in the industry." I rebut this opinion below, showing that Walgreens and CVS trained their pharmacists using misleading materials, at times sponsored and provided by Manufacturer Defendants, designed to increase dispensing and allay concerns about opioids.

24. The Manufacturer Defendants conveyed their misleading messages to pharmacists. An American Pharmacists Association publication supported by Endo and promoting Endo's opioid product Opana ER that claimed that fears of addiction and abuse were "based largely on misunderstanding and misuse of terminology."[30] False and misleading information in the publication included the following passages:

    - "The term pseudoaddiction is used to describe behavior of a patient who is focused on obtaining medication because of poor pain control rather than drug craving. The apparently excessive drug-seeking behavior ceases when the patient's pain is effectively treated."[31]

    - "Such fears of addiction seem to be largely unfounded. In patients receiving opioids for the treatment of pain, who have no history of substance abuse, the prevalence of addiction appears to be low.[7] A recent literature review reported a minimal risk of addiction among patients with chronic pain who are being treated with opioids.[8]"[32]

    - To support the false claim about low prevalence of addiction in chronic pain patients, the publication deceptively cites a paper that relies on a the infamous Porter and Jick letter to the editor of the New England Journal of Medicine that describes a review of opioid use in hospitalized patients with acute pain.[33] To support the additional claim that a "A recent literature review reported a minimal

[30] ENDO-CHI_LIT-00540303 at 304. CVS promoted this concept in patient handouts as well, in its Prescriber Toolkit, CVS-NYAG, at 000044737, which asked "Is it true that I will become addicted to opioid pain medicine?" with the answer minimizing the fear: "Many patients fear becoming addicted to opioids. Addiction and physical dependence is not the same…. Most people will not become addicted to their prescribed pain medicine…"
[31] ENDO-CHI_LIT-00540303 at 308.
[32] ENDO-CHI_LIT-00540303 at 305.
[33] Donna Bloodworth, Issues in opioid management, *Am. J. Phys. Med. Rehabil.*, Vol. 84, No. 3 (2005), S42-S55.

risk of addiction" the publication cites a journal article that makes no mention of such a literature review.[34]

- The publication also included a reproduced version of the World Health Organization's Cancer Pain Ladder with the word "Cancer" deceptively removed to give the impression that the recommendations for opioid use apply to non-cancer pain.

- This publication promoted the misrepresentation, discussed in my opening report at (f), that patients can be safely taken off opioids "without development of withdrawal symptoms by slowly tapering the daily dose."[35] As I explained, after long-term use of opioids, patients often experience severe and disabling withdrawal symptoms. The APA collaborated with Endo to promote the dangerous idea that pharmacists should tell patients that the development of tolerance to opioids should be "overcome by increasing the dose." This document misinformed pharmacists who in turn would be likely to misinform patients.

25. The Pharmacy Defendants worked with the other Defendants to promote these misleading messages. CVS and Purdue collaborated with Purdue's front group, Partners against Pain, whose history and additional activities are discussed in the report of David Courtwright. See, for example, a joint letter by CVS and Purdue to CVS pharmacists promoting the partnersagainstpain.com Purdue web site.[36] This Purdue web site promoted false and misleading information about opioids.[37]

    - For example, the Partners Against Pain web site had an article – which it referred to as a "Pain Control Guide" for patients, entitled How You Can Be a Partner Against Pain and Gain Control Over Your Own Pain," explaining "Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking the pain medication for medical purposes. The medical purpose is clear and the effects are beneficial, not harmful. *True addiction very rarely occurs* when opioids are being used properly under medical supervision to relieve pain."[38]

26. The Pharmacy Defendants also engaged in misleading training and education of dispensing pharmacists. As explained in my opening report, CVS trained its pharmacists that a "barrier to effective pain management" included "overestimated expectation of addiction or tolerance," echoing the manufacturers' deceptive materials described above. One training told pharmacists that "there are behaviors that make you think twice, but are

[34] Jane C. Ballantyne and Jianren Mao, Opioid Therapy for Chronic Pain, *N Engl. J Med.*, 349;20, 1943-53, (Nov. 13, 2003).
[35] ENDO-CHI_LIT-00540303 at 309.
[36] PDD1701189357.
[37] PPLPC008000017980.
[38] PDD1701205785, at PDD1701205831 (emphasis added).

not as likely a sign of a serious abuse / misuse problem, such as aggressive complaining about pain and the need for medication, requests for a specific drug, limited duration unsanctioned dose escalations, hoarding pills, misusing a drug to treat a different symptom, and drinking more alcohol when in pain."[39] The training also promoted the discredited Opioid Risk Tool described above and claimed that "the tendency is to overestimate the likelihood of abuse and undertreat pain."[40]

27. Walgreens distributed materials to its pharmacists highlighting pseudoaddiction as "the seeking of a drug due to untreated or sub-optimally treated pain" that "subsides when pain is appropriately managed."[41] Walgreens also circulated a document titled "Management of Acute and Chronic Pain" that promotes the Opioid Risk Tool.[42] The Opioid Risk Tool, which was developed by KOL Lynn Webster, was promoted as an evidence-based tool that could allow a prescriber to reliably predict which patients were at greater risk of becoming addicted to prescribed opioids.[43] In reality, the risk of opioid addiction from long-term use is inherent in the opioid, not the patient, and with long-term daily use, every patient is at high risk of becoming addicted. A recent federal government review of evidence related to opioid prescribing found that the Opioid Risk Tool that it lacked specificity and sensitivity for predicting OUD.[44]

28. The Pharmacies' experts, including Anderson, opine that the pharmacies did not conspire to promote opioid use. This is inaccurate. In addition to the misrepresentations described above and in my opening report that were disseminated to their pharmacists, the pharmacies also collaborated in using their deceptive messages to try to prevent the "upscheduling" of hydrocodone combination products from less-regulated Schedule III drugs to more highly regulated Schedule II drugs.

29. As background, the federal Controlled Substances Act (CSA) places drugs with similar abuse risks into distinct categories called schedules. Hydrocodone combination products were initially classified as Schedule 3. By 2011, the most prescribed class of drug in the United States were hydrocodone combination products, even surpassing cholesterol lowering drugs and antihypertensives,[45] and they had become the most misused opioid

[39] CVS-MDLT3-000015263-at 15273.
[40] *Id.* at 15283-84.
[41] WAGNMAG00021894.
[42] WAGMDL00303140.
[43] WAGFLAG01853612.
[44] Chou R, Hartung D, Turner J, et al. Opioid treatments for chronic pain. Agency for Healthcare Research and Quality, 2020. doi:10.23970/AHRQEPCCER229.
[45] The Use of Medicines in the United States: Review of 2011. Report by the IMS Institute for Healthcare Informatics.

drugs in the United States.[46] This led to efforts to change their classification to Schedule II, which would allow for tighter regulation. In response, the Pharmacy Defendants used front groups and trade associations, including the National Association of Chain Drugstores (NACDS), the Pain Care Forum and the American Academy of Pain Management, with whom they worked jointly with the Manufacturer Defendants,[47] to oppose increased regulation of hydrocodone. In their opposition, they relied on deceptive messages, arguing that increased regulation would inappropriately "reduce patient access to medications and cause harm," including by requiring "patients to see their doctor … with greater frequency" as opposed to refilling prescriptions "by telephone or fax."[48] These deceptive messages were similar to those they advanced in response to government efforts to control diversion of their products, discussed in more detail below, claiming that any efforts to limit or regulate the overprescribing of opioids would wrongly deprive legitimate pain patients of needed medicine. *See section VIII, infra.*

30. Defendants' expert Kyle opines that my opinion only addresses Allergan's promotional materials in passing, without analyzing how those materials contributed to overprescribing of opioids. Defendants, including Allergan, re-framed appropriate concerns about opioids as barriers to pain treatment. For example, Allergan's Kadian Learning system stated "Concern about abuse, addiction, and diversion should not prevent the proper management of pain." This message was echoed in a Kadian stocking offer, "Concerns about abuse, addiction, and diversion, should not, however, prevent the proper management of pain."[49] The claim that concerns about abuse, diversion, and addiction should not prevent proper pain management implies that opioid harms are limited to people who abuse diverted opioids. This is false. Patients who take opioids exactly as prescribed can become addicted and concern about the development of addiction is appropriate. Prescribers should, of course, also be concerned about the possibility of diversion. Further, expert Warfield disputes my characterization of a Kadian document found at ALLERGAN_MDL_01466431. The Kadian training material in question states that "abuse of opioid drugs" can be "limit[ed]" by "proper assessment of the patient." As I have explained, opioids are inherently addictive, even when taken as prescribed. It is false and misleading to suggest that a "proper assessment" before initiating long-term opioids will reduce addiction and abuse from occurring.

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[46] Trends in Nonmedical Use of Oxycodone and Hydrocodone Products among Persons Aged 12 or Older Who Used Pain Relievers Non-medically for the First Time in the Past Year: Numbers in Thousands, 2002-2010. Source: SAMSHA.

[47] See, for example, CVS-MDLT1-000022717 (email from Kevin Nicholson of NACDS to members explaining an AAPM proposal that would help keep these products Schedule III); CVS-MDLT1-000025430 (email from NACDS and other pharmacy association groups opposing tighter regulation of hydrocodone).

[48] NACDS_MDL0003564.

[49] Acquired_Actavis_00369188.

31. Kadian's Personalized Pain Relief patient brochure downplays the risk of addiction and the role played by tolerance in limiting long-term effectiveness.[50] For example, the brochure states "You can become addicted to morphine-based drugs, but it is less likely if you have never had an addiction problem. Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Similar statements are reproduced in the report of Matthew Perri (pp. 189-196). Another example is Endo's publication *Taking a Long-Acting Opioid – What does it Mean to Me*" which assured patients that "Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medications usually do not become addicted."[51]

32. Defendants' experts, including Nicholson, pointed to my statement that information about opioids' addictive risks were previously well known. My point is that Defendants used deceptive education and marketing messages to falsely characterize these well-known concerns about addiction as overblown, as in the examples in my report, this rebuttal, and the reports of Perri and Clauw.

III. Opioid Prescribing

33. Prescription opioids, when taken on a long-term daily basis, have not been proven safe and effective in treating chronic non-cancer pain. I understand that Plaintiff's expert Dr. Clauw, a pain specialist, will also opine on this point in greater detail. Dr. Wailes opines that the standard of care to treat chronic pain includes prescription opioids and states "the majority consensus among the medical community is that the benefits of prescription opioids for treating patients with chronic pain outweigh the known risks (pg. 27)." This opinion is in stark contrast to the position of the United States Centers for Disease Control, which stated in a 2016 article in the New England Journal of Medicine:

> "The science of opioids for chronic pain is clear: for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits."[52]

Dr. Wailes' opinion is also countered by Defendant expert Dr. Yong who states that "it is a fundamental tenet in the field of pain medicine that opioid medication is not seen as a first-line treatment option (pg. 40)."

34. There is not, and has never been, adequate evidence to support the long-term use of opioids despite the Defendants' experts, including Drs. Warfield, Michna, Rosenblatt,

[50] ALLERGAN_MDL_02169261.
[51] ENDO_OPIOID_DEPMAT-000019696.
[52] Thomas R. Frieden and Debra Houry, Reducing the Risks of Relief--The CDC's Opioid-Prescribing Guideline, *N Engl J Med.*,374(16):1501-4, (Apr. 21, 2016), doi: 10.1056/NEJMp1515917. Epub 2016 Mar 15. PMID: 26977701; PMCID: PMC4852278.

Yong, and Wailes, stating so. This is because the risks of long-term opioid use far outweigh the potential benefit. Defendants' experts cite several systematic reviews and meta-analyses to support their opinion, such as Busse et al[53] and Noble et al[54]. However, these papers do not provide adequate evidence to support long-term, daily opioid use. For example, Busse et al[55] found small improvements in pain and physical functioning from using opioids for chronic non-cancer pain, though, when compared to non-opioid medications, there was no difference and opioids were associated with less pain relief during longer trials. Noble et al[56] only found "weak evidence" for the effectiveness of long-term opioid therapy in chronic non-cancer pain patients. Importantly, Noble's analysis is flawed because it includes low quality studies that were funded by industry. The Noble review was funded by The Mayday Fund, an opioid advocacy organization discussed in an investigation by members the United States House of Representatives,[57] and it relies on several opioid manufacturer KOLs and front groups (as mentioned in the acknowledgement section), including Drs. James Campbell, Rollin Gallagher, Daniel Carr, Kathleen Foley, Russell Portenoy, and others with leadership roles in APS, AAPM and the American Pain Foundation.

35. The most recent evidence-based review on the use of opioids for chronic pain concluded that "at short-term follow-up, for patients with chronic pain, opioids are associated with small beneficial effects versus placebo but are associated with increased risk of short-term harms and do not appear to be superior to nonopioid therapy. Evidence on intermediate-term and long-term benefits remains very limited, and additional evidence confirms an association between opioids and increased risk of serious harms that appears to be dose-dependent (pg. viii)."[58] A guideline published by the Department of Veterans Affairs and Department of Defense in 2017 *strongly* recommends against initiation of long-term opioid therapy for chronic pain.[59] Based on the lack of evidence showing that

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[53] Jason W. Busse et al., "Opioids for Chronic Noncancer Pain: A Systematic Review and Meta-Analysis," *JAMA* 320, no. 23 (December 18, 2018): 2448–60, https://doi.org/10.1001/jama.2018.18472.

[54] Meredith Noble et al., "Long-term Opioid Management for Chronic Noncancer Pain," *The Cochrane Database of Systematic Reviews* 2010, no. 1 (January 20, 2010): CD006605, https://doi.org/10.1002/14651858.CD006605.pub2.

[55] Busse et al., "Opioids for Chronic Noncancer Pain."

[56] Noble et al., "Long-term Opioid Management for Chronic Noncancer Pain."

[57] Offices of Representatives Katherine Clark and Hal Rogers, "Exposing Dangerous Opioid Manufacturer Influence at the World Health Organization," 2019, https://halrogers.house.gov/_cache/files/c/3/c359e585-8748-4949-9768-6767d800e91c/1A59F877D85021445276B30C420C1556.5.22.19-who-purdue-report.pdf.

[58] Roger Chou et al., "Opioid Treatments for Chronic Pain" (Agency for Healthcare Research and Quality, 2020), https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/opioids-chronic-pain.pdf.

[59] Department of Veterans Affairs/Department of Defense, "VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain," 2017,

long-term opioid use benefits patients and the serious risks posed by opioids, including the risk of addiction and overdose, it is clear that clinicians should avoid initiating long-term opioid use.

36. Round-the-clock, long-term prescription opioid use should not be initiated except when treating pain at the end of life. Dr. Yong cites the SPACE Trial[60] as evidence that there is efficacy after one year of long-term opioid therapy. However, the SPACE trial was a comparative effectiveness trial without a placebo arm and did not control for the placebo effect which is especially significant in clinical trials for chronic pain. Of note, the authors of the SPACE trial concluded that "results do not support initiation of opioid therapy for moderate to severe chronic back pain or hip or knee osteoarthritis pain (pg. 881)" and "opioids did not demonstrate any advantage over non-opioid medications that could potentially outweigh their greater risk of harms (pg. 880)." The findings from the SPACE Trial add to the body of evidence that long-term use of prescription opioids should be avoided.

37. Despite the lack of evidence supporting effectiveness of long-term opioid use, likely due to dependence, tolerance and hyperalgesia, the opioid industry promulgated false information and invented concepts and phenomena such as pseudoaddiction, breakthrough pain, and opioid rotation to promote aggressive prescribing and to justify the adding their new branded opioids to pharmacy benefit formularies. Defendants' experts Drs. Warfield, Yong, and Rosenblatt state that pseudoaddiction is a real phenomenon among patients on long-term opioid therapy. See Dr. Rosenblatt (pp. 48-49) (citing an article authored by KOLs Passik and Webster -- also cited by Michna -- and citing an article by Haddox, a Purdue employee), Yong (p. 21) (calling pseudoaddiction an "important concept in opioid treatment and citing articles by KOL Charles Argoff,), and Warfield (p. 99). The Defendants' experts cite statements by the very same KOLs who pushed the dangerous message that opioid doses should be increased in patients who exhibit aberrant drug seeking behavior because evidence in the medical literature that pseudoaddiction is a valid, reliable concept or condition does not exist.

    - As discussed above and in my initial report, patients on opioids who demonstrate aberrant drug use require an urgent assessment for OUD, a life-threatening condition. Instead, educational materials disseminated by the Defendants (directly and indirectly through KOLs and front groups) encouraged clinicians that they could distinguish between true addiction and so-called pseudoaddiction by

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https://www.va.gov/HOMELESS/nchav/resources/docs/mental-health/substance-abuse/VA_DoD-CLINICAL-PRACTICE-GUIDELINE-FOR-OPIOID-THERAPY-FOR-CHRONIC-PAIN-508.pdf.

[60] Erin E. Krebs et al., "Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain: The SPACE Randomized Clinical Trial," *JAMA* 319, no. 9 (March 6, 2018): 872–82, https://doi.org/10.1001/jama.2018.0899.

increasing the opioid dose for these patients. The idea being that "the apparently excessive drug-seeking behavior ceases when the patient's pain is effectively treated."[61] Teaching clinicians to increase an opioid dose for patients who could be addicted served the interests of the Defendants by allowing them to sell even higher doses of their products to patients who should have been tapered off but it was exceptionally reckless and no doubt contributed to overdose deaths.

- The term Pseudoaddiction was described in the Defendants' "educational" materials as if it was a validated medical condition. In reality, use of the term was based on a case report authored by David Haddox (a KOL who later became a Vice President for Purdue Pharma) describing a hospitalized patient with Leukemia who appeared drug seeking to nursing staff.[62]

- A number of Defendants' experts, including Drs. Warfield, Rosenblatt, Yong, and Michna promote and defend the related concept of breakthrough pain, whereby the Defendants pushed the idea that people on long-acting opioids should also take short-acting opioids, including fentanyl products, for "breakthrough pain." I understand that Dr. Clauw will explain why this concept does not justify prescribing short-acting and immediate-release opioids for patients receiving extended-release opioids for chronic, non-cancer pain. The notion that complaints of pain in patients on round-the-clock opioids should be understood as so-called "breakthrough pain" served the interests of Defendants because it allowed them to maintain patients on opioids who should have been tapered off and even allowed them to promote use of their short acting formulations. In reality, complaints of pain in patients on long-term opioids are common because chronic opioid use results in tolerance and hyperalgesia which are reason to avoid initiation of long-term opioids. Moreover, as in other areas, Defendants' experts' opinions on this issue are tainted by their reliance on the same KOLs who helped invent and disseminate these terms – for example, Dr. Yong relies at n.53 on studies by Portenoy and Webster, two prominent KOLs discussed herein.

38. Inappropriate medical prescribing of opioids was not limited to treating chronic pain. Inappropriate prescriptions for acute pain have been and continues to be a serious public health problem. Defendants' experts Dr. Wailes and Dr. Garthwaite attempt to justify aggressive opioid prescribing for acute pain. While it is true that opioids are effective for certain types of acute pain, it is also true that they are massively overprescribed in the United States. A recently published study comparing post-surgical opioid use in the United States to other countries found that "US physicians prescribe alarmingly high amounts of opioid medications postoperatively. Further efforts should focus on limiting

[61] ENDO-CHI_LIT-00540305.
[62] Weissman DE, Haddox DJ. Opioid pseudoaddiction--an iatrogenic syndrome. Pain. 1989 Mar;36(3):363-366. doi: 10.1016/0304-3959(89)90097-3. PMID: 2710565.

opioid prescribing and emphasize non-opioid alternatives in the US."[63] Of note, non-opioid analgesics have been found to be just as effective as opioids for severe acute pain in the emergency department[64] and after some surgeries.[65] Harm from unnecessary and overly aggressive opioid prescriptions is not limited to the patients who receive these prescriptions as excess opioids prescribed for acute pain remain readily available in medicine cabinets for later misuse by friends and family.[66]

39. As stated in my report, screening tools that can predict risk of developing OUD before initiating long-term opioid therapy do not exist. While it is prudent to closely monitor patients on long-term opioid, monitoring strategies have not been shown to prevent OUD. At best, these strategies can allow a prescriber to identify OUD earlier in the course of the disease (as a form of secondary prevention) but they do not prevent OUD from occurring (see Kolodny Report p. 31). Several Defendants' experts including Drs. Warfield, Michna, Rosenblatt, Yong, and Wailes opine that screening and monitoring tools are available to mitigate the risks of prescription opioids. High quality evidence that these so-called "tools" can predict or prevent OUD, improve outcomes or somehow make long-term opioid use safe does not exist.[67]

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[63] Kaafarani HMA, Han K, El Moheb M, Kongkaewpaisan N, Jia Z, El Hechi MW, van Wijck S, Breen K, Eid A, Rodriguez G, Kongwibulwut M, Nordestgaard AT, Sakran JV, Ezzeddine H, Joseph B, Hamidi M, Ortega C, Flores SL, Gutierrez-Sougarret BJ, Qin H, Yang J, Gao R, Wang Z, Gao Z, Prichayudh S, Durmaz S, van der Wilden G, Santin S, Ribeiro MAF Jr, Noppakunsomboom N, Alami R, El-Jamal L, Naamani D, Velmahos G, Lillemoe KD. Opioids After Surgery in the United States Versus the Rest of the World: The International Patterns of Opioid Prescribing (iPOP) Multicenter Study. Ann Surg. 2020 Dec;272(6):879-886. doi: 10.1097/SLA.0000000000004225. PMID: 32657939.

[64] Billy Sin et al., "Comparing Nonopioids Versus Opioids for Acute Pain in the Emergency Department: A Literature Review," *American Journal of Therapeutics* 28, no. 1 (November 13, 2019): e52–86, https://doi.org/10.1097/MJT.0000000000001098.

[65] Julio F. Fiore et al., "Preventing Opioid Prescription after Major Surgery: A Scoping Review of Opioid-Free Analgesia," *British Journal of Anaesthesia* 123, no. 5 (November 2019): 627–36, https://doi.org/10.1016/j.bja.2019.08.014.

[66] Cornelius A. Thiels et al., "Wide Variation and Overprescription of Opioids After Elective Surgery," *Annals of Surgery* 266, no. 4 (October 2017): 564–73, https://doi.org/10.1097/SLA.0000000000002365; Mark C. Bicket et al., "Prescription Opioid Analgesics Commonly Unused After Surgery: A Systematic Review," *JAMA Surgery* 152, no. 11 (November 1, 2017): 1066–71, https://doi.org/10.1001/jamasurg.2017.0831.

[67] Roger Chou et al., "The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain," 2014, https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/chronic-pain-opioid-treatment_research.pdf; Dennis C. Turk, Kimberly S. Swanson, and Robert J. Gatchel, "Predicting Opioid Misuse by Chronic Pain Patients: A Systematic Review and Literature Synthesis," *The Clinical Journal of Pain* 24, no. 6 (August 2008): 497–508, https://doi.org/10.1097/AJP.0b013e31816b1070.

IV. Regulatory Oversight

40. A number of Defendants' experts suggest that defendant-disseminated materials that exaggerated opioid benefits and minimized risks were not deceptive because they were permitted by the FDA. I disagree with the suggestions of these experts (especially Minnie Henry) that the FDA's regulation of promotional material prevented misleading statements from influencing prescribers and patients. *See*, *e.g.*, Henry Report (¶¶ 41-43). As a general matter – and as Henry acknowledges – the FDA requires that promotional materials be submitted to the FDA, but there is no requirement that the FDA ever review them. *See* Henry Report (p. 42). The process for a manufacturer to solicit comments from the FDA on promotional materials is entirely voluntary. *See* Henry Report (p. 47).

41. I have seen no evidence that the vast majority of misleading statements regarding opioid efficacy and risks were commented on by the FDA. One study showed that even for the limited set of core promotional materials, the FDA had reviewed only 41% submitted to it in 2016; the universe of promotional materials is far larger.[68] And where there is evidence of FDA review, it shows that there were, in fact, misleading statements made by opioid makers about opioid effectiveness and risks. On occasions when opioid manufactures were caught minimizing risks and/or exaggerating effectiveness in branded materials they received warning letters and untitled letters from the FDA. Numerous warning letters were issued by the FDA to opioid manufacturers for misleading statements about the risks and efficacy of opioids. For example, Actavis received a warning letter for a deceptive Kadian Co-Pay Assistance Program and Comparison Detailer. According to the FDA:

> "The Co-Pay Assistance Program brochure and Comparison Detailer are false or misleading because they omit and minimize the serious risk associated with the drug, broaden and fail to present the limitations to the approved indication of the drug, and present unsubstantiated superiority and effectiveness claims. Therefore, the Co-Pay Assistance Program brochure and Comparison Detailer misbrand the drug in violation of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 352(a) & 321(n). Cf. 21 CFR 202.1(e)(3)(i); (e)(5); (e)(6)(i), (ii) & (xviii); (e)(7)(i) & (viii). These violations are a concern from a public health perspective because they suggest that the product is safer and more effective than has been demonstrated. "[69]

42. Of note, the FDA's regulatory role is limited to branded marketing. The FDA does not regulate the unbranded materials disseminated by opioid makers, front groups and KOLs that promote opioids as a class of drug or that surreptitiously promote a branded product without mentioning the brand name. The many deceptive promotional materials disguised

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[68] *See*, *e.g.*, Lisa Schwartz and Steven Woloshin, Medical Marketing in the United States, 1997-2016, *JAMA,* 2019; 321(1):80-96, https://jamanetwork.com/journals/jama/fullarticle/2720029.

[69] Warning Letter from FDA to Doug Boothe, Chief Executive Officer, Actavis US RE: NDA #20-616 Kadian® (morphine extended-release) Capsules, CII MACMIS #18148.

as education and discussed above in this report and in my initial report, were not regulated by the FDA.

43. I disagree with the opinions of Defendants' experts Drs. Rosenblatt, Warfield, Carl, Henry, Nicholson, and Michna that the existence of the FDA's ER and TIRF REMs programs, and the predecessor risk management programs ("RMPs"), mean that the Defendants could not have marketed their opioids misleadingly. Contrary to the claims of these experts, these programs were not effective in curbing the misunderstandings of prescribers and patients regarding the risks and efficacy of opioids that were caused by Defendants' misstatements. *See* Rosenblatt Report (¶¶ 8(e), 56-61), Michna Report (¶¶ 23-24, 60-90); Nicholson Report (¶¶ 33-37).

44. The FDA first adopted RMPs for certain opioids as far back as 1998. *See* Michna Report (¶¶ 63-71). These programs included educational components that were implemented by the same Defendant opioid manufacturers who were making misstatements regarding the risks and efficacy of opioids.[70]

45. In 2009, FDA outlined its plan for an opioid REMS for Extended Release and Long Acting (ER/LA) opioids.[71] The FDA's original proposal included a requirement for prescribers to obtain a certification to prescribe ER/LA opioids."[72] The FDA also called for certifications for pharmacists that would "reflect that persons dispensing the drug (e.g., pharmacists or hospital personnel) are familiar with educational materials, risks of the drug and conditions for safe use." Lastly, the proposal included a plan for a "database of all enrolled entities including prescribers, pharmacies, practitioners and healthcare settings."

46. The opioid industry, through the Pain Care Forum, immediately set out to "coordinate strategy and water down the FDAs ER/LA REMS proposal."[73] The Pain Care Forum and its members, formed its own working group (the "internal IWG)" to address the threat to industry that a robust REMS would pose.[74] They relied on the same misleading narrative: that stricter regulation would have a negative "impact" on "patient care and access to appropriate medications" and "that the abuse and diversion problem should not, and could not, be solved on the backs of people with pain."[75] As in other efforts by the

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[70] *See generally* TEVA_MDL_A_00564336 (Actiq RMP); TEVA_MDL_A_00265075 (Fentora RiskMAP); ENDO_OPIOID_DEPMAT-000003901 Craven Ex. 9 (Opana ER Riskmap 2007).
[71] PPLP004065860-878 (Slide presentation by FDA on proposed Risk Evaluation and Mitigation Strategies).
[72] *Id.*
[73] Rosen Deposition at 191:1-9.
[74] EPI001059511 (2008 Will Rowe email RE: PCF REMS Task Force with recipients from organizations including APHA, PPSG, Allergan, Endo, Purdue, J&J, NHPCO, Cephalon, HDMA, and APF); Rosen Deposition at Ex. 23, Ex. 24, and Ex. 25 (PCF emails re REMS Task Force, including email from HDMA commenting on proposed letter to FDA).
[75] PPLP004298301-303 (Summary of Pain Care Forum Media Committee).

Pain Care Forum, there was agreement that industry players should operate behind the scene with a public plan that "should be driven by the not-for-profit community, potentially with multiple industry sponsors."[76]

47. Defendants' effort to weaken the opioid REMS was highly effective. FDA's revised final plan, which called for voluntary educational programs funded by opioid makers, was so weak that when it was presented to an external expert Advisory Committee, the plan was voted down 25-10.[77] When asked at the meeting to explain their vote against the FDA proposal, multiple committee members explained that the REMS "lacked teeth."[78]

48. The Defendants then used the new ER/LA opioid REMS education, with a curriculum largely drafted by an industry group led by David Haddox[79] as an opportunity to continue disseminating the false and misleading messages to prescribers. They also used their KOLs as faculty for these programs. For example, an investigation of the ER/LA opioid REMS program found that:

> "While the courses themselves are funded by opioid manufacturers, some faculty also have individual financial ties with the pharmaceutical companies. *Mother Jones* reviewed federal data available through the Physician Payments Sunshine Act for the two dozen faculty listed as teachers for the FDA-mandated courses.[80] Seven had received a combined $1.6 million between 2013 and 2016 from the opioid-makers: Drs. Charles Argoff, Jeffrey Gudin, Michael Brennan, Bill McCarberg, Steven Stanos, Oscar de Leon Casasola, and Lynn Webster. The funding paid for services like speeches, consulting, and research for a range of opioid and non-opioid medications.
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> Some of the faculty on the list have made news in recent years: Argoff and Stanos were cited in Sen. Claire McCaskill's February investigation[81] into pain

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[76] *Id.*
[77] Transcript of the Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC) & Drug Safety and Risk Management Advisory Committee (DSaRM), July 23, 2010 12, 8:00 a.m. to 3:30 p.m.
[78] *Id.*
[79] PPLPC021000287232; PPLPC021000272827; PPLPC021000272826.
[80] *See* https://openpaymentsdata.cms.gov/.
[81] Julie Lurie, "Doctors Receive Opioid Training. Big Pharma Funds It. What Could Go Wrong?," *Mother Jones*, April 27, 2018, https://www.motherjones.com/politics/2018/04/doctors-are-required-to-receive-opioid-training-big-pharma-funds-it-what-could-go-wrong/; Staff of U.S. Senate Homeland Security & Governmental Affairs Committee, Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups, https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf.

advocacy groups for receiving roughly $600,000 and $90,000, respectively, from opioid manufacturers between 2013 and 2016. Brennan, of Fairfield, Connecticut, is among the top 10 Medicare prescribers of OxyContin in the country."[82]

49. Unlike the ER/LA REMS which relied on voluntary educational programs, FDA's REMS for transmucosal immediate release fentanyl (TIRF) opioids relied on a certification process. But, like the ER/LA REMS, it was similarly ineffective.

50. Studies have demonstrated the ineffectiveness of the ER/LA and TIRF REMS programs:

- Generally, the HHS OIG found in 2013 that FDA REMS were ineffective across the board. The OIG reviewed 49 REMS adopted by the FDA between 2008 and 2011. In nearly half the sponsors, did not submit information that the FDA needed to assess the efficacy of the plans, and the FDA was able to determine that only 7 of the 49 met their goals.[83]

- In 2019, Rollman et al studied the TIRF REMS. One of the primary goals was to prevent prescribing of TIRF opioids to non-opioid tolerant individuals (because of the risk of overdose) yet an astonishing 51 percent of patients receiving TIRF opioids as of the 48 month report were opioid non-tolerant.[84] That result persisted in the FDA's 60-month report showing that, depending on the product, 34.6% to 55.4% of TIRF recipients were opioid non-tolerant. Similarly, another one of the goals was limiting TIRF opioids to use for cancer pain, but the 24, 36, and 48-month reports showed that 39.4%, 37.3%, and 34.2% of patients were receiving TIRF opioids for non-cancer pain. *See id.* at 681.

- In 2019, Heyward et al. studied the ER/LA REMS. Unlike the TIRF REMS, the CME courses were voluntary. The goal was to reach 60% of the 320,000 ER/LA opioid prescribers by 2016, but the ER/LA REMS only reached 27.5% of subscribers in that time period.[85] The study further found that, despite requirements to assess whether ER/LA REMS met its goals, there was insufficient data to do so. *See id.* at 307.

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[82] https://www.motherjones.com/politics/2018/04/doctors-are-required-to-receive-opioid-training-big-pharma-funds-it-what-could-go-wrong/.

[83] *See* Office of Inspector General, FDA Lacks Comprehensive Data to Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety, at 2 (Feb. 2013), https://oig.hhs.gov/oei/reports/oei-04-11-00510.pdf.

[84] *See* Rollman et al, *Assessment of the FDA Risk Evaluation and Mitigation Strategy for Transmucosal Immediate-Release Fentanyl Products*, 321 JAMA 676, 678 JAMA (2019).

[85] *See* Heyward et al, *Evaluation of the Extended-Release/Long Acting Opioid Prescribing Risk Evaluation and Mitigation Strategy Program by the US Food and Drug Administration*, 180 JAMA 301, 302 (2019).

- A 2020 HHS OIG Report mirrored the findings of the two studies published in JAMA.[86]

V. Physiological Dependence

51. Physiological dependence and opioid addiction are not identical phenomena but they are closely related. One of the main reasons why opioids are highly addictive is because when a physiologically dependent individual tries to discontinue using opioids they are likely to experience the acute opioid withdrawal, including flu-like symptoms, a worsening of pain, and severe anxiety akin to a panic attack. After the acute symptoms subside, protracted withdrawal symptoms including fatigue, insomnia and cravings can persist for several months. Dr. Wailes misunderstands my position when he argues that I conflate physiological dependence with addiction. Physiological dependence leads to and reinforces OUD, as an individual with this disease must maintain a constant supply of opioids or face severe withdrawal symptoms (see Kolodny Report, p. 7). Therefore, physiological dependence, while not the same as addiction, is one of the main reasons why opioids are highly addictive.

VI. Selection Bias

52. Several Defendants' experts state that my opinions are affected by selection bias. For example, Dr. Yong opines that my "points of view are flawed with selection bias because he is referred patients who are already experiencing poor outcomes from opioid medication (pg. 41)" and Dr. Wailes states that I "do not see and treat the majority of patients who are doing better on opioid medications under the supervision of a physician to alleviate chronic pain (pg. 20)". It is true that opioid-dependent pain patients referred to me for treatment are often experiencing severe symptoms of OUD. But because of my experience treating OUD with buprenorphine, I have also had the opportunity to see patients function well on an opioid. What is clear to me from my clinical experience and the medical literature is that patients on long-term opioids who appear to be doing well are doing well *despite* their long-term opioid use, not because of it. It is also important to recognize that the perception of pain specialists who prescribe opioids for chronic pain is influenced by the reports they receive from opioid-dependent patients who are desperate to leave each visit with a new prescription. If these patients acknowledged their concerns about addiction, dependence, misuse, and decreased function they would risk getting cut off from their opioid supply. Moreover, I understand that Dr. Clauw, an expert in the sub-field of pain medicine, will opine in greater detail on the ineffectiveness of opioids for chronic pain.

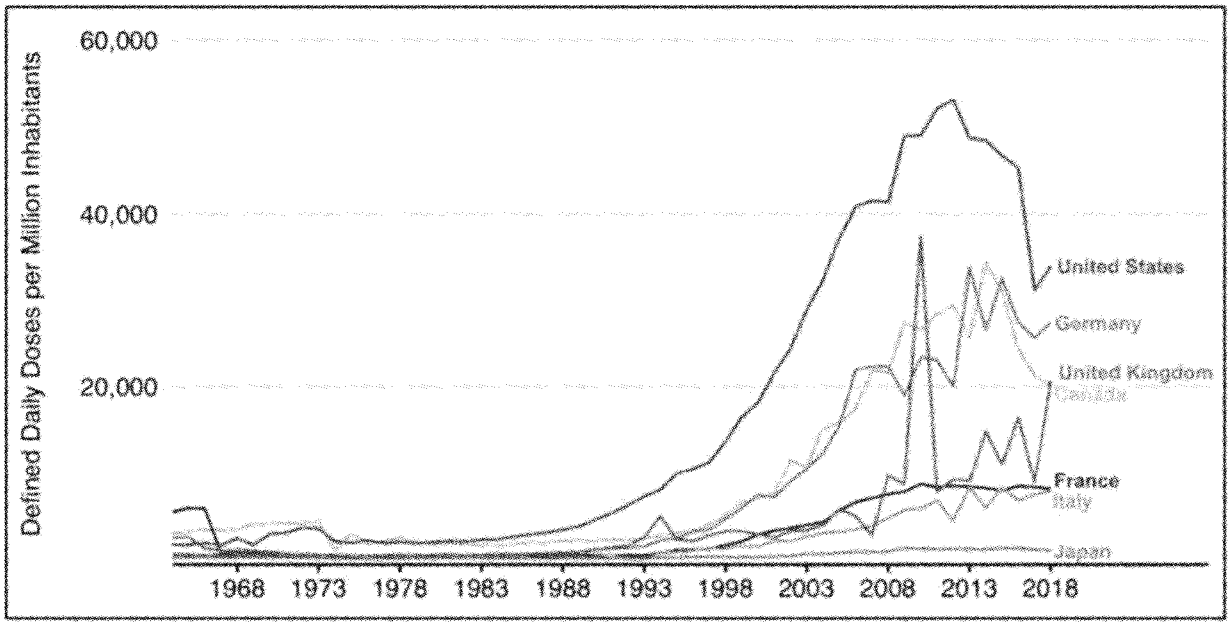
[86] *See* https://www.oig.hhs.gov/oei/reports/OEI-01-17-00510.pdf.

VII. Baseline

53. The volume of prescription opioids supplied in 1997 is a conservative baseline to measure unjustified prescribing. Prior to 1997, the opioid supply had been gradually increasing for more than a decade and Americans were already consuming more opioids per capita than people in other countries with advanced health care systems. After 1997, the dramatic increase in supply cannot be explained by an increase in clinical need. Despite several Defendants' experts including Drs. Warfield, Garthwaite, McCrary, Baker, and Nicholson highlighting other factors that could have led to an expansion in the prescription opioid supply, the most significant factors that increased this supply were the actions of the Defendants that are described in my report.

54. An increase in the supply of prescription opioids and an oversupply of these medications are not the same thing, as noted in the McCrary Report. However, I disagree with Dr. McCrary that I am conflating an increase in supply with an oversupply. The Figure below (and Figure 8 in my report) depict international comparisons of opioid consumption. It was in the late 1980's that opioid consumption began to increase in the United States and, beginning in 1997, it began to rise exponentially. My opinion is that this exponential increase was driven by the branded and unbranded campaign to promote aggressive and inappropriate opioid prescribing, of which the Defendants were a part of. The soaring increase in opioid consumption was not driven by an exponential increase in pain or an increase in the incidence of end-of-life cancer pain, or an increase in health insurance coverage in the United States as alleged by Defendants' experts. For example, Dr. Baker opines that an increase in the prevalence of chronic conditions and increased cancer survivorship are factors that could have increased the prescription opioid supply. However, as discussed above, prescription opioids should not be initiated for chronic conditions, and increased cancer survivorship should imply that fewer terminal conditions, where opioid may be warranted, are being diagnosed.

Figure 1: Total Opioid Consumption for G-7 Countries



Source: Congressional Research Service (2021)

55. Examining opioid consumption by the prescription rate can be misleading. For example, Figure 5 in Dr. McCrary's report shows schedule II opioid prescriptions per capita for Florida and the United States and leads him to conclude "Florida's rate of prescribing of Schedule II opioid medicines is moderately higher than that of the U.S. through 2011 and moderately lower afterward (pg. 31)." However, Figure 9 in my report shows that using the rate of prescriptions for Florida is misleading. When opioid consumption is appropriately measured using sales per kilogram instead of rate of prescriptions, consumption in Florida dramatically increased starting in 2005, was more than 3.5-fold higher than the national rate in 2010 for oxycodone, and remained higher than the national rate throughout the time period 2000-2019 (p. 24).

    Dr. McCrary also uses the number of prescriptions instead of a more accurate measure of consumption, such as morphine milligram equivalents (MME), when assessing Endo prescriptions over time. According to this methodology, an acute pain prescription for Percocet 5mg with 10 tablets (total 75 MME) would be counted the same as a 30-day prescription for Opana ER 40mg taken twice a day for moderate to severe chronic pain (total 7,200 MME), though there is a nearly 100-fold difference in MME between these two prescriptions.

VIII. Impact Rebuttal

56. There has been a sharp increase in the prevalence of OUD in the United States and the State of Florida as a result of overexposing the population to prescription opioids. This increased prevalence has resulted in an array of opioid-related health and social problems

commonly referred to as the opioid crisis. The disease of OUD arises from repeated exposure to opioids and can occur through iatrogenic exposure in individuals using opioids to relieve pain and in non-medical users.

57. The risk of developing OUD increases with duration of use and dose, but the incidence (that is, the number of new cases) is unknown because prospective, randomized controlled trials designed to answer this question have not been performed. Patients in a clinical trial, as well as patients in a clinical practice, may withhold concerns about development of OUD because they feel ashamed or because they fear being cut off from a legal supply of opioids. In addition, some pain patients with OUD lack insight that their opioid use is harming them and that they have become addicted. Opioid manufacturers have pointed to data from clinical trials designed to assess opioid efficacy (and systematic reviews that combine results from these trials) to falsely claim that addiction rarely develops in patients prescribed opioids for chronic pain. Defendants' experts have used these studies to argue that developing OUD during long-term opioid therapy is rare. For example, the Yong report states that "the SPACE trial did not detect any deaths, doctor shopping, diversion, or opioid use disorder in the opioid treatment group (pg. 40)." However, the SPACE trial was not designed to measure OUD, nor was there a clinically recognized tool used to assess OUD. Also, the authors explicitly stated that "this trial did not have sufficient statistical power to estimate rates of death, opioid use disorder, or other serious harms associated with prescribed opioids (pg. 881)."

58. Developing OUD from long-term opioid therapy is not a rare occurrence.[87] I rely in part on Boscarino et al.[88] to estimate the prevalence of mild OUD among individuals receiving long-term opioid therapy. Boscarino and colleagues measured the prevalence of OUD in patients prescribed opioids with a structured diagnostic interview via telephone that did not put the patient at risk of losing access to their prescription opioid supply. Assessment methods for OUD that opioid-dependent patients perceive as putting their prescription opioid access at risk are likely to produce biased results. As noted by Defendants' expert Dr. Fryzek, this study was done in a large healthcare system in Pennsylvania. I reviewed the demographics and clinical characteristics of these study participants and saw no evidence of outliers that would affect the generalizability of these results to long-term opioid therapy patients in Florida.

59. The risk of iatrogenic OUD and opioid-related harms increases with higher doses and longer duration of opioid therapy. This dose-response relationship has been found across a range of studies.[89] As stated in my report (p. 9, ¶ 19), in a study of more than 500,000

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[87] Jane C. Ballantyne, "Assessing the Prevalence of Opioid Misuse, Abuse, and Addiction in Chronic Pain," *Pain* 156, no. 4 (April 2015): 567–68, https://doi.org/10.1097/j.pain.0000000000000105.

[88] Joseph A. Boscarino, Stuart N. Hoffman, and John J. Han, "Opioid-Use Disorder among Patients on Long-Term Opioid Therapy: Impact of Final DSM-5 Diagnostic Criteria on Prevalence and Correlates," *Substance Abuse and Rehabilitation* 6 (2015): 83–91, https://doi.org/10.2147/SAR.S85667.

[89] Chou et al., "The Effectiveness and Risks of Long-Term Opioid Therapy for Chronic Pain."

individuals with new-onset chronic non-cancer pain, exposure to prescription opioids was a strong risk factor for OUD, with duration of opioid therapy being the most important factor, followed by dose. For example, those taking 120 MME or more daily for 90 days or more had 122 times higher odds of developing OUD compared those who had not been prescribed opioids after controlling for potential confounders.[90]

60. Even brief exposure to the medical use of opioids leads to an increased risk of OUD for adolescents. Defendants' expert Warfield points to a study showing no increase of subsequent addiction following medical use of opioids in adolescents.[91] The same authors of the study cited by Warfield showed, in a later prospective study, that there was, in fact, an increased risk in the 1997-2000 cohort (when the supply of opioids dramatically increased), as the odds of heroin use were 2.7 times higher for the group that reported medical use only at age 18 compared with the group that reported no NMPOU or medical use.[92] This is an adjusted odds ratio that controlled for a range of sociodemographic and clinical characteristics. The authors suggested that "the stronger association between medical use of prescription opioids and transitioning to heroin use in more recent cohorts could be due to the changes in opioid prescribing (pg. 243)." Other studies have found that legitimate prescription opioid use before high school graduation was independently associated with a 33% increase in the risk of future opioid misuse after high school,[93] and that college students who were previously prescribed opioids were subsequently more likely to misuse them.[94] For these reasons, I disagree with Warfield's opinion that medical use of opioids is not associated with subsequent addiction in adolescents.

61. Prior history of a substance use disorder is considered a risk factor for OUD. However, a precondition for developing OUD is exposure to an opioid,[95] and the strongest risk factors for developing OUD among those given a prescription opioid are the dose and

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[90] Edlund et al., "The Role of Opioid Prescription in Incident Opioid Abuse and Dependence among Individuals with Chronic Noncancer Pain."

[91] Sean Esteban McCabe et al., "A Prospective Study of Nonmedical Use of Prescription Opioids during Adolescence and Subsequent Substance Use Disorder Symptoms in Early Midlife," *Drug and Alcohol Dependence* 194 (January 1, 2019): 377–85, https://doi.org/10.1016/j.drugalcdep.2018.10.027.

[92] Sean Esteban McCabe et al., "Pills to Powder: A 17-Year Transition From Prescription Opioids to Heroin Among US Adolescents Followed Into Adulthood," *Journal of Addiction Medicine* 15, no. 3 (June 1, 2021): 241–44, https://doi.org/10.1097/ADM.0000000000000741.

[93] Richard Miech et al., "Prescription Opioids in Adolescence and Future Opioid Misuse," *Pediatrics* 136, no. 5 (November 2015): e1169-1177, https://doi.org/10.1542/peds.2015-1364.

[94] Sean Esteban McCabe, Christian J. Teter, and Carol J. Boyd, "Illicit Use of Prescription Pain Medication among College Students," *Drug and Alcohol Dependence* 77, no. 1 (January 7, 2005): 37–47, https://doi.org/10.1016/j.drugalcdep.2004.07.005.

[95] Deborah Dowell, Hillary V. Kunins, and Thomas A. Farley, "Opioid Analgesics--Risky Drugs, Not Risky Patients," *JAMA* 309, no. 21 (June 5, 2013): 2219–20, https://doi.org/10.1001/jama.2013.5794.

duration of opioid therapy.[96] That is, the longer people are on prescription opioids, and the higher the dose, the more likely they are to get addicted. This highlights the fact that the inherent addictive potential of opioids is more significant for the development of addiction than an individual's characteristics. OUD is primarily a disease of exposure or, as is sometimes said, the problem is "risky drugs, not risky people." Despite the known risks of these medications, Defendants repeatedly downplayed the risk of addiction and put out publications and messages suggesting that addiction could be avoided with the right screening of patients. *See section II* of my rebuttal.

62. The expansion of non-medical users would not have occurred without the widespread availability of opioids prescribed for conditions where use is inappropriate and/or in far greater quantities and doses than needed, leaving a surplus of opioids that could be diverted. Dr. McCrary opines that "changing drug trends, intentional misuse, and the illegal actions of non-defendants all contribute to diversion (pg. 65)." This statement is misleading because it ignores the role of the Defendants in making prescription opioids easily available for diversion. Evidence supporting this view includes:

    - A systematic review estimates that 67-92% of patients reported having unused prescription opioids after surgery,[97] and another study found that more than half of the opioids prescribed for dental surgery were unused three weeks after surgery.[98] This underscores the widespread availability of prescription opioids for non-medical use.

    - The branded and unbranded campaign to increase sales of prescription opioids in the United States and the State of Florida was successful in decreasing the perceived risk of opioids. This led to increased consumption for medical use as well as decreased perceived risk of non-medical use among youth.[99]

    - Increased availability and decreased perceived risk spurred diversion. There is evidence that living in a household with a prescription opioid user is associated

[96] Edlund et al., "The Role of Opioid Prescription in Incident Opioid Abuse and Dependence among Individuals with Chronic Noncancer Pain."
[97] Bicket et al., "Prescription Opioid Analgesics Commonly Unused After Surgery."
[98] Brandon C. Maughan et al., "Unused Opioid Analgesics and Drug Disposal Following Outpatient Dental Surgery: A Randomized Controlled Trial," *Drug and Alcohol Dependence* 168 (November 1, 2016): 328–34, https://doi.org/10.1016/j.drugalcdep.2016.08.016.
[99] Raminta Daniulaityte, Russel Falck, and Robert G. Carlson, "'I'm Not Afraid of Those Ones Just 'cause They've Been Prescribed': Perceptions of Risk among Illicit Users of Pharmaceutical Opioids," *The International Journal on Drug Policy* 23, no. 5 (September 2012): 374–84, https://doi.org/10.1016/j.drugpo.2012.01.012.

with an increased risk of prescription opioid use,[100] parental prescription opioid use is associated with adolescent prescription opioid use and misuse,[101] and having a family member who is prescribed opioids is associated with increased risk for prescription opioid overdose among youths.[102]

- Despite knowing about the diversion of their products, opioid manufacturers and other stakeholders in the supply chain supported initiatives portraying efforts to reduce opioid prescribing as restricting access to legitimate pain patients who were allegedly benefiting from the medication, while focusing the blame of increased diversion on the actions of "drug abusers".[103]

63. The driving force in increasing opioid-related morbidity and mortality was, and continues to be widespread availability of opioids. This overexposure of the population to prescription opioids led to a dramatic increase in OUD. My report shows that opioid-related harm soared in Florida as the supply of prescription opioids increased (see Figure 9 and 10 from Kolodny Report). This sharp increase in opioid-related harms occurred before the infiltration of fentanyl, suggested by Dr. Garthwaite as a missing link in explaining an increase in opioid-related morbidity and mortality. As I discuss in detail in Section B of my report, some examples in Florida include:

- The rate of admissions to state-licensed treatment programs for primary addiction to prescription opioids rose from 7 per 100,000 in 1997 to 164 per 100,000 in 2011, an increase of more than 2,000%.

- A 250% increase in opioid-related overdose deaths from 1999-2010, with a six-fold increase in prescription opioid-related overdose deaths from 1999-2010 and a nearly five-fold increase in overdose deaths that were caused by oxycodone in just a six-year period from 2005-2010.

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[100] Marissa J. Seamans et al., "Association of Household Opioid Availability and Prescription Opioid Initiation Among Household Members," *JAMA Internal Medicine* 178, no. 1 (January 1, 2018): 102–9, https://doi.org/10.1001/jamainternmed.2017.7280.

[101] Pamela C. Griesler et al., "Assessment of Prescription Opioid Medical Use and Misuse Among Parents and Their Adolescent Offspring in the US," *JAMA Network Open* 4, no. 1 (January 4, 2021): e2031073, https://doi.org/10.1001/jamanetworkopen.2020.31073.

[102] Anh P. Nguyen et al., "Association of Opioids Prescribed to Family Members With Opioid Overdose Among Adolescents and Young Adults," *JAMA Network Open* 3, no. 3 (March 2, 2020): e201018, https://doi.org/10.1001/jamanetworkopen.2020.1018.

[103] Defendants promoted this concept through unbranded work like *Responsible Opioid Prescribing*, discussed herein, ENDO_OPIOID_DEPMAT-000040854, which argued at 26-27 that the "specter of scrutiny" limited legitimate pain relief. ENDO-OPIOID_MDL-02841004 at 1010 (Endo employees discussing how crackdown on diversion impacts "the lack of access for patients" to opioids).

- A doubling of opioid-related hospitalization and a 43% increase in opioid-related emergency department visits from 2005-2011.

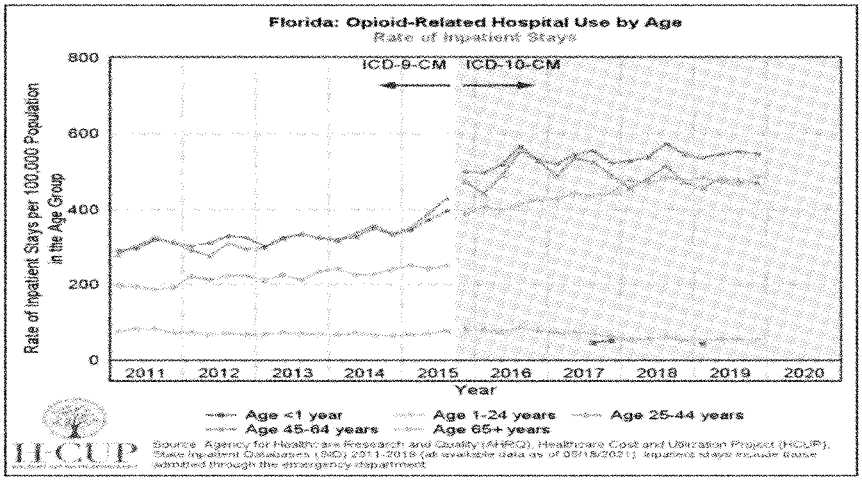
- A nearly sixteen-fold increase in the rate of Neonatal Abstinence Syndrome (NAS), rising from 0.4 per 1,000 live births in 1999 to 6.3 per 1,000 live births in 2013.

- A more than thirteen-fold increase in the rate of maternal OUD at delivery, rising from 0.5 per 1,000 deliveries in 1999 to 6.6 per 1,000 deliveries in 2014.

64. The exponential increase in these indicators for opioid-related harm make clear that the opioid crisis is not confined to people who were already drug users. Several Defendants' experts including Drs. Wailes, McCrary, Warfield, and Nicholson opine that other substances serve as a gateway to opioid misuse and OUD, and that a subset of these drug abusers switch between substances over time. As discussed above, the disease of OUD arises from repeated exposure to opioids and can occur through iatrogenic exposure in individuals using opioids to relieve pain and in non-medical users. The oversupply of opioids led to an increase in iatrogenic OUD and increased OUD from prescription opioids that had become more available for non-medical use.

    - Defendants' expert McCrary relies on past-year rates of illicit drug use to conclude that "the available evidence and data show that illicit drug use is prevalent and persistent throughout time and that when forces such as interdiction or prohibition limit drug supply, drug use shifts between substances (pg. 21)." However, using past-year rates, which captures individuals who report using an illicit substance just one time in the past year, is a proxy for *recreational* use, not addiction and related morbidity and mortality. Dr. McCrary notes that past-year non-medical use of prescription opioids is not highly correlated with the supply of prescription opioids, leading him to conclude that "this fact demonstrates that non-medical use of prescription opioid medications has no necessary connection to the allegedly deceptive marketing of which Plaintiff complains (pg. 14)." However, the decline in past-year non-medical use starting in the early 2000's does not correlate with indicators of opioid-related harm discussed above (e.g., opioid-related treatment admissions, hospitalizations, overdoses, NAS rates). In fact, during that time frame, measures of opioid-related morbidity and mortality were *increasing* in older adults, who are more likely to be frequently exposed to opioids through medical use (see Figure 2 below for trends in opioid-related hospitalizations in Florida). In short, measuring recreational use in the past year does not get at the real problem, which is addiction.

Figure 2: Trends in Opioid-Related Hospitalizations in Florida by Age



Source: Healthcare Cost and Utilization Project

- Many individuals who reported non-medical use of opioids likely developed OUD over a period of many years. Research shows that earlier initiation of non-medical use is associated with higher odds of OUD but also slower transition to OUD.[104] The incidence and prevalence of addiction to specific drugs is not static- it changes over time and in different groups and is influenced by availability, cultural norms, and attitudes, all factors that were influenced by the Defendants in relation to opioid use.

- In Figure 13 and 14 of his report, Dr. McCrary shows a negative correlation between the age distributions of prescription opioid-related treatment admissions in Florida by age of first use and opioid medication prescriptions to conclude that "the data are more consistent with prescription opioid abuse and addiction resulting from misuse (pg. 58)." Given the limitations of the data source used and the fact that opioid-related morbidity and mortality was higher in older adults (see Figure 2 above),[105] this conclusion is misguided. These figures use TEDS data, which is limited because it only includes state-licensed treatment facilities and does not include non-specialty treatment settings, such as a private doctor's office. In addition, these figures are misleading because 5% of the population indicating age of first use as "30 and over" are excluded as well as 2,160 admits

[104] Ty S. Schepis and Jahn K. Hakes, "Age of Initiation, Psychopathology, and Other Substance Use Are Associated with Time to Use Disorder Diagnosis in Persons Using Opioids Nonmedically," *Substance Abuse* 38, no. 4 (December 2017): 407–13, https://doi.org/10.1080/08897077.2017.1356791.

[105] Andrew Kolodny et al., "The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction," *Annual Review of Public Health* 36 (March 18, 2015): 559–74, https://doi.org/10.1146/annurev-publhealth-031914-122957.

that had a missing age of first use. Lastly, Figure 2 above shows high levels of morbidity in older adults in Florida, and evidence shows that earlier initiation of non-medical use is associated with higher odds of OUD but also slower transition to OUD.[106] Nevertheless, OUD is a disease of exposure that develops from repeated use, both medical and non-medical use.

- Defendants' expert Warfield points to a study by Cicero et al.[107] that shows that the large majority of individuals who developed iatrogenic OUD had a lifetime history of substance use. The sample used for this study were individuals who entered treatment and reported past-month opioid abuse. About half of the study participants were first exposed to opioids through a medical prescription, so it is likely assumed that the other half were exposed to opioids through non-medical use. In other words, there is a mix of individuals who developed both iatrogenic OUD and OUD through non-medical use. Lifetime use of alcohol and marijuana was reported by 93% and 87% of study participants respectively. In the general population, lifetime use of alcohol and marijuana is 86% and 54% respectively.[108] In addition to these being somewhat similar, lifetime use of a substance tells us nothing about frequency, which is more closely related to addiction. Also, the study does not differentiate whether other controlled substances (e.g., amphetamine, benzodiazepines) were prescribed or used non-medically. Another limitation is that this is a study of individuals in treatment, which likely would not be representative of all individuals with OUD. Lastly, data for this study was collected by RADARS, which was founded by Purdue and is funded by opioid manufacturers including the Defendants.[109] Prior history of a substance use disorder is believed to be a risk factor for OUD. However, as highlighted above, the inherent addictive potential of opioids is more significant for the development of addiction than an individual's characteristics.

- The Wailes report states "there is a strong argument that increased recreational drug consumption of all other types (i.e., alcohol, marijuana, heroin, and other illicit drugs) is more likely a causative factor in the substantial year-over-year

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[106] Schepis and Hakes, "Age of Initiation, Psychopathology, and Other Substance Use Are Associated with Time to Use Disorder Diagnosis in Persons Using Opioids Nonmedically."
[107] Theodore J. Cicero, Matthew S. Ellis, and Zachary A. Kasper, "Psychoactive Substance Use Prior to the Development of Iatrogenic Opioid Abuse: A Descriptive Analysis of Treatment-Seeking Opioid Abusers," *Addictive Behaviors* 65 (February 2017): 242–44, https://doi.org/10.1016/j.addbeh.2016.08.024.
[108] SAMHSA, "Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health" (Rockville, MD: Center for Behavioral Health Statistics and Quality, 2020), https://www.samhsa.gov/data/.
[109] Bob Herman, "The Opioid Tracking Group with Big Pharma Ties," *Axios*, June 11, 2019, https://www.axios.com/opioid-monitoring-group-purdue-pharma-radars-8c71c4a8-ef96-4145-bdf1-0f7f37dbaf80.html.

rises in heroin and illicit fentanyl deaths than are prescription opioids (pg. 26)" and "the data strongly suggests that prescription opioids did not cause the heroin use and, instead, other illicit drug use and psychological factors were a more likely cause of heroin use (and prescription opioids misuse) (pg. 26)." Dr. Wailes posits that marijuana is a gateway to opioid misuse and subsequent OUD, that a mental health crisis is driving people to self-medicate with opioids, and that other illicit drug use is responsible for an increase in heroin use. Though prior marijuana use may be a modest risk factor in non-medical use of prescription opioids among adolescents,[110] recreational cannabis laws are associated with a decrease in opioid-related emergency department visits,[111] suggesting that marijuana use is not a gateway to OUD. There is not evidence of a mental health crisis causing an opioid crisis. Rates of major depressive disorder have remained stable throughout the opioid crisis in adults aged 26 and older, the population most impacted by opioid-related morbidity and mortality, and only began increasing in adolescents and young adults in 2012 and 2014 respectively.[112] Dr. Wailes ignores the nature of OUD and the interchangeability of prescription opioids and heroin to erroneously draw the conclusion that other illicit drug use leads to heroin use (see Section IX below for further discussion).

- The Nicholson report used Florida Medicaid claims data and found that "of those who were first diagnosed with OUD between 2012 and 2019, between 6.5 percent (in 2019) and 14.9 percent (in 2015) had a prior diagnosis of non-opioid drug disorder (pg. 52)." However, these disorders are common in the Medicaid population, with around 12% of all Medicaid beneficiaries over the age of 18 having a substance use disorder.[113] Prior history of a substance use disorder is believed to be a risk factor for OUD, but it is unclear if Florida Medicaid beneficiaries with OUD who had a prior substance use disorder were any different than the total population of Medicaid beneficiaries.

65. The State of Florida is experiencing an epidemic of OUD, not a "substance abuse crisis" as stated by several Defendants' experts including Drs. Yong, Kyle, Fryzek, Nicholson,

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[110] Arthur Robin Williams, "Cannabis as a Gateway Drug for Opioid Use Disorder," *The Journal of Law, Medicine & Ethics : A Journal of the American Society of Law, Medicine & Ethics* 48, no. 2 (June 2020): 268–74, https://doi.org/10.1177/1073110520935338.

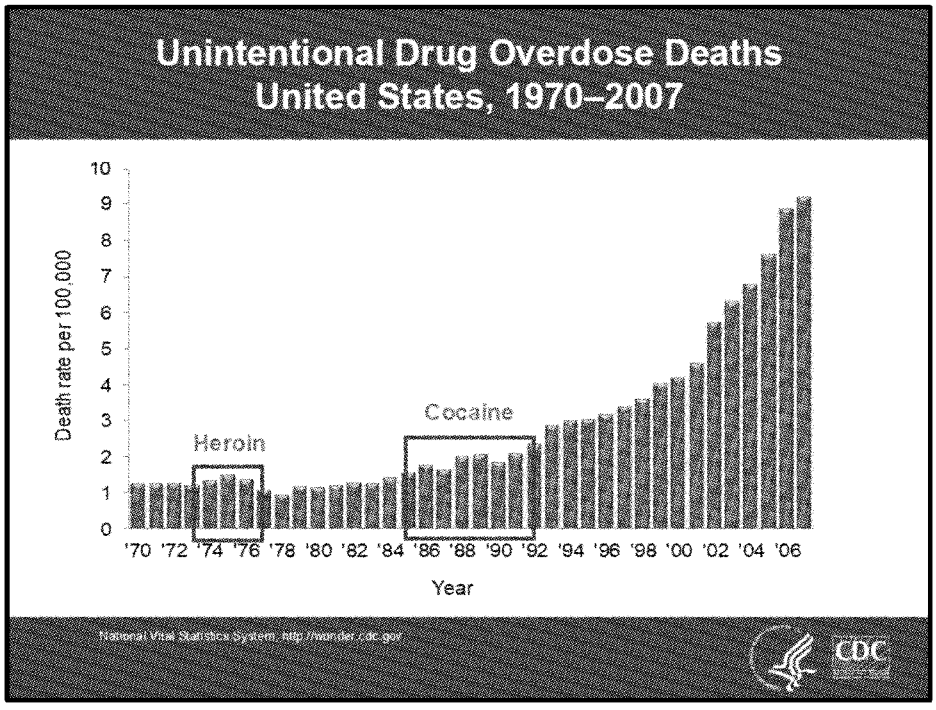
[111] Coleman Drake et al., "Recreational Cannabis Laws and Opioid-Related Emergency Department Visit Rates," *Health Economics* 30, no. 10 (September 2021): 2595–2605, https://doi.org/10.1002/hec.4377.

[112] SAMHSA, "Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health."

[113] Medicaid.gov, Substance Use Disorders, n.d., https://www.medicaid.gov/medicaid/benefits/behavioral-health-services/substance-use-disorders/index.html.

and McCrary. Several Defendants' experts refer to Jalal et al.[114] to support their view that the opioid crisis has been driven by a common source underlying all historical drug epidemics. This study found compelling data showing how overdose mortality has impacted different racial and age groups differently over time. When referring to these differences, authors state "these findings add to the paradox by revealing how disparate the individual drug epidemics are (pg. 3)." This suggests that drug mortality has been driven by different phenomena rather than the same phenomenon, as Defendants' experts suggest. In addition, the starting point of this study to the time when the opioid supply began to rapidly increase in the United States, which included the crack-cocaine epidemic of the 1980's, saw an increase in the drug overdose death rate from a little more than 1 per 100,000 people to around 3 per 100,000, which could be capturing the effect of better surveillance, whereas the beginning of the opioid crisis (1997) to the end of the study period showed an increase of the drug overdose death rate from 3 to 17 per 100,000 people. Figure 3 below shows drug-related mortality from 1970-2007. What is obvious is that there was a small increase in mortality from 1980 to the mid-1990's, when defendants ramped up their push for aggressive prescribing of opioids, and that, in the absence of the opioid crisis caused by the Defendants, mortality may have plateaued or decreased after the crack-cocaine epidemic.

Figure 3: Unintentional Drug Overdose Mortality, 1970-2007



Source: National Vital Statistics System. http://wonder.cdc.gov

[114] Hawre Jalal et al., "Changing Dynamics of the Drug Overdose Epidemic in the United States from 1979 through 2016," *Science (New York, N.Y.)* 361, no. 6408 (September 21, 2018): eaau1184, https://doi.org/10.1126/science.aau1184.

66. There are a variety of factors that can affect opioid-related outcomes in a population. However, the substantial factor was the branded and unbranded campaign to increase opioid prescribing in the United States and Florida. Several Defendant's experts including Drs. McCrary, Nicholson, Garthwaite, and Kyle mention the role of other factors, such as socioeconomic and macroeconomic conditions. For example, the Nicholson report cites several papers to support this view. However, when contextualizing these associations, Venkataramani et al.[115] concludes that "our findings should not be interpreted in such a way as to diminish the role of opioid supply (pg. 260)", Hollingsworth et al.[116] concludes "we know little about the mechanisms for the effects observed here… our results could be consistent with a role for supply-side factors (pg. 232)", and Charles et al.[117], although appearing not to be peer-reviewed, highlights that "these results suggest that a combination of both opioid supply and opioid demand are contributing to the rise in opioid use and opioid deaths during the 2000s (pg. 62)." The McCrary Report (p. 82) notes that "differences in economic opportunities, drug-use patterns, socioeconomic status, and demographics can all play a significant role in determining drug-related outcomes, such as opioid-related mortality". Though a variety of factors are likely to play a role in any crisis, research has shown that these conditions play a minor role at best in causing the opioid crisis and that the driving force in increasing opioid-related morbidity and mortality was access to and widespread availability of opioids. The following studies illustrate the point that the rise in deaths was specific to opioids and OUD, and not part of some kind of general rise in "deaths of despair."

    - Ruhm[118], affiliated with the National Bureau of Economic Research, used econometric methods to examine the role of both changes in county-level economic conditions and the drug environment in explaining opioid-related mortality. The study found that "after controlling for confounding factors, less than one-tenth of the increase in drug mortality rates was explained by economic factors…even modest amounts of omitted variables bias may be sufficient to completely eliminate any remaining associations (pg. 40)" and concludes that supply-side factors have primarily caused the crisis, stating that "rising drug

[115] Atheendar S. Venkataramani et al., "Association Between Automotive Assembly Plant Closures and Opioid Overdose Mortality in the United States: A Difference-in-Differences Analysis," *JAMA Internal Medicine* 180, no. 2 (February 1, 2020): 254–62, https://doi.org/10.1001/jamainternmed.2019.5686.
[116] Alex Hollingsworth, Christopher J. Ruhm, and Kosali Simon, "Macroeconomic Conditions and Opioid Abuse," *Journal of Health Economics* 56 (2017): 222–33.
[117] Kerwin Kofi Charles, Erik Hurst, and Mariel Schwartz, "The Transformation of Manufacturing and the Decline in US Employment," *NBER Macroeconomics Annual* 33, no. 1 (2019): 307–72.
[118] Christopher J. Ruhm, "Drivers of the Fatal Drug Epidemic," *Journal of Health Economics* 64 (March 2019): 25–42, https://doi.org/10.1016/j.jhealeco.2019.01.001.

mortality was initially driven by opioid analgesics, with more recent growth being mostly due heroin and fentanyl (pg. 40)."

- Cutler and Glaeser[119], both affiliated with the National Bureau of Economic Research, used an econometric analysis to examine whether the increase in the prescription opioid supply had a larger impact on opioid shipments and deaths in communities with more pain and with more despair. They found that despair played no role in their model and pain that is severe enough to interfere with work only explained 4% of the increase in opioid use. The authors concluded that "great shift was not in the level of reported pain or in feelings of despair, but in the willingness of doctors to prescribe opioids for pain."[120]

- Masters et al[121] examined trends in all-cause and cause-specific mortality rates among younger and middle-aged U.S. white men and women between 1980 and 2014. The authors found relatively stable rates of suicide deaths or alcohol-related deaths during this time period, but dramatic increases in drug-related deaths beginning in the 1990s. The authors did not find support for the Deaths of Despair hypothesis that a common source was driving increased suicides, alcohol-related deaths, and drug-related deaths, concluding that "it is unlikely that recent trends in U.S. white men's and women's mortality rates have been driven by an epidemic of pain and rising distress (pg. 87)" and "recent mortality increases among younger and middle-aged US White men and women have likely been shaped by the US opiate epidemic and an expanding obesogenic environment (pg. 81)."

- Dow et al[122], whose lead author is affiliated with the National Bureau of Economic Research, used causal models to examine the potential impact of economic policies on deaths of despair. They found no significant effects on drug or alcohol-related mortality, concluding that their results support Ruhm's finding that supply-side drivers – that is, the supply of opioids, and not economic conditions -- are primarily responsible for rise in fatal overdoses.

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[119] David M. Cutler and Edward L. Glaeser, "When Innovation Goes Wrong: Technological Regress and the Opioid Epidemic," *National Bureau of Economic Research Working Paper*, 2021, https://www.nber.org/system/files/working_papers/w28873/w28873.pdf.
[120] David M. Cutler and Edward L. Glaeser, "Understanding the Opioid Epidemic: When Innovation Fails," VoxEU & CEPR, 2021, https://voxeu.org/article/understanding-opioid-epidemic-when-innovation-fails.
[121] Ryan K. Masters, Andrea M. Tilstra, and Daniel H. Simon, "Explaining Recent Mortality Trends among Younger and Middle-Aged White Americans," *International Journal of Epidemiology* 47, no. 1 (February 1, 2018): 81–88, https://doi.org/10.1093/ije/dyx127.
[122] William H. Dow et al., "Can Labor Market Policies Reduce Deaths of Despair?," *Journal of Health Economics* 74 (December 2020): 102372, https://doi.org/10.1016/j.jhealeco.2020.102372.

- Krueger[123], affiliated with the National Bureau of Economic Research, used econometric models to examine trends in labor force participation, with a particular focus on the role of prescription opioids. The study found that 30% of middle-aged working men who were not participating in the labor force reported using prescription pain medication, mostly likely opioids, and that "labor force participation is lower in areas of the United States with a high rate of opioid prescriptions, and labor force participation fell more over this 15-year period in areas with a high rate of opioid prescriptions (pg. 21)." The author concludes "regardless of the direction of causality, the opioid crisis and depressed labor force participation are now intertwined in many parts of the United States. And despite the massive rise in opioid prescriptions in the 2000s, there is no evidence that the incidence of pain has declined… Addressing the opioid crisis could help support efforts to raise labor force participation and prevent it from falling further (pg. 23-24)."

- MacLean et al[124], whose lead author and multiple co-authors are affiliated with the National Bureau of Economic Research reviews more than 100 economic studies examining the causes and consequences of the opioid crisis. The review found that studies investigating the role of economic factors showed mixed results and generally did not point to declining economic conditions as the main cause of the opioid crisis. The authors concluded that "supply-side factors (e.g., aggressive pharmaceutical industry promotion of prescription opioids) were a primary cause of the epidemic, but with demands-side factors determining which groups have been most adversely affected (pg. 25)."

IX. Causal relationship between prescription opioids, OUD, and heroin use

67. The disease of OUD arises from repeated exposure to opioids and can occur through iatrogenic exposure in individuals using opioids to relieve pain and in non-medical users. Defendant expert Warfield opines that non-medical users "were not patients with painful conditions prescribed opioids by physicians but likely were addicts who received them from friends, purchased them on the street or stole them (pg. 106)." Actions of the Defendants that led to a medically inappropriate expansion in the supply of opioids are responsible for increasing the prevalence of OUD among both medical and non-medical users. Many medical users subsequently became non-medical users. Based on published research findings and my clinical experience, many individuals who developed OUD

[123] Alan B. Krueger, "Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate," *Brookings Papers on Economic Activity* 2017, no. 2 (2017): 1–87, https://doi.org/10.1353/eca.2017.0012.
[124] Johanna Catherine Maclean et al., "Economic Studies on the Opioid Crisis: A Review," *National Bureau of Economic Research Working Paper*, 2020, https://www.nber.org/system/files/working_papers/w28067/w28067.pdf.

from prescription opioids transitioned to heroin use to ensure an adequate opioid supply and avoid withdrawal.

68. Opioid use disorder that develops from prescription opioid use is associated with subsequent heroin use, and in turn, heroin use contaminated with fentanyl. Were it not for the actions of the Defendants, there would not have been a sharp increase in the prevalence of OUD and the associated increase in heroin-related and fentanyl-related harms. Although Dr. McCrary mischaracterizes my position as "prescription opioid users (pg. 66)" who are dying from illicit opioids, my opinion is that a majority of Florida's heroin- and fentanyl-related deaths occurred in individuals who developed OUD from medical and non-medical use of prescription opioids. Prescription opioids, heroin, and fentanyl have similar pharmacological profiles and are used interchangeably by individuals with OUD.

69. The increased prevalence of OUD led to a sharp rise in the use and availability of heroin and illicitly synthesized fentanyl. Several Defendants' experts including Drs. Warfield, Garthwaite, Kyle, Fryzek, Wailes, and McCrary call into question the causal relationship between prescription opioid, heroin use, and fentanyl use, citing the lack of experimental evidence and potential confounders not considered. However, there is a large body of observational evidence that can be used to deduce a causal relationship between prescription opioid use and heroin use. This evidence includes:

    - Jones[125] compared pooled data from the 2002-2004 NSDUH and the 2008-2010 NSDUH and found that the rate of heroin use among individuals aged 12 and over reporting past-year nonmedical prescription opioid use (NMPOU) nearly doubled between 2002-04 and 2008-10, from 1.8% to 3.4%, while there was no increase among people who did not report NMPOU. In addition, the study also showed that, among respondents that reported past-year heroin use and NMPOU, the proportion that reported NMPOU first increased from 64% in 2002-04 to 83% in 2008-10. The author concludes that "the findings in this study support a relationship between increases in nonmedical use of opioid pain relievers and increases in heroin use (pg. 98)."

    - Muhuri et al.[126] used NSDUH data from 2002-2011 and found a strong association between prior NMPOU and the subsequent past year initiation of heroin use among individuals aged 12-49. Specifically, the heroin incidence rate

[125] Christopher M. Jones, "Heroin Use and Heroin Use Risk Behaviors among Nonmedical Users of Prescription Opioid Pain Relievers - United States, 2002-2004 and 2008-2010," *Drug and Alcohol Dependence* 132, no. 1–2 (September 1, 2013): 95–100, https://doi.org/10.1016/j.drugalcdep.2013.01.007.
[126] Pradip K. Muhuri, Joseph C. Gfroerer, and M. Christine Davies, "CBHSQ Data Review," *Center for Behavioral Health Statistics and Quality, SAMHSA* 1 (2013): 17.

was 19 times higher among those who reported prior NMPOU than among those who did not report this type of use. Also, 80% of recent heroin initiates previously reported NMPOU whereas only 1% of recent NMPOU initiates had prior use of heroin. Defendant expert Fryzek noted that this study did not control for cofounders and did not perform statistical tests, and therefore cannot be relied upon to assess causation. Controlling for potential confounders may have attenuated this very large effect (19-fold difference), but a strong association would likely remain. In addition, this study was administered by the federal government and promoted by the National Institute on Drug Abuse, and is just one of the many studies that I use and multiple lines of evidence to deduce causation. The study also found that transition from prescription opioid use to heroin use was rare (4%), as noted by Defendant's experts Dr. McCrary, Dr. Warfield, and Dr. Wailes. However, because the population of heroin users in the United States is small and the number of people reporting NMPOU is much larger than the number of people reporting heroin use, even 4% of individuals moving to heroin use after reporting NMPOU is significant.

- Cicero et al.[127] surveyed nearly 3,000 individuals entering treatment from 2010-2013 who reported that heroin was their primary drug of choice. Findings from the study showed that about 85% opioid-addicted heroin users who initiated opioid use in the 2000's reported using prescription opioids before switching to heroin. The reason for switching, reported by 94% of survey participants, was that prescription opioids were far more expensive and harder to obtain, highlighting a motivation among nearly all participants to switch from prescription opioids to heroin. In other words, nearly all participants report a switching from prescription opioids to heroin, suggesting a causal relationship.

- McCabe et al[128] used results from nationally representative youth survey to place adolescents into 5 subgroups based on survey responses at age 18: 1) no lifetime exposure to prescription opioids, 2) medical prescription opioid use without a history of NMPOU, 3) medical use followed by NMPOU, 4) NMPOU followed by medical use, and 5) NMPOU only. These individuals were then followed prospectively to assess for heroin use. For the cohort that was initially assessed from 1997-2000 (when the prescription opioid supply began to rise dramatically), the study found that the odds of subsequent heroin use were 13.4 time higher for the group that reported NMPOU only compared with the group that reported no NMPOU or medical use. To quantify this effect, nearly 1 in 3 high school seniors who reported NMPOU used heroin by age 35. The odds of heroin use were 2.7

[127] Theodore J. Cicero et al., "The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years," *JAMA Psychiatry* 71, no. 7 (July 1, 2014): 821–26, https://doi.org/10.1001/jamapsychiatry.2014.366.
[128] McCabe et al., "Pills to Powder."

times higher for the group that reported medical use only compared with the group that reported no NMPOU or medical use. This is an adjusted odds ratio that controlled for a range of sociodemographic and clinical characteristics. The authors conclude that "there is increased risk for heroin use among adolescents who initiated nonmedical misuse or adolescents prescribed opioids in more recent cohorts (pg. 241)" and "the stronger association between medical use of prescription opioids and transitioning to heroin use in more recent cohorts could be due to the changes in opioid prescribing (pg. 243)."

- Cerda et al[129] used NSDUH data from 2004-2011 and found that heroin initiation was 13.12 times higher among adolescents and young adults with a prior history of NMPOU than among those with no prior history of NMPOU, after controlling for potential confounding factors. The authors concluded that prior NMPOU is a strong predictor of heroin use onset in adolescence and young adulthood, regardless of the user's race/ethnicity or income group.

- Kelly-Quon et al[130] prospectively followed teenagers from 10 high schools in Los Angeles who initially reported no NMPOU, prior NMPOU, and current NMPOU. At the end of the 42-month study period, 1.7% of those not reporting NMPOU, 10.7% of those reporting prior NMPOU, and 13.1% of those reporting current NMPOU were found to have initiated heroin use. Authors state that findings of this study provide "new evidence of a prospective association between nonmedical prescription opioid use and an increased risk of future heroin use initiation among adolescents (pg. 5)" and highlight a dose-response relationship by stating that "graded patterns of association with heroin use were observed for nonmedical prescription opioid use (pg. 5)."

- Banerjee et al[131] prospectively showed that NMPOU is a strong risk factor for heroin initiation. More than 3,000 Veterans with no history of NMPOU or heroin use and had no OUD diagnoses at baseline were followed between 2002 and 2012, and it was found that NMPOU was positively and independently associated with heroin initiation (hazard ratio = 5.4) after controlling for a range of sociodemographic and clinical characteristics. The authors also found an effect

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[129] Magdalena Cerdá et al., "Nonmedical Prescription Opioid Use in Childhood and Early Adolescence Predicts Transitions to Heroin Use in Young Adulthood: A National Study," *The Journal of Pediatrics* 167, no. 3 (September 2015): 605-612.e1-2, https://doi.org/10.1016/j.jpeds.2015.04.071.

[130] Lorraine I. Kelley-Quon et al., "Association of Nonmedical Prescription Opioid Use With Subsequent Heroin Use Initiation in Adolescents," *JAMA Pediatrics* 173, no. 9 (September 1, 2019): e191750, https://doi.org/10.1001/jamapediatrics.2019.1750.

[131] Geetanjoli Banerjee et al., "Non-Medical Use of Prescription Opioids Is Associated with Heroin Initiation among US Veterans: A Prospective Cohort Study," *Addiction (Abingdon, England)* 111, no. 11 (November 2016): 2021–31, https://doi.org/10.1111/add.13491.

for receiving a short-term opioid prescription, leading them to conclude "the finding that receipt of a short-term opioid prescription was associated independently with an increased hazard of heroin initiation adds to the literature demonstrating a strong correlation between therapeutic exposure to opioid analgesics and their abuse (pg. 111)."

- DiNardi[132] used a quasi-experimental design and national youth survey data to examine whether the reformulation of OxyContin (which made the medication more difficult to snort or inject) affected adolescent lifetime heroin use. The study found that the reformulation of OxyContin was associated with a decrease in adolescents reporting ever using heroin. The author concluded that the decrease in prescription opioid misuse among adolescents after the reformulation reported in the literature is a likely mechanism for the decrease in adolescent lifetime heroin use found in this study, highlighting the trajectory from prescription opioid use and heroin use.

70. There are also other studies with smaller sample sizes, such as qualitative and ethnographic, that show the transition from prescription opioid use to heroin use. They include:

- Lankenau et al[133] interviewed fifty young injection drug users in Los Angeles and New York City who had reported NMPOU within three months prior to the study. This study found that 86% used opioids non-medically before using heroin.

- Carlson et al[134] prospectively followed 338 young people who reported NMPOU and had no history of opioid dependence or heroin use at baseline. The researchers found that 7.6% transitioned to heroin use over a three-year period, a rate nearly twice of what was reported in Muhuri et al.[135]

- Several ethnographic studies in subpopulations around the United States document the trajectory of prescription opioid use to heroin use,[136] with Mars et

[132] Michael DiNardi, "The Release of Abuse-Deterrent OxyContin and Adolescent Heroin Use," *Drug and Alcohol Dependence* 229, no. Pt B (September 29, 2021): 109114, https://doi.org/10.1016/j.drugalcdep.2021.109114.
[133] Stephen E. Lankenau et al., "Initiation into Prescription Opioid Misuse amongst Young Injection Drug Users," *The International Journal on Drug Policy* 23, no. 1 (January 2012): 37–44, https://doi.org/10.1016/j.drugpo.2011.05.014.
[134] Robert G. Carlson et al., "Predictors of Transition to Heroin Use among Initially Non-Opioid Dependent Illicit Pharmaceutical Opioid Users: A Natural History Study," *Drug and Alcohol Dependence* 160 (March 1, 2016): 127–34, https://doi.org/10.1016/j.drugalcdep.2015.12.026.
[135] Muhuri, Gfroerer, and Davies, "CBHSQ Data Review."
[136] James A. Inciardi et al., "Prescription Opioid Abuse and Diversion in an Urban Community: The Results of an Ultrarapid Assessment," *Pain Medicine (Malden, Mass.)* 10, no. 3 (April

al[137] concluding that supplies of less stigmatized prescription opioids compared with heroin eventually led to "pharmaceutical opioid initiates typically reported switching to heroin for reasons of cost and ease-of-access to supply after becoming physically and emotionally dependent on opioid pills (pg. 14)."

- In his non-fiction book *Dreamland*, Sam Quinones, whose journalistic approach is akin to an ethnographical study, shows that the deception of the opioid industry, including the actions of the Defendants, contributed to an increase in prescription opioid addiction that, in turn, led to an expansion in the illicit heroin market as a result of the dramatic increase in demand for a practical opioid supply.[138]

71. In addition to these individual-level studies, there are also population-level studies examining opioid-related hospitalizations and treatment admissions that support a causal relationship between prescription opioid use and heroin use. They include:

    - Unick et al[139] used trends in hospitalizations for prescription opioid and heroin overdoses from 1993-2009 to show that these two types of overdoses were similar until 1997 when prescription opioid overdoses increased sharply while heroin overdoses began to increase starting in 2006. Also, changes in the rate of prescription opioid overdoses were correlated with changes in the rate of heroin overdoses. The authors stated that their hypothesis of the interchangeability of prescription opioids and heroin was supported and called prescription opioid and heroin use "intertwined epidemics".

    - Unick and Ciccarone[140] again used trends in hospitalizations for prescription opioid and heroin overdoses, this time from 2000-2014 and trends were also stratified by census region. Specifically, from 2012-2014 prescription opioid overdoses largely occurred in older adults whereas as rates for overdose among younger adults declined for prescription opioids while, at the same time, increased for heroin overdoses. This data supports switching from prescription opioids to

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2009): 537–48, https://doi.org/10.1111/j.1526-4637.2009.00603.x; Sarah G. Mars et al., "'Every 'Never'I Ever Said Came True': Transitions from Opioid Pills to Heroin Injecting," *International Journal of Drug Policy* 25, no. 2 (2014): 257–66.

[137] Mars et al., "'Every 'Never'I Ever Said Came True': Transitions from Opioid Pills to Heroin Injecting."

[138] Sam Quinones, *Dreamland: The True Tale of America's Opiate Epidemic* (Bloomsbury Publishing USA, 2015).

[139] George Jay Unick et al., "Intertwined Epidemics: National Demographic Trends in Hospitalizations for Heroin- and Opioid-Related Overdoses, 1993-2009," *PloS One* 8, no. 2 (2013): e54496, https://doi.org/10.1371/journal.pone.0054496.

[140] George Jay Unick and Daniel Ciccarone, "US Regional and Demographic Differences in Prescription Opioid and Heroin-Related Overdose Hospitalizations," *The International Journal on Drug Policy* 46 (August 2017): 112–19, https://doi.org/10.1016/j.drugpo.2017.06.003.

heroin in younger adults while older adults may have been able to maintain an opioid supply from a physician. Demographic and geographic differences highlight other factors, like the heterogenous infiltration of fentanyl, are likely at play.

- Mallatt[141] examined the effect of organizational and state policies (e.g. PDMPs, reformulation of OxyContin) on the substitution to heroin and illicit opioids. The author found that these public interventions had unintended spillover effects into illicit opioid markets. Specifically, she found that PDMPs and the OxyContin reformulation are causing heroin substitution in more opioid-dense areas to a greater degree than in less opioid-dense areas with magnitude of the effect is large, stating that "a 10% increase in the pre-policy level of oxycodone shipments per capita leading to a 1.8% and 1.4% increase in heroin possession and dealers, respectively, in response to the PDMP (pg. 28)."

72. Many of the studies highlighted above cite the limitation of evaluating associations rather than causation. However, this is a limitation of any single study that is not a randomized controlled trial or a rigorous quasi-experimental study, though results from these designs do not infer causality outright either. The total body of evidence must be examined to deduce causality, and the studies that I have reviewed are sufficiently diverse in population and design while consistent in showing a strong association of prescription opioid use and heroin use. There is a strong association after controlling for confounders that is consistent across studies, a dose-response relationship is present when comparing a history of NMPOU to current NMPOU, and prospective studies establish temporality (i.e., cause came before effect). Therefore, it is logical to deduce that NMPOU is causally related to heroin use for both youth and adults and, in turn, heroin use contaminated with fentanyl.

73. Illicit and licit polydrug use is common in individuals who become addicted opioids. Pain patients prescribed opioids are often co-prescribed benzodiazepines and other drugs that can increase the risk of respiratory depression when combined with opioids.[142] Sedative use is also common among illicit opioid overdose decedents.[143] There is also evidence that an increasing number of opioid-addicted individuals have started using

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[141] Justine Mallatt, "Policy-Induced Substitution to Illicit Drugs and Implications for Law Enforcement Activity," *American Journal of Health Economics*, 2021, https://www.journals.uchicago.edu/doi/abs/10.1086/716462.
[142] Kathleen W. Saunders et al., "Concurrent Use of Alcohol and Sedatives among Persons Prescribed Chronic Opioid Therapy: Prevalence and Risk Factors," *The Journal of Pain* 13, no. 3 (March 2012): 266–75, https://doi.org/10.1016/j.jpain.2011.11.004.
[143] Joshua A. Barocas et al., "Sociodemographic Factors and Social Determinants Associated with Toxicology Confirmed Polysubstance Opioid-Related Deaths," *Drug and Alcohol Dependence* 200 (July 1, 2019): 59–63, https://doi.org/10.1016/j.drugalcdep.2019.03.014.

amphetamines.[144] Therefore, involvement of other drugs in opioid-related overdose deaths does not indicate a "polysubstance use crisis" distinct from the opioid crisis as some Defendants' experts contend. The McCrary Report points to opioid-related overdose deaths as only involving opioids rather than being the cause of the overdose death and states that I "fail to accurately account for polysubstance use and its impact on overdose deaths" and my "conclusions appear to assume that deaths resulting from concurrent substance abuse are causally attributable to opioids." My opinion is that OUD was essentially the cause of death in the vast majority of opioid-related deaths, regardless of whether they also used another drug at the time of death. In other words, these deaths are largely occurring in people with OUD which developed from both medical and non-medical prescription opioid use. The fact that many decedents used other drugs that may have contributed to respiratory depression does not change this.

74. Linking electronic health records, medical examiner records, and treatment data can make it possible to examine clinical characteristics in overdose death decedents. This type of analysis is enhanced when family members and friends are interviewed because of the various limitations of the healthcare system making a clinical diagnosis of OUD. Although there are few studies that employ this design, they provide evidence that most opioid-related overdose decedents had a history of opioid addiction. For example, a study that linked medical examiner data, treatment data, and the PDMP in West Virginia found that nearly four in five prescription opioid overdose decedents had a history of substance use disorder.[145] Another study that interviewed family members of prescription opioid overdose decedents showed that 76% were concerned about the decedent's prescription opioid misuse.[146] A more recent study that linked several databases in Rhode Island to examine opioid overdose decedents in 2016 found that nearly three-fourths had a known history of OUD, even in the context of 83% of these deaths involving two or more substances.[147] A study in Pennsylvania that linked medical examiner data and human

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[144] Justin C. Strickland, Jennifer R. Havens, and William W. Stoops, "A Nationally Representative Analysis of 'Twin Epidemics': Rising Rates of Methamphetamine Use among Persons Who Use Opioids," *Drug and Alcohol Dependence* 204 (November 1, 2019): 107592, https://doi.org/10.1016/j.drugalcdep.2019.107592; Justin C. Strickland et al., "The Continued Rise of Methamphetamine Use among People Who Use Heroin in the United States," *Drug and Alcohol Dependence* 225 (August 1, 2021): 108750, https://doi.org/10.1016/j.drugalcdep.2021.108750.

[145] Aron J. Hall et al., "Patterns of Abuse among Unintentional Pharmaceutical Overdose Fatalities," *JAMA* 300, no. 22 (December 10, 2008): 2613–20, https://doi.org/10.1001/jama.2008.802.

[146] Erin M. Johnson et al., "Unintentional Prescription Opioid-Related Overdose Deaths: Description of Decedents by next of Kin or Best Contact, Utah, 2008-2009," *Journal of General Internal Medicine* 28, no. 4 (April 2013): 522–29, https://doi.org/10.1007/s11606-012-2225-z.

[147] Yongwen Jiang et al., "State Unintentional Drug Overdose Reporting Surveillance: Opioid Overdose Deaths and Characteristics in Rhode Island," *Rhode Island Medical Journal (2013)* 101, no. 7 (September 4, 2018): 25–30.

services data from 2008-2014 showed that 74% of drug overdose decedents had a history of addiction treatment and 37% had been in addiction treatment in the past year.[148]

75. Data from the Florida Medical Examiners Commission reports causal occurrences of opioids among decedents in Florida from 2005 to 2017,[149] which is represented by Figure 4 in my initial report (note that deaths caused by heroin can be represented by morphine due to biodegradation). There is a dramatic increase in deaths caused by oxycodone, spiking in 2010, which is accompanied by an increase in deaths caused by oxymorphone in the same time period. This is followed by an increase in deaths caused by morphine (likely including heroin) starting in 2011, then a surge in deaths caused by fentanyl and fentanyl analogs beginning in 2014. These causal occurrences of opioids in deaths in Florida are aligned with the evolution of the opioid crisis, where a sharp increase in OUD, caused by oversupply of prescription opioids, led to an increase in deaths caused by prescription opioids, followed by an increase in deaths caused by heroin and fentanyl as some of these individuals switched to other opioids, as discussed above. Research also shows that opioid overdose deaths, as a portion of all overdose deaths, may have been 20-35% higher than reported from 1999-2015.[150]

X. Prevalence of OUD

76. OUD is a chronic, life-threating disease. This widely held view is based on clinical experience, neurobiology, and epidemiological studies (see my opening report pp. 5 and 66 for further discussion). Therefore, most people with OUD will need long-term treatment. However, it is a disease that can be prevented and effectively treated, and its worse effects mitigated through public health strategies.

77. It is my opinion that at least 350,629 Floridians suffer from OUD, which is adjusted from my opening report for the reasons explained below. A national surveillance system that would allow adequate measurement of OUD incidence and prevalence does not yet exist. The National Survey on Drug Use and Health (NSDUH), which can be used to estimate drug use trends, cannot be used to adequately measure prevalence of OUD. Numerous

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[148] Karen Hacker et al., "Linking Opioid-Overdose Data to Human Services and Criminal Justice Data: Opportunities for Intervention," *Public Health Reports (Washington, D.C.: 1974)* 133, no. 6 (November 2018): 658–66, https://doi.org/10.1177/0033354918803938.
[149] Florida Department of Children and Families, "Patterns and Trends of the Opioid Epidemic in Florida," 2018, https://www.myflfamilies.com/service-programs/samh/publications/docs/Florida%20SEOW%20Annual%20Report%202018.pdf.
[150] Christopher J. Ruhm, "Corrected US Opioid-Involved Drug Poisoning Deaths and Mortality Rates, 1999-2015," *Addiction (Abingdon, England)* 113, no. 7 (July 2018): 1339–44, https://doi.org/10.1111/add.14144.

scholars have recognized this.[151] I chose not to use the NSDUH for estimating OUD prevalence in Florida because the survey's methodology is not designed for measuring OUD prevalence, rather it is designed for measuring active symptoms of OUD. The reliability of OUD prevalence reported by the NSDUH is further complicated by the limitations of survey. These are all discussed in more detail below.

78. The NSDUH only measures active symptoms of OUD. Therefore, if a person is stable on MOUD, then that person will not be counted as part of the OUD prevalence calculated by the NSDUH even though this person is being treated for OUD. In other words, the NSDUH does not include anyone with early or sustained OUD remission, which constitutes a significant portion of individuals with OUD in a population. For reference, the prevalence of diabetes in the United States would not just capture individuals suffering from active symptoms of this chronic disease but would also include those whose diabetes is controlled with treatment.

79. Several Defendants' experts, including Dr. Choi and Ms. Bramer, highlight that adding all homeless and incarcerated individuals in Florida into the estimated OUD prevalence of the NSDUH will still result in a number that is lower than my estimation for OUD prevalence. This is true. However, this adjustment only addresses one limitation of the NSDUH, which is that the sample frame does not include institutionalized populations. Though this is a significant limitation, I believe that there are even more significant limitations. In addition to the NSDUH not being designed to measure true OUD prevalence as discussed above, Reuter et al.[152] identifies the following significant limitations: selective non-response, small sample size for rare events, underreporting, and an inadequate sample frame.

80. Selective non-response occurs when individuals that respond to the survey are different than those who do not respond to the survey. In 2016, 55% of the sampling units became respondents for the NSDUH.[153] It is logical to assume that those with moderate or severe OUD are less likely to participate in the survey as these individuals are consumed with

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[151] Beau Kilmer and Jonathan Caulkins, "Hard Drugs Demand Solid Understanding: Column," *USA Today*, March 8, 2014, https://www.usatoday.com/story/opinion/2014/03/08/heroin-abuse-hoffman-research-column/6134337/; Keith Humphreys, "The Federal Government Is Systematically Undercounting Heroin Users," *Washington Post*, August 22, 2017, https://www.washingtonpost.com/news/wonk/wp/2017/08/22/the-federal-government-is-systematically-under-counting-heroin-users/; Peter Reuter, Jonathan P. Caulkins, and Greg Midgette, "Heroin Use Cannot Be Measured Adequately with a General Population Survey," *Addiction (Abingdon, England)*, March 2, 2021, https://doi.org/10.1111/add.15458; Timothy P. Johnson, "Sources of Error in Substance Use Prevalence Surveys," *International Scholarly Research Notices* 2014 (2014): 923290, https://doi.org/10.1155/2014/923290.

[152] Reuter, Caulkins, and Midgette, "Heroin Use Cannot Be Measured Adequately with a General Population Survey."

[153] Reuter, Caulkins, and Midgette.

maintaining their opioid supply, which frequently involves illegal activity that they may fear discussing in a face-to-face interview with a government surveyor. Thus, this population would likely be overrepresented as non-respondents to NSDUH, leading to an underestimation of the true prevalence.

81. When measuring rare events, the NSDUH relies on relatively few responses to make population-based estimates. Reuter et al.[154] uses an example to illustrate this point, showing that only two respondents reporting past-year heroin use were responsible for half of the dramatic increase in past-year heroin use nationally as reported by the 2006 NSDUH. Extrapolating from small sample sizes of rare events result in unreliable prevalence estimates and large fluctuations over time, which can lead to misleading trends.

82. Underreporting can result from individuals not being forthcoming about answering questions about their use of a stigmatized substance in a government-funded survey, also known as social desirability bias. This would underestimate prevalence rates. One study compared self-report in NSDUH's predecessor, the National Household Survey on Drug Abuse (NHSDA), to biological samples and found that the large majority of recent cocaine users (as determined by biological samples) did not self-report that use.[155] The inadequate sampling frame was highlighted by Defendants' experts and discussed above. The culmination of all these limitations leads to an unreliable estimation of OUD prevalence. Evidence that corroborates this is discussed below.

83. Research has shown that the NSDUH likely underestimates the number of frequent heroin users by at least 75%, and including the incarcerated population into the sample frame, addressing just one of the many limitations of the NSDUH, increases the prevalence of drug use disorders by 25%. Because of the well-known unreliability of the NSDUH to estimate OUD prevalence, researchers in the field use other methodologies to measure OUD prevalence, which lead to estimates closer to the range of prevalence in my report. For example, Barocas et al.[156] employed a capture-recapture method using several linked administrative databases to estimate OUD prevalence in Massachusetts, finding that 4.6% of the population aged 12 and over had an OUD in 2015. In comparison, aggregated data from the NSDUH (2015-2017) estimated OUD prevalence to be 1.2% in Massachusetts, nearly fourfold less than the prevalence estimate from the

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[154] Reuter, Caulkins, and Midgette.

[155] Lana D. Harrison et al., "Comparing Drug Testing and Self-Report of Drug Use among Youths and Young Adults in the General Population" (SAMHSA Office of Applied Studies, 2007), https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.182.9980&rep=rep1&type=pdf.

[156] Joshua A. Barocas et al., "Estimated Prevalence of Opioid Use Disorder in Massachusetts, 2011-2015: A Capture-Recapture Analysis," *American Journal of Public Health* 108, no. 12 (December 2018): 1675–81, https://doi.org/10.2105/AJPH.2018.304673.

capture-recapture method.[157] In addition to the capture-recapture method mentioned above, researchers have used an adjustment factor and a mortality multiplier to estimate OUD prevalence (see Kolodny Report, p. 43, ¶ 19). Studies using claims data, which represents only individuals who have been clinically diagnosed with OUD, by definition will be an underestimation of the overall OUD prevalence. This underscores the limitations of using the NSDUH to estimate OUD prevalence (see Kolodny Report pp. 41-42, ¶ 16 for citations and further discussion). Evidence shows that even individuals with OUD who touch the healthcare system are commonly not diagnosed.[158]

84. In 2019, the NSDUH added questions on MOUD, as pointed out in the Bramer Report (p. 25), specifically "the survey estimates that in the South region, approximately 0.2 percent, or 183,000 individuals aged 12 or older received MAT for opioids in 2019." This South region encompasses 17 states and only 183,000 were estimated to have had MOUD in 2019.[159] Applying this 0.2% regional prevalence to Florida's population aged 15 and over would yield an estimate of around 35,000 individuals on MOUD in 2019. However, PDMP data shows that more than 75,000 Floridians received a prescription for buprenorphine (specifically, an OUD treatment formulation) in 2019, just one of the three FDA-approved medications for OUD treatment. Thus, a more reliable data source reveals that more than double the number of Floridians received just one type of MOUD than what the NSDUH estimated for all types of MOUD.

85. For the reasons described above, I do not agree with Defendants' experts including Dr. Choi, Dr. Fryzek, and Ms. Bramer that OUD prevalence can be estimated using the NSDUH. The Choi Report states that "the methodology that has enjoyed general acceptance, the use of the NSDUH to quantify OUD prevalence, indicates a reasonable expectation of 165,000 individuals experiencing OUD in Florida" (p. 87) and the Bramer Report describes my approach as "using a novel approach in lieu of relying on well-accepted sources" (p. 20). Choi and Bramer do not appear to have experience or training

[157] SAMHSA, "Behavioral Health Barometer: Massachusetts, Volume 5," 2019, https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/Massachusetts-BH-BarometerVolume5.pdf.
[158] Sarah A. Palumbo et al., "Assessment of Probable Opioid Use Disorder Using Electronic Health Record Documentation," *JAMA Network Open* 3, no. 9 (September 1, 2020): e2015909, https://doi.org/10.1001/jamanetworkopen.2020.15909.
[159] SAMHSA, "2016-2018 National Surveys on Drug Use and Health: Guide to Substate Tables and Summary of Small Area Estimation Methodology," 2019, https://www.samhsa.gov/data/sites/default/files/reports/rpt29372/NSDUHsubstateMethodology2018_0/NSDUHsubstateMethodology2018.htm; SAMHSA, "Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health."

in the substance use field generally or with OUD specifically. Experts in this field understand that NSDUH does not provide a reliable estimate of OUD prevalence.[160]

86. New methodologies to estimate OUD prevalence are emerging and informed by increasingly available data sources. My approach to estimate OUD prevalence in Florida using a methodology that incorporates the number of people on MOUD and the OUD treatment gap among the Florida Medicaid population is reliable and is supported by research in the field of public health showing that the true prevalence is a combination of the treated prevalence and the untreated prevalence.[161] Because estimating prevalence by accounting for treatment of a condition along with the treatment gap is an established method in the field of public health, I do not agree with the claims of Defendants' experts Drs. Fryzek, Choi, and Ms. Bramer that I am using a novel, unsupported, or unreviewed approach to calculating prevalence. The position of the Defendants' experts is unfounded for the following reasons:

    - Given their lack of experience in the field of addiction, it is understandable that they misunderstand the components of calculating overall OUD prevalence in a population. As stated in my report, OUD is a chronic, relapsing disease and long-term treatment with MOUD is often required, as discussed below. OUD prevalence, like other chronic conditions, can be expected to increase over time. For example, once a person is HIV positive, they remain HIV positive for the duration of their lifetime. With a chronic condition, like HIV or OUD, if the incidence rate (new cases) exceeds the death rate, prevalence can be expected to increase over time. The goal of the abatement recommendations is to flatten the growth in overall OUD prevalence by decreasing the incidence of OUD through primary prevention interventions, while increasing the "treated prevalence" through secondary and tertiary prevention interventions.

    - The true prevalence of OUD will be a combination of the treated prevalence and the untreated prevalence, and, by definition, the treated prevalence will always be less than the true prevalence. Calculating the treated prevalence (through medication utilization) and the true prevalence (through physical examination and laboratory testing) is a method used in the fields of public health to estimate the untreated prevalence and the treatment gap for chronic diseases like hypertension, diabetes, and hyperlipidemia.[162] Ideally, we would like every individual with

[160] Kilmer and Caulkins, "Hard Drugs Demand Solid Understanding: Column"; Humphreys, "The Federal Government Is Systematically Undercounting Heroin Users"; Reuter, Caulkins, and Midgette, "Heroin Use Cannot Be Measured Adequately with a General Population Survey"; Johnson, "Sources of Error in Substance Use Prevalence Surveys."
[161] Charles Roehrig and Matthew Daly, "Prevalence Trends for Three Common Medical Conditions: Treated and Untreated," *Health Affairs (Project Hope)* 34, no. 8 (August 2015): 1320–23, https://doi.org/10.1377/hlthaff.2015.0283.
[162] Roehrig and Daly.

OUD to be identified by the healthcare system, but ambiguities in clinical diagnosis and a lack of biological markers results in many with OUD who remain unknown to the healthcare system. Indeed, identifying and treating everyone in Florida with OUD is a goal of many of the secondary and tertiary prevention interventions.

- Several Defendants' experts including Dr. Wailes, Dr. Choi, and Ms. Bramer point to the number of individuals being treated with buprenorphine in non-OTP programs in the 2019 NNSATS report. However, the number of individuals treated with buprenorphine at state-licensed non-OTP treatment facilities in Florida, does not include individuals prescribed buprenorphine from private practices, community health centers, emergency departments, and health care organizations that do not offer formal, state-licensed addiction treatment programs. Data from Florida's PDMP captures individuals treated in these settings as well as individuals treated in non-OTP treatment facilities. In fact, PDMP data shows that more than 75,000 Floridians received a prescription for an OUD treatment formulation of buprenorphine in 2019, a number nearly 19-fold higher than those receiving this type of treatment just in non-OTP treatment facilities. For this reason, I do not believe that using the NNSATS non-OTP numbers is a reliable way of measuring the number of individuals in buprenorphine treatment in Florida.

- Defendants' experts question the inclusion of all individuals on any type of MOUD who are receiving this treatment from an OTP, noting that "7.0% of these clients were treated with buprenorphine or naltrexone" (Choi Report, p. 83) and stating that this would double count individuals receiving buprenorphine or extended-release naltrexone treatment. All individuals getting treatment in OTPs, regardless of the type of MOUD, should be included in the treated prevalence because they will not be captured in the PDMP due to a federal confidentiality rule, 42 CFR Part 2, that does not allow PDMPs and OTPs to be linked. In other words, individual being treated with buprenorphine in OTPs will not appear in PDMP data.

- Several Defendants' experts, including Dr. Choi and Dr. Fryzek, note that the three data sources used to measure the treatment prevalence (individuals being treated at OTPs using NNSATS, individuals being treated with naltrexone at non-OTPs using NNSATS, and individuals being treated with buprenorphine using PDMP data) may not be mutually exclusive. For example, an individual might be treated with methadone at an OTP and with buprenorphine at a private doctor's office in the same year. This is certainly a possibility, though, based on my experience and expertise in treatment of people with OUD, it is an uncommon occurrence. The pharmacological effects of these medications make it difficult to switch between them. For example, an individual switching from a modest dose

of methadone to buprenorphine would experience a precipitated withdrawal reaction without a long taper. An individual switching from buprenorphine or methadone to extended-release naltrexone would have to go through detoxification before the first injection. As stated in my report, the measurement used for the number of individuals on naltrexone is conservative because it does not include individuals getting this type of treatment at a private doctor's office. To illustrate this, a program administered by the Florida Alcohol and Drug Abuse Association reported treating more than 6400 individuals with an extended-release naltrexone injection in a 2019 article,[163] which is almost three time higher than the number I use from NNSATS. This certain underestimation in the number of individuals on naltrexone should more than account for the rare occurrence that individuals were switching types of MOUD within a single year in 2019.

- Dr. Wailes, argues that most people who received a buprenorphine prescription in 2019 were prescribed the medication for chronic pain. Dr. Wailes is incorrect. Buprenorphine formulations used to treat chronic pain can be differentiated from the formulations used for OUD.[164] The total number of unique individuals receiving a prescription for buprenorphine in 2019 was 85,347, according to data queried by the PDMP. When limiting these prescriptions to only products indicated for OUD treatment, there were 76,479 unique individuals who obtained a prescription for buprenorphine in 2019.[165] Therefore, a total of 98,176 received MOUD in 2019, which combines 76,479 unique individuals on buprenorphine, 19,436 being treated at OTPs, and 2,261 individuals on extended-release naltrexone. This yields an adjusted OUD prevalence estimation of 350,629 or 2.0% of the Florida population aged 15 and older.

- I rely on a study that measures the treatment gap among the Medicaid population in Florida to apply a treatment gap multiplier.[166] This is a more conservative estimate compared with the general population for two reasons. *First*, the treatment gap that I use is among individuals who have been clinically diagnosed with OUD and, therefore, more likely to be in treatment compared with those who

[163] Rebecca Roberts, "FADAA Opioid Treatment Programs Continue to See Positive Outcomes," Florida Alcohol and Drug Abuse Association, 2019, https://www.fadaa.org/news/445430/FADAA-Opioid-Treatment-Programs-Continue-to-See-Positive-Outcomes.htm.
[164] Jacqueline Pratt Cleary and Joseph Gottwald, "A Brief Review of Buprenorphine Products," Pharmacy Times, 2016, https://www.pharmacytimes.com/view/a-brief-review-of-buprenorphine-products.
[165] Supporting analysis is provided in the backup materials to the October 29, 2021 McCann Report.
[166] Kimberly Johnson et al., "Treatment for Opioid Use Disorder in the Florida Medicaid Population: Using a Cascade of Care Model to Evaluate Quality," *The American Journal of Drug and Alcohol Abuse*, October 15, 2020, 1–9, https://doi.org/10.1080/00952990.2020.1824236.

have OUD but have not been diagnosed by the healthcare system. *Second*, it is well-documented that the OUD treatment gap for Medicaid beneficiaries is smaller than the general population (see Kolodny Report, p. 42, ¶ 18). In addition, in Florida there is a large uninsured population[167] that I would expect to have a much larger treatment gap compared with the Medicaid population as there are several studies that show that Medicaid expansion is associated with an increase in MOUD utilization.[168]

- The Bramer report (p. 24) argues that I should have relied on readily available NDSUH data to calculate the number of individuals in Florida on MOUD. I did not consider this data source due to the limitations that I have highlighted in my report and this rebuttal. NSDUH data from 2019 shows that only 18% of individuals aged 12 and over with a past-year OUD received treatment with MOUD. [169] Using this data source would have produced a much larger treatment gap than the one I have used to estimate OUD prevalence and, in turn, would result in a much larger estimated OUD prevalence.

- As done in my report, I used an adjustment factor method and a mortality multiplier method, which have been used in the peer-reviewed literature to estimate OUD prevalence (see Kolodny Report, p. 43, ¶ 19), to show that the treatment gap multiplier method I use results in an OUD prevalence that is similar but more conservative than these alternative methods that are in the literature.

- As noted in the McCrary Report, not everyone with OUD started with prescription opioids or has ever used prescription opioids. The method I use to estimate OUD prevalence includes individuals with heroin use disorder, prescription opioid use disorder, or both. My understanding is that Dr. McCollister applies a formula to this prevalence to approximate the number of individuals with OUD who never used prescription opioids, and these individuals are excluded from the costing analysis.

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[167] Kaiser Family Foundation, "Florida: Health Coverage & Uninsured," 2020, https://www.kff.org/state-category/health-coverage-uninsured/?state=FL.
[168] Hefei Wen et al., "Impact of Medicaid Expansion on Medicaid-Covered Utilization of Buprenorphine for Opioid Use Disorder Treatment," *Medical Care* 55, no. 4 (April 2017): 336–41, https://doi.org/10.1097/MLR.0000000000000703; Angélica Meinhofer and Allison E. Witman, "The Role of Health Insurance on Treatment for Opioid Use Disorders: Evidence from the Affordable Care Act Medicaid Expansion," *Journal of Health Economics* 60 (July 2018): 177–97, https://doi.org/10.1016/j.jhealeco.2018.06.004; Ramin Mojtabai et al., "The Affordable Care Act and Opioid Agonist Therapy for Opioid Use Disorder," *Psychiatric Services (Washington, D.C.)* 70, no. 7 (July 1, 2019): 617–20, https://doi.org/10.1176/appi.ps.201900025.
[169] SAMHSA, "Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health."

XI. Rebuttal – Abatement Recommendations

87. Defendants' experts, such as Dr. McCrary and Ms. Bramer, criticize the fact that tertiary prevention interventions are recommended for 30 years, or that people remain on medication treatment for 30 years or more. This argument is based on a misunderstanding about OUD treatment and the typical course of the disease. To achieve the best outcomes, individuals with OUD often require long-term treatment with MOUD. For many, treatment will be lifelong. Dr. Wailes, one of the Defendant's experts who has clinical experience with OUD, echoes this expert consensus, stating "It [MOUD] is usually required (or recommended) for long term and occasionally lifelong treatment for this challenging condition" (Wailes Report, p. 50). Defendants' experts who lack OUD expertise state that this is inappropriate, with one citing outdated SAMHSA guidelines from 2004 to make the argument that "neither Dr. McCollister nor Dr. Kolodny shows that it is appropriate or necessary for patients starting MOUD treatment to stay on the treatment continuously for the entire 30-year period" (McCrary Report, p. 116). I highlight the protective effect from MOUD retention on mortality in my report (see p. 66) and provide further discussion on the reasons for my recommendation of indefinite but likely lifelong treatment for MOUD (see pp. 85-86). To reiterate, American Society of Addiction Medicine guidelines[170] and expert consensus[171] generally recommend use of all three types of MOUD with no predefined length of treatment. I am not aware of any empirical studies that suggest a specific length of time for MOUD treatment, although studies have shown that discontinuing MOUD can lead to detrimental outcomes.[172] Therefore, I believe the assumption that the large majority of individuals with OUD in Florida should be treated with MOUD is appropriate given the current evidence. There will be some individuals in the treatment gap that have mild OUD, though research

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[170] American Society of Addiction Medicine, "The ASAM Performance Measures for the Addiction Specialist Physician," 2014, https://www.asam.org/docs/default-source/advocacy/performance-measures-for-the-addiction-specialist-physician.pdf.

[171] Nora D. Volkow et al., "Medication-Assisted Therapies--Tackling the Opioid-Overdose Epidemic," *The New England Journal of Medicine* 370, no. 22 (May 29, 2014): 2063–66, https://doi.org/10.1056/NEJMp1402780; National Academies of Sciences, Engineering, and Medicine, *Medications for Opioid Use Disorder Save Lives* (National Academies Press, 2019), https://www.careinnovations.org/wp-content/uploads/MOUD-Saves-Lives_NAS_2019.pdf.

[172] Brandon S. Bentzley et al., "Discontinuation of Buprenorphine Maintenance Therapy: Perspectives and Outcomes," *Journal of Substance Abuse Treatment* 52 (May 2015): 48–57, https://doi.org/10.1016/j.jsat.2014.12.011; Jo Kimber et al., "Survival and Cessation in Injecting Drug Users: Prospective Observational Study of Outcomes and Effect of Opiate Substitution Treatment," *BMJ (Clinical Research Ed.)* 341 (July 1, 2010): c3172, https://doi.org/10.1136/bmj.c3172; Arthur Robin Williams et al., "Acute Care, Prescription Opioid Use, and Overdose Following Discontinuation of Long-Term Buprenorphine Treatment for Opioid Use Disorder," *The American Journal of Psychiatry* 177, no. 2 (February 1, 2020): 117–24, https://doi.org/10.1176/appi.ajp.2019.19060612.

shows that many will have moderate or severe OUD.[173] Although methadone should not be the first line of treatment for individuals with mild OUD,[174] these individuals are good candidates for buprenorphine or extended-release naltrexone, especially in the context of an illicit opioid supply contaminated with fentanyl where a relapse could lead to a fatal opioid overdose. I understand that Dr. McCollister has built in an assumption in her costing analysis that 90% of the treatment gap will be treated with MOUD, which I think is appropriate given clinical and individual preference for OUD treatment without MOUD in some individuals.

88. I understand that Dr. McCollister has built in an assumption in her costing analysis that there will be a 90% treatment retention rate for individuals who receive MOUD. I believe that a goal of retaining 90% of these individuals on medications for a 30-year period is appropriate in order to reasonably abate the opioid crisis. Nonadherence is common among individuals on MOUD, so a significant number will come on and off and will experience recurrence of OUD symptoms and periods of remission. Defendant's experts, as well as my own expert report, emphasize that around half of those beginning MOUD are still on the treatment regimen after one year (see Kolodny Report, p. 85). However, the robust and comprehensive abatement recommendations include many interventions that should increase the treatment retention rate and link individuals with treatment after a recurrence of OUD symptoms. The 90% treatment rate would also account for individuals who have been stable on MOUD for many years and decide to taper off the medication, although there is no predefined length of medication treatment and discontinuation can be risky as discussed above. Also, maintaining a constant OUD prevalence over time is likely a conservative estimate, as more people are certain to develop OUD over the 30-year time period than is costed by Dr. McCollister.

89. The proposed abatement recommendations account for the success of implemented interventions over time by staggering time horizons for the different levels of prevention and assuming that individuals with OUD will be identified, linked to, and retained in treatment. A number of Defendants' experts, including Ms. Bramer and Dr. McCrary, incorrectly argue that the plan ignores or does not account for the success of the interventions. Ms. Bramer and Dr. McCrary misinterpret the meaning of the different levels of prevention interventions. An advantage of categorizing the comprehensive response needed to address the opioid crisis in Florida by the level of prevention (primary, secondary, and tertiary) is that each level, by definition, should be associated with a different duration. For example, primary prevention interventions intend to reduce

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[173] Kimberly Johnson, Khary K. Rigg, and Cary Hopkins Eyles, "Receiving Addiction Treatment in the US: Do Patient Demographics, Drug of Choice, or Substance Use Disorder Severity Matter?," *International Journal of Drug Policy* 75 (January 2020): 102583, https://doi.org/10.1016/j.drugpo.2019.10.009.

[174] SAMHSA, "Medications for Opioid Use Disorder: For Healthcare and Addiction Professionals, Policymakers, Patients, and Families," 2021, https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP21-02-01-002.pdf.

new cases of OUD. Therefore, the need for these interventions would be expected to diminish over time, for example as prescribers in Florida are counter-detailed on the risks and benefits of prescription opioids. On the other hand, tertiary prevention interventions treat cases of OUD and reduce opioid-related harms. Given the chronic nature of OUD as discussed above, treatment and other services to reduce opioid-related harms would need to be in place for an individual's lifetime, similar to other chronic diseases. In other words, the number of individuals needing tertiary prevention interventions should remain relatively constant over time. Even though I would expect the incidence rate (new cases of OUD/year) to decline as opioid prescribing trends in a more cautious direction, the incidence is likely to remain until opioid prescribing reaches pre-epidemic levels. A conservative assumption is that new cases of OUD will, at the very least, balance out natural and opioid-related deaths among individuals with OUD, keeping the OUD prevalence constant over time. Success is built into the abatement recommendations, for example by assuming that a large majority of individuals in the treatment gap will be linked to treatment and the large majority of individuals who initiate MOUD will be retained on MOUD as a result of the wide array of tertiary interventions, and by identifying and treating cases of OUD early in its progression, either in the community or among those on long-term opioid therapy, as a result of secondary prevention interventions. Success is also built into the recommendations by the staggered time horizons of the different levels of prevention.

90. Ms. Bramer's report highlights the role of various entities in the opioid market, distributors, and consultants in the opioid crisis and the monetary and non-monetary contributions these entities will be required to make through litigation settlements and other means. I was asked to opine on the steps needed to abate the opioid crisis and was not asked to comment on other cases or on the impact of settlement agreements. Regarding the non-monetary agreements of previous and current Defendants in this case, summarized in Bramer's report (pp. 9-11), such steps may enhance primary prevention interventions, but are unlikely to impact secondary and tertiary prevention interventions because they primarily promote more cautious opioid prescribing.

91. Many individuals who are on long-term opioid therapy for chronic pain in Florida currently have or will develop OUD.[175] These individuals are unlikely to be captured in the approach I use to estimate OUD prevalence, especially those with mild OUD. As discussed above, I chose to use the study results from Boscarino et al.[176] to estimate the current prevalence of OUD among individuals receiving long-term opioid therapy in Florida. Ms. Bramer misunderstands that these individuals have both mild OUD and chronic pain, not just mild OUD (Bramer Report, p. 23). Contrary to what is stated in the

[175] Kevin E. Vowles et al., "Rates of Opioid Misuse, Abuse, and Addiction in Chronic Pain: A Systematic Review and Data Synthesis," *Pain* 156, no. 4 (April 2015): 569–76, https://doi.org/10.1097/01.j.pain.0000460357.01998.f1.
[176] Boscarino, Hoffman, and Han, "Opioid-Use Disorder among Patients on Long-Term Opioid Therapy."

McCrary Report, I do not agree that individuals with likely mild OUD receiving long-term opioids for chronic non-cancer pain will need the same package of services as those with moderate to severe OUD who are in the treatment gap, though they are likely good candidates for long-term buprenorphine treatment (see Kolodny Report, pp..64-65, ¶ 15). My understanding is that Dr. McCollister attributes long-term buprenorphine treatment without additional services (e.g., outpatient) to 28% of Floridians on long-term opioid therapy who likely have mild OUD in her costing analysis, which I think is appropriate. Given the various secondary prevention interventions I recommend to identify and treat OUD among individuals on long-term opioid therapy, my opinion is also that it is reasonable for Dr. McCollister to assume that many of these individuals will immediately have access to buprenorphine treatment.

92. One of the criticisms that Defendants' experts, including Ms. Bramer, make is that not all interventions I recommend are based on peer-reviewed evidence. It is imperative that, in addition to interventions with a strong evidence base, promising interventions that are evidence-informed and have a strong scientific rationale be implemented to address the opioid crisis in Florida, while being studied to determine whether they are in fact effective. It can take many years to establish an evidence base for an intervention and even longer for research evidence to be implemented into clinical practice.[177] Many of the interventions to address the opioid crisis are novel and evidence is beginning to emerge on their effectiveness. In addition, some of the interventions, such as community coalitions and recovery community organizations, serve purposes beyond addressing individual-level factors, such as increasing cross-sector collaboration and reducing public stigma (see Kolodny Report, p. 40, ¶ 11). Dr. McCollister and I both recommend continuing to study emerging interventions and pilot programs to determine the most effective approaches that should be scaled up.

93. Some of the interventions I recommend are not opioid-specific but are critical to a comprehensive response to the opioid crisis. These include implementing school-based prevention, ensuring safe storage and disposal of opioids, increasing the number of school counselors, and expanding both dependency courts and recovery community organizations across the state. It is complex and infeasible to apportion the opioid-specific role of these interventions.

94. As laid out in my report, the ripple effect of the opioid crisis is vast and one of the affected populations is children (see Kolodny Report, Section e.i). Children that have experienced NAS are more likely to be referred for a disability evaluation, to meet

[177] Zoë Slote Morris, Steven Wooding, and Jonathan Grant, "The Answer Is 17 Years, What Is the Question: Understanding Time Lags in Translational Research," *Journal of the Royal Society of Medicine* 104, no. 12 (December 2011): 510–20, https://doi.org/10.1258/jrsm.2011.110180.

criteria for a disability, and to require classroom therapies or services.[178] In addition to children that have experienced NAS, it is estimated that 138,000 children in Florida were affected by the opioid crisis in 2017, including children that are living with a parent with OUD, children that have had a parent die of an opioid overdose, children that have incarcerated parents because of opioids, children that have been removed from their homes and placed with foster care or relatives because of parental opioid use, children that have had an accidently exposure to opioids, and children that suffer from OUD themselves.[179] There is evidence that the collateral consequences of the opioid crisis have negatively impacted the educational outcomes of children that have been affected (see Kolodny Report, p. 115). Therefore, it is critical that school-based interventions are implemented to address the opioid crisis, including increasing school counselors and delivering school-based prevention programs.

95. School counselors play a role in helping students to manage emotions and apply interpersonal skills, and the American School Counselor Association has recognized the role that school counselors should play in addressing substance use among students.[180] Although the role of school counselors is not limited to addressing opioid use, the newly-hired counselors can become trained in trauma-informed care and addiction counseling, equipping them to deliver many of the interventions needed to address the opioid crisis. These include:[181]

    - Recognizing signs of opioid use to provide targeted screening, early identification, and linkage to appropriate services and care.

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[178] Mary-Margaret A. Fill et al., "Educational Disabilities Among Children Born With Neonatal Abstinence Syndrome," *Pediatrics* 142, no. 3 (September 2018): e20180562, https://doi.org/10.1542/peds.2018-0562.

[179] Suzanne C. Brundage, Adam Fifield, and Lee Partridge, "The Ripple Effect: National and State Estimates of the US Opioid Epidemic's Impact on Children" (United Hospital Fund, 2020), https://uhfnyc.org/media/filer_public/6e/80/6e80760f-d579-46a3-998d-1aa816ab06f6/uhf_ripple_effect_national_and_state_estimates_chartbook.pdf.

[180] American School Counselor Association, "The Role of the School Counselor," n.d., https://www.schoolcounselor.org/getmedia/ee8b2e1b-d021-4575-982c-c84402cb2cd2/Role-Statement.pdf; Edward T. Dunbar Jr, Mark D. Nelson, and Dawn S. Tarabochia, "Substance Use Disorders: What School Counselors Should Know.," *Journal of School Counseling* 17, no. 21 (2019): n21.

[181] Allison Paolini, "School Counselors and Fighting the Opioid Epidemic: Consequences, Impact on Academic Performance, and Treatment to Overcome the Battle," *Journal of Family Counseling and Education* 5, no. 1 (2020): 1–12; Richard Tench, "The Opioid Epidemic" (Idaho School Counselor: The Official Publication of the Idaho School Counselor Association, 2019), https://www.schoolcounselor.org/newsletters/april-2019/the-opioid-epidemic?st=ID; Justine W. Welsh, Valeria Tretyak, and Nancy Rappaport, "The Opioid Crisis and Schools-A Commentary," *The Journal of School Health* 88, no. 5 (May 2018): 337–40, https://doi.org/10.1111/josh.12617.

- Helping students deal with grief or difficulties from parental overdose death or opioid use.

- Monitoring students who are being treated for OUD in collaboration with treatment providers.

- Helping to deliver and augment school-based prevention programs.

- Providing opioid-specific information and resources to students and their families.

- Building and leveraging relationships with students for addressing opioid misuse and collateral consequences of parental OUD.

- Collaboration with community-based organizations.

- Training in overdose education and naloxone administration.

- Improving overall educational outcomes of students that have been affected by the opioid crisis.

96. I understand that Dr. McCollister includes the cost of increasing the number of school counselors in her report, and has adjusted the recommended number from opening reports. I agree that her recommendation is sound. It is my opinion that the increase in school counselors, while only recommended for a ten-year period, will allow for increased delivery of interventions around primary prevention of OUD and supporting the children of the opioid crisis..

97. The Bramer Report argues that my recommendations regarding medical education are redundant, because existing education addresses opioids. There has been a legacy of industry influence of continuing medical education (CME),[182] including by the Defendants in this case. Although it is a fact that CME has been provided to prescribers of opioids in Florida, I disagree that this education should be deemed adequate for the primary intervention purposes discussed in my recommendations. As I laid out in my expert report, measures should be taken to ensure that CME is developed completely free of industry bias and appropriately educates prescribers on the risks and appropriate uses of prescription opioids in order to encourage more cautious prescribing (see Kolodny Report, pp. 46-47).

[182] https://www.motherjones.com/politics/2018/04/doctors-are-required-to-receive-opioid-training-big-pharma-funds-it-what-could-go-wrong/; Benjamin Goodwin et al., "Increase Your Confidence in Opioid Prescribing: Marketing Messages in Continuing Medical Education Activities on ER/LA Opioids," *Pain Physician* 24, no. 5 (August 2021): E529–38.

98. The Bramer Report argues that my recommendations are not reliable because they do not assess policy barriers or feasibility issues. Counsel instructed me to put forth a set of interventions that are reasonably necessary to abate the opioid crisis in Florida, not to make policy recommendations or to assess political feasibility of the recommended abatement interventions. Although there is a dearth of literature on cost-benefit and cost-effectiveness analysis to guide a prioritization of abatement strategies, based on my expertise and the current literature, Florida might consider prioritizing these interventions in the face of a partial settlement or judgment: expanding access to MOUD, linking people to OUD treatment, overdose prevention, and counter detailing of the medical profession. I propose an evaluation team whose purpose would be to rigorously monitor and evaluate many of the implemented interventions, so that priorities can be modified based on evolving needs and the developing evidence (see Kolodny Report, p. 115, ¶ 52).

[redacted]

October 29, 2021
Date

SCHEDULE 1

ANDREW KOLODNY, M.D., MATERIALS CONSIDERED – REBUTTAL REPORT

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CASE MATERIALS

Expert Report of Andrew Kolodny, M.D. (July 30, 2021)

Expert Report of Daniel Clauw, M.D. (July 30, 2021)

Expert Report of Matthew Perri III, BS Pharm, Ph. D., RPh. (July 30, 2021)

Expert Report of Kathryn E. McCollister, Ph. D. (July 30, 2021)

Expert Report of David T. Courtwright, Ph. D. (July 30, 2021)

Expert Rebuttal Report of Craig J. McCann, Ph. D., CFA (October 29, 2021)

Expert Report of Carol A. Warfield, M.D. (Sept. 17, 2021) (Allergan)

Expert Report of Craig Garthwaite, Ph. D. (Sept. 17, 2021) (CVS)

Expert Report of Edward Michna, J.D., M.D. (Sept. 17, 2021) (Teva-Actavis)

Expert Report of Henry Grabowski, Ph. D (Sept. 17, 2021) (Endo)

Expert Report of Jason Yong, M.D. (Sept. 17, 2021) (Endo)

Expert Report of Jon P. Fryzek, MPH, Ph. D. (Sept. 17, 2021) (Endo)

Expert Report of Justin McCrary, Ph. D. (Sept. 17, 2021) (Endo)

Expert Report of Laurence C. Baker, Ph.D. (Sept. 17, 2021) (Walgreens)

Expert Report of Margaret K. Kyle, Ph. D (Sept. 17, 2021) (Allergan)

Expert Report of Melanie H. Rosenblatt, M.D. (Sept. 17, 2021) (Teva-Actavis)

Expert Report of Pradeep K. Chintagunta, Ph. D. (Sept. 17, 2021) (Teva-Actavis)

Expert Report of Robert E. Wailes, M.D. (Sept. 17, 2021) (CVS)

Expert Report of Sean Nicholson, Ph. D. (Sept. 17, 2021) (Teva-Actavis)

Expert Report of William S. Choi, Ph.D. (Sept. 17, 2021) (CVS)

Expert Report of Erica Bramer, CFA, CVA, CIRA (Sept. 17, 2021) (Allergan)

OTHER

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WAGNMAG00021894

WAGMDL00303140

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ENDO_OPIOID_DEPMAT-000060572

TEVA_MDL_A_13610632

ENDO_FLAG-00644111

ENDO_OPIOID_MDL-00771761

ENDO-OPIOID_MDL-01064673

ENDO-OPIOID_MDL-01064677

Acquired_Actavis_00369188

ENDO_OPIOID_DEPMAT-000001779

TEVA_MDL_A_00564336

TEVA_MDL_A_00265075

ENDO_OPIOID_DEPMAT-000003901

PDD1701018717

PDD1701225811

ENDO-CHI_LIT-00540305

PPLP004065860

EPI001059511

PPLP004298301

ENDO_OPIOID_DEPMAT-000033205

ENDO_FLAG-00253781

PPLPC021000287232

PPLPC021000272827

PPLPC021000272826

PXEND-61 (ENDO-OPIOID_MDL-00681622)

PXEND-103 (ENDO_OPIOID_DEMAT-000060572)

EXEND-106 (ENDO_OPIOID)DEMAT-000087545)

UPDATED SCHEDULE 2

Testimony

Trial Testimony:
State of Oklahoma, et al. v. Purdue Phamra L.P., et al., District Court of Cleveland County, State of Oklahoma Case No. CJ-2017-816

Deposition Testimony:

The State of Rhode Island v. Purdue Pharma, et al.

The State of Alabama v. Endo Health Solutions, et al.

The State of New Hampshire v. Johnson & Johnson, et al. Case No. Docket No. 217-2018-CV-00678

The City of Huntington v. AmerisourceBergen Drug Corporation; Case No. 3:17-01362; and *Cabell County Commission*, Case No. 3:17-01665 (S.D.W. Va.)

In Re.: National Prescription Opiate Litigation, Northern District of Ohio Case No. 2017-md-2804

State of Oklahoma, et al. v. Purdue Phamra L.P., et al., District Court of Cleveland County, State of Oklahoma Case No. CJ-2017-816

County of Dallas v. Purdue Pharma L.P., et al., District Court of Dallas County, Texas MDL Pretrial No. 2018-77098

State of Washington v. Johnson & Jonhson, et al., King County Superior Court, State of Washington Case. No. 20-2-00184-8 SEA

Exhibit 2

IN THE CIRCUIT COURT OF THE SIXTH JUDICIAL CIRCUIT
IN AND FOR PASCO COUNTY, FLORIDA

STATE OF FLORIDA, OFFICE OF THE ATTORNEY GENERAL, DEPARTMENT OF LEGAL AFFAIRS,

Plaintiff,

v. Case No. 2018-CA-001438

PURDUE PHARMA L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS INC., JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, CEPHALON, INC., TEVA PHARMACEUTICALS USA, INC., ALLERGAN FINANCE, LLC, ACTAVIS PHARMA, INC., ACTAVIS LLC, INSYS THERAPEUTICS, INC., AMERISOURCEBERGEN DRUG CORPORATION, CARDINAL HEALTH, INC., MCKESSON CORPORATION, MALLINCKRODT LLC, WALGREEN CO., CVS HEALTH CORPORATION, and CVS PHARMACY, INC.,

Defendants.

Expert Report of Andrew Kolodny, M.D.

HIGHLY CONFIDENTIAL

TABLE OF CONTENTS

GLOSSARY OF ABBREVIATED TERMS

ACOG	American College of Obstetrics and Gynecology
CDC	Centers for Disease Control and Prevention
CDSS	clinical decision support systems
CME	continuing medical education
CRP	collegiate recovery programs
CTC	Communities that Care
ECC	early childhood courts
ED	emergency department
EDIB	emergency department initiated buprenorphine
E-FORSCE	Electronic-Florida Online Reporting of Controlled Substance Evaluation Program
ER/LA	extended-release and long-acting
FDA	United States Food and Drug Administration
GSL	Good Samaritan Laws
HCV	Hepatitis C Virus
IWG	Industry Working Group
J&J	Johnson & Johnson
LEAD	Law Enforcement Assisted Diversion
MME	morphine milligram equivalent
MORE	Maternal Opioid Recovery Effort
MOUD	medications for opioid use disorder
NAS	Neonatal Abstinence Syndrome
NSDUH	National Survey on Drug Use and Health
OB-GYN	obstetrics-gynecology
OBOT	office-based opioid treatment
OEND	overdose education and naloxone distribution
OPRC	Opioid Policy Research Collaborative
OTP	Opioid Treatment Program
OUD	opioid use disorder
PCF	Pain Care Forum
PDMP	prescription drug monitoring program
PROP	Physicians for Responsible Opioid Prescribing
PRSS	peer-based recovery support services
RCO	recovery community organizations
REMS	Risk Evaluation and Mitigation Strategies
ROSC	recovery-oriented systems of care
RSS	recovery support services
SAMHSA	Substance Abuse and Mental Health Services Administration
SBIRT	Screening, Brief Intervention, and Referral to Treatment
SSP	syringe service program
STIR	Screening, Treatment, Initiation, and Referral
UHDU	ultra-high dosage unit

I. INTRODUCTION AND SUMMARY OF OPINIONS

I have been retained on behalf of the State of Florida to opine on the nature of opioid addiction, on the conduct of the Defendants in its case against Purdue Pharma L.P., et al, on the public health crisis caused by the oversupply of opioids in Florida, and on strategies to abate the opioid crisis.

In undertaking this assignment, I have applied my years of experience in public health, public policy, addiction medicine, and research on opioid prescribing, marketing of opioids, and on the root causes of the opioid crisis.

My opinions, offered in greater detail, can be summarized as follows:

1. There has been a sharp increase in the prevalence of opioid addiction in the United States and the State of Florida. The increased prevalence of opioid addiction has resulted in an array of health and social problems commonly referred to as the opioid crisis. These problems include but are not limited to overdose deaths, neonatal opioid withdrawal syndrome, increased use of illicit drugs, and an impact on the workforce.

2. The increased prevalence of opioid addiction and other opioid-related harms were primarily caused by overexposing the United States population, including people in the State of Florida, to prescription opioids. The volume of opioids being prescribed in 1997, which was already higher per capita than in other countries, is a conservative and appropriate baseline against which to evaluate the subsequent rise in opioid prescribing and use. The growth in opioids after that year was not medically justifiable. Prescription opioid consumption increased rapidly after 1996, far beyond levels that could be clinically needed.

3. The overexposure of the population to prescription opioids was a consequence of the Defendants' multi-faceted campaign to increase sales of opioid analgesics in the United States, including Florida. The unbranded campaign and branded campaigns relied on deceptive statements about opioids. Defendants disseminated false and misleading statements and materials that downplayed the serious risks of opioids, particularly the risk of addiction, and exaggerated the benefits of long-term use.

4. The massive increase in supply of opioids caused a public health crisis of opioid addiction and related harms. Despite overwhelming evidence that an oversupply of opioids was fueling a public health crisis, Defendants attempted to preserve the massive oversupply by misleading regulators and policymakers.

5. The opioid crisis, while severe, can be abated. There are evidence-based strategies to abate the opioid crisis that should be implemented in the State of Florida. Opioid addiction, also called opioid use disorder (OUD), is a chronic disease. Many people with OUD will need long-term or even lifetime treatment. Yet it is a disease that can be prevented and treated, and its worst effects mitigated through public health strategies. I will opine on the strategies needed to abate the crisis.

My opinions, and the basis for those opinions, are further summarized in Section 6 and are based on my knowledge, training and personal experience practicing in the fields of addiction medicine and public health. I have also based my opinions on medical literature, publicly available documents, including documents and information developed by Florida and federal health agencies, and documents produced in this litigation by Defendants, other opioid manufacturers and distributors, and third parties.

I reserve the right to amend or supplement the facts and opinions upon which I am expected to testify as additional information is made available.

II. BACKGROUND AND QUALIFICATIONS

1. I am a medical doctor, Board Certified in Addiction Medicine, Psychiatry & Neurology. My clinical specialty is the treatment of opioid use disorder. I have been working on the opioid crisis for the past 18 years, initially as a public health official for New York City, then as a clinician, researcher and co-founder of an organization working to promote more cautious opioid use described in the next paragraph.

2. I currently serve as the Medical Director of the Opioid Policy Research Collaborative (OPRC) at the Heller School for Social Policy and Management at Brandeis University. The OPRC studies policies and interventions to address the opioid crisis and advises policymakers, health officials, legislators, government officials and other stakeholders regarding evidence-based solutions to the opioid crisis. Additionally, I teach a course about the opioid crisis to Master in Public Health students at Columbia University. In the course, students learn about the origin of the crisis, the epidemiology of opioid use disorder and strategies for controlling the epidemic. I am also the co-founder of Physicians for Responsible Opioid Prescribing, an organization with a mission to reduce morbidity and mortality caused by overprescribing of opioid analgesics.

3. I received my medical degree from Temple University School of Medicine in 1999, followed by an internship at Mount Sinai School of Medicine, and a residency in Psychiatry at Mount Sinai School of Medicine. During that time, I began to focus on public health issues, completing a fellowship in health policy in the United States Senate and also a fellowship in Public Psychiatry at Columbia University School of Medicine. In 2003, during my fellowship at Columbia, I went to work for the New York City Department of Health and Mental Hygiene, where I later became the Medical Director in the Office of the Executive Deputy Commissioner.

4. As a medical director in the New York City Department of Health and Mental Hygiene, I led one of the nation's first public health efforts to address the opioid crisis, including an initiative to reduce opioid overdose deaths by distributing naloxone through syringe exchange programs and an initiative to expand access to treatment of opioid addiction with buprenorphine. In 2004, while still working for New York City, I began a clinical practice specializing in the treatment of opioid use disorder.

5. Having the opportunity to work in public health, a field focused on population-based disease prevention, while maintaining a clinical practice allowed me to recognize that a

new epidemic of opioid addiction had emerged. Recognizing that many of the opioid-addicted patients streaming into my office developed opioid use disorder from taking prescription opioids led me to question medical education that was downplaying prescription opioid risks. And because my public health work gave me ready access to national surveillance data, I was also able to see that in other parts of the country the rate of opioid-related overdose deaths and hospital visits were even higher than in New York City and were increasing at an alarming rate.

6. In 2006, I became the Vice Chair (and later the Chair in 2008) of the Department of Psychiatry at Maimonides Medical Center, one of the largest teaching hospitals in the country, located in Brooklyn, New York. While in this position I supervised the psychiatric treatment in the medical center's emergency department, outpatient programs, and inpatient units, and I witnessed first-hand a rising number of patients suffering from opioid addiction. Shortly after arriving at Maimonides Medical Center, I came across a journal article written by the Centers for Disease Control and Prevention (CDC), which helped me better understand the sharp rise in opioid-related morbidity and mortality.[1] The CDC showed that opioid overdose deaths had increased in parallel with sales for opioid analgesics and explained that the opioid crisis had been caused by "more aggressive pain management." For the first time, a primary cause of the crisis was made clear, however, in the same medical journal a university-based opioid industry front group published a commentary attacking the CDC paper, attempting to cast doubt on its findings. Recognizing that the opioid industry was interfering with efforts to understand and respond to a crisis it had caused sparked my research interest in the industry-funded campaign to increase prescribing and in the relationship between the opioid industry and pain organizations.[2] It also precipitated my interest in advocacy for more cautious prescribing of opioids.

7. In 2010, several of my colleagues and I founded Physicians for Responsible Opioid Prescribing (PROP). PROP's leadership has conducted research, published papers, petitioned federal agencies and communicated with state and federal policymakers about the opioid crisis. PROP's citizens' petition to the United States Food and Drug Administration, (FDA) resulted in changes to the labeling of opioids, ending marketing for "moderate" pain.

8. In 2013, I left Maimonides to become the Chief Medical Officer of Phoenix House, a national, nonprofit addiction treatment provider, offering affordable evidence-based care to teens, adults, and families, including unique programming for mothers with young children and veterans. In this capacity, I helped Phoenix House adapt its clinical programming nationwide to meet the needs of patients with opioid use disorder.

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[1] Paulozzi LJ, Budnitz DS, Xi Y. (2006) Increasing deaths from opioid analgesics in the United States. *Pharmacoepidemiol Drug Saf.*, 15(9), 618-627. doi: 10.1002/pds.1276.

[2] Joranson DE, Gilson AM. Wanted: a public health approach to prescription opioid abuse and diversion. Pharmacoepidemiol Drug Saf. 2006 Sep;15(9):632-4. doi: 10.1002/pds.1293. PMID: 16862603.; Fishman SM. Commentary in response to Paulozzi et al.: prescription drug abuse and safe pain management. Pharmacoepidemiol Drug Saf. 2006 Sep;15(9):628-31. doi: 10.1002/pds.1292. PMID: 16862601.

9. In 2012, because of my work on the opioid industry's role in causing the opioid crisis, I was consulted by the United States Senate Finance Committee with respect to its investigation of opioid manufacturers and pain organizations. I have also been asked to provide my expertise on the causes of, and potential solutions to the opioid crisis for numerous stakeholders including the World Health Organization, the National Governors Association, the National Association of State Attorneys General, the National Judicial Opioid Task Force, the National Academy of Sciences, and Bi-partisan Members of Congress. I have been invited to testify before committees of the United States Senate and House of Representatives, including the Senate International Drug Caucus, the Senate Committee on Homeland Security, and the House Energy and Commerce Committee.

10. My work tackling the opioid crisis as a health official, clinician, researcher and advocate has given me the knowledge and experience to discuss facts and offer opinions on the root causes of the opioid crisis and the actions that must be taken to bring this urgent public health crisis under control.

My background and qualifications for offering expert opinions are further summarized in my Curriculum Vitae, a copy of which is attached hereto as **Schedule 1**.

III. COMPENSATION

I am being compensated for my work in this case at the following rate: $725 per hour for testimony and preparation, and my fee is not contingent upon the outcome of this case.

IV. PRIOR TESTIMONY AND PUBLICATIONS

A list of the testimony I have provided in the last three years in legal matters is attached hereto as **Schedule 2**.

A list of the publications I have authored in the last ten years is included in my CV, attached hereto as **Schedule 1.**

V. MATERIALS CONSIDERED

In addition to my knowledge, training and experience and the documents and publications cited throughout this Report, attached as **Schedule 3** is a list of the materials, facts, and data I considered in forming my opinions in this Report. I will supplement this list as additional materials become available.

VI. DETAILED OPINIONS AND BASIS:

A. The Effects of Opioid Use

1. Opioids are drugs that stimulate the brain's opiate receptors. Some are made from opium and some are completely synthetic. In the U.S., the most commonly prescribed opioids are hydrocodone and oxycodone, which are classified as semi-synthetic because they are synthesized from opium.

2. Heroin is also a semi-synthetic opioid. The effects of hydrocodone and oxycodone on the brain are nearly indistinguishable from the effects produced by heroin. In fact, in a study performed at Columbia University, experienced heroin users preferred the effects of oxycodone to heroin.[3]

3. Opioids interact with the mu or kappa receptors in the brain, spinal cord, and other areas of the body, especially those involved in feelings of pleasure and pain. Opioids can produce an analgesic effect by acting on neuronal cell receptors. Opioids also affect the central part of the brain that regulates breathing. When a high enough dose of opioids is taken, respiratory depression can result in a fatal overdose.

4. Opioid overdoses – caused mainly by the effects of opioids on the brainstem's breathing circuitry – have become the leading cause of unintentional injury death in the United States, including Florida.[4] Provisional data from the Florida Department of Health shows that 4,294 Floridians lost their life to an opioid overdose in 2019 alone, a 69% increase compared with data from 2015.[5]

5. Addiction is defined as continued use of a drug despite negative consequences.[6] Opioids are highly addictive because they induce positive effects, such as euphoria and pain relief (positive reinforcement) and cessation of chronic use produces dysphoric withdrawal symptoms (negative reinforcement). This is reflected in an individual pathologically pursuing reward and/or avoidance of dysphoria by continuing to use a substance. Chronic exposure to opioids results in structural and functional changes in regions of the brain that mediate affect, impulse, reward, and motivation.[7] Opioid addiction is similar to other chronic diseases in that individuals are often prone to cycles of relapse and remission. Without treatment, opioid addiction can be progressive and life-threatening.

6. According to the American Psychological Association's Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V), opioid addiction, also referred to as OUD, is defined as a problematic pattern of opioid use leading to clinically significant impairment

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[3] Comer SD, et al. (2008). Abuse liability of prescription opioids compared to heroin in morphine-maintained heroin abusers. *Neuropsychopharmacology*, 33(5), 1179-1191. https://doi.org/10.1038/sj.npp.1301479.

[4] Nat'l Acads. of Science, Eng'g and Medicine, *Pain Mgmt. and the Opioid Epidemic*, National Academies Press (2017) at 17 (citing Rose Rudd, et al, (2016). Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015, MMWR *Morb Mortal Wkly Rep,* 65 (50-51), 1445-52. DOI: http://dx.doi.org/10.15585/mmwr.mm655051e1.

[5] Florida Department of Health, "Substance Use Dashboard," n.d., http://www.flhealthcharts.com/ChartsReports/rdPage.aspx?rdReport=SubstanceUseDashboard.Dashboard.

[6] Angres DH, Bettinardi-Angres K. (2008). The disease of addiction: origins, treatment, and recovery. *Dis. Mon.*, 54(10), 696–721 doi: 10.1016/j.disamonth.2008.07.002.

[7] Upadhyay J, et al. (2010). Alterations in brain structure and functional connectivity in prescription opioid-dependent patients. *Brain*, 133(Pt7), 2098–114 doi: 10.1093/brain/awq138; Younger JW, et al. (2011). Prescription opioid analgesics rapidly change the human brain. *Pain*, 152(8), 1803–10. doi: 10.1016/j.pain.2011.03.0280.

or distress, as manifested by meeting at least two of the following diagnostic criteria below within a 12-month period:[8]

- Using larger amounts of opioids or over a longer period than was intended
- Persistent desire to cut down or unsuccessful efforts to control use
- Great deal of time spent obtaining, using, or recovering from use
- Craving, or a strong desire or urge to use substance
- Failure to fulfill major role obligations at work, school, or home due to recurrent opioid use
- Continued use despite recurrent or persistent social or interpersonal problems caused or exacerbated by opioid use
- Giving up or reducing social, occupational, or recreational activities due to opioid use
- Recurrent opioid use in physically hazardous situations
- Continued opioid use despite physical or psychological problems caused or exacerbated by its use
- Tolerance (marked increase in amount; marked decrease in effect)
- Withdrawal syndrome as manifested by cessation of opioids or use of opioids (or a closely related substance) to relieve or avoid withdrawal symptoms.

7. There are three levels of OUD severity: mild (meet 2-3 criteria), moderate (meet 4-5 criteria), and severe (meet 6 or more criteria). Notably, tolerance and withdrawal are not assessed for individuals taking prescription opioids under medical supervision. Early remission of OUD is defined as no diagnostic criteria being met for at least 3 months and no more than 12 months, and sustained remission is defined as no diagnostic criteria being met for 12 months or longer. Craving for opioids is an exempt criterion for identifying OUD remission, and tolerance and withdrawal are not assessed for individuals on medication treatment with methadone or buprenorphine. Recovery is used in this expert report as being synonymous with sustained remission, and a goal of OUD treatment is to achieve recovery for individuals with OUD.

8. The disease of opioid addiction arises from repeated exposure to opioids and can occur in individuals using opioids to relieve pain and in non-medical users. Studies have found that many patients on long-term opioids for chronic pain meet criteria for DSM-V opioid use disorder and DSM-IV opioid dependence.[9]

9. Opioid Use Disorder is a chronic disease. For many, it can require lifelong treatment, and many people experience relapses. It is important to note that OUD is a preventable and

[8] American Psychiatric Association., American Psychiatric Association. DSM-5 Task Force. *Diagnostic and statistical manual of mental disorders: DSM-5.* 5th ed. Washington, D.C.: American Psychiatric Association; 2013.

[9] Boscarino JA, Hoffman SN, Han JJ. (2015). Opioid-use disorder among patients on long-term opioid therapy: impact of final DSM-5 diagnostic criteria on prevalence and correlates. *Subst Abuse Rehabil.*, 6, 83-91. doi: 10.2147/SAR.S85667; Boscarino JA, Rukstalis MR, Hoffman SN, et al. (2011). Prevalence of prescription opioid-use disorder among chronic pain patients: comparison of the DSM-5 vs. DSM-4 diagnostic criteria. *J Addict Dis.*, 30(3), 185-194. doi: 10.1080/10550887.2011.581961.

treatable disease. Its worst effects can be mitigated or avoided using tested treatments and emerging interventions, discussed below.

10. Not only can opioid use cause addiction, overdose and death, but for all opioid users physiological dependence sets in within a few days of regular use.[10] The opioid withdrawal symptoms experienced when a physiologically dependent patient attempts to cease use can be severe, especially in patients who have used opioids for a prolonged period of time or were taking high doses. In the first few days after opioids are discontinued, withdrawal effects include flu-like symptoms, nausea, vomiting, diarrhea, pain hypersensitivity, insomnia and severe anxiety, akin to a panic attack and described in the medical literature as "a sense of impending doom."[11] Patients who have experienced opioid withdrawal often describe the experience as "feeling like I was going to die." Individuals who are physiologically dependent on opioids will often engage in desperate and sometimes illegal activities obtaining opioids to avoid withdrawal.

11. Individuals who take high doses of opioids for an extended period of time can experience opioid withdrawal symptoms for several months after use is discontinued.[12] These prolonged symptoms include metabolic abnormalities, insomnia, fatigue, depression and cravings to use opioids.

12. Opioids are useful medicines for end-of-life care. They can also be helpful when used for a few days after major surgery or a serious accident. Unfortunately, the bulk of opioid consumption in the U.S. is for common, chronic conditions, like back pain, where opioids are more likely to harm patients than help them. There is not, and has never been, adequate evidence to support the long-term use of opioids.[13]

13. In identifying a baseline above which opioid use, controlling for population growth, is medically inappropriate, I opine that the volume of opioids being prescribed in 1997 is a very conservative baseline. In that year, Americans were already being prescribed more opioids than people in other countries. After that, the dramatic expansion was primarily in the area of opioids for chronic conditions and was unjustifiable from a medical and public health standpoint.

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[10] Kosten, T. et al., (2002). The Neurobiology of Opioid Dependence: Implications for Treatment, *1 Science Practical Perspective*, 1, 13–20 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2851054; Bailey, C. & Connor, M. *Opioids: Cellular Mechanisms of Tolerance and Physical Dependence*, 5 Current Opinion in Pharmacology 1, at 60, https://www.ncbi.nlm.nih.gov/pubmed/15661627; Shah, A. et al., *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use- Unites States, 2006-2015*, Morbidity and Mortality Weekly Report (Mar. 17, 2017), *available at* https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm.

[11] San, L. et al., (1992) Assessment and Management of Opioid Withdrawal Symptoms in Buprenorphine-Dependent Subjects, *British J. of Addiction*, 87(1), 55-62; Kosten, *supra* at note 31.

[12] Martin WR, Jasinski DR. (1969) Physiological parameters of morphine dependence in man--tolerance, early abstinence, protracted abstinence. *J Psychiatr Res*., 7(1), 9-17 DOI: 10.1016/0022-3956(69)90007-7.

[13] Jason Busse. (2018). Opioids for Chronic Noncancer Pain A Systematic Review and Meta-analysis. *JAMA* 320(23), 2448-2460. doi:10.1001/jama.2018.18472); National Academies of Science, Engineering and Medicine, *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use* 17 (Phillips, et al. eds., 2017) (hereinafter, "NASEM, *Pain Management and the Opioid Epidemic*").

14. In 2016, CDC released a "Guideline for Prescribing Opioids for Chronic Pain." In developing the CDC Guideline for Opioid Prescribing for Chronic Pain, the CDC conducted a systematic review of the scientific evidence to identify the effectiveness, benefits, and harms of long-term opioid therapy for chronic pain.[14] In a New England Journal of Medicine editorial that accompanied the release of its guideline, the CDC wrote:

> "Most placebo-controlled, randomized trials of opioids have lasted 6 weeks or less, and we are aware of no study that has compared opioid therapy with other treatments in terms of long-term (more than 1 year) outcomes related to pain, function, or quality of life. The few randomized trials to evaluate opioid efficacy for longer than 6 weeks had consistently poor results. In fact, several studies have showed that use of opioids for chronic pain may actually worsen pain and functioning, possibly by potentiating pain perception. A 3-year prospective observational study of more than 69,000 postmenopausal women with recurrent pain conditions showed that patients who had received opioid therapy were less likely to have improvement in pain (odds ratio, 0.42; 95% confidence interval [CI], 0.36 to 0.49) and had worsened function (odds ratio, 1.25; 95% CI, 1.04 to 1.51). An observational case–control study of patients undergoing orthopedic surgery showed that those receiving long-term opioid therapy had significantly higher levels of preoperative hyperalgesia. After surgery, patients who had received long-term opioid therapy reported higher pain intensity (a rating of 7.6 vs. 5.5 out of 10) in the recovery room than patients who had not been taking opioids."
>
> "Whereas the benefits of opioids for chronic pain remain uncertain, the risks of addiction and overdose are clear."[15]

15. Opioid molecules (i.e. morphine, oxycodone, hydrocodone, fentanyl, etc.) differ in the amount required to produce an effect of given intensity, also called potency. The morphine milligram equivalent per day (MME/day) for each opioid can be calculated using a conversion factor. In the editorial the CDC called special attention to the serious harms related to high dose opioid therapy:

> "Overdose risk increases in a dose–response manner, at least doubling at 50 to 99 morphine milligram equivalents (MME) per day and increasing by a factor of up to 9 at 100 or more MME per day, as compared with doses of less than 20 MME per day. Overall, 1 of every 550 patients started on opioid therapy died of opioid-related causes a median of 2.6 years after the first opioid prescription; the proportion was as high as 1 in 32 among patients receiving doses of 200 MME or higher. We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."

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[14] Dowell D, et al. (2016). CDC guideline for prescribing opioids for chronic pain—United States, 2016. JAMA, 315(15), 1624-1645. doi:10.1001/jama.2016.1464.

[15] Freiden T, Houry D. 2016. Reducing the Risks of Relief — The CDC Opioid-Prescribing Guideline. N Engl J Med 2016; 374:1501-1504. DOI: 10.1056/NEJMp1515917.

16. When opioids are taken every day, patients quickly become tolerant to the pain-relieving effect, which means that the patient will experience a loss of pain relief unless the dose is increased. Unfortunately, the medical community was misled to believe that dose escalation was safe and appropriate. In fact, as doses get higher the risks for serious adverse effects increase, including depression, neuroendocrine dysfunction, addiction and death.[16] And as doses increase patients are also more likely to experience sedation and a decreased level of functioning.

17. Many patients on long-term opioids are not doing well. A large observational study of long-term opioids found that four out of five chronic pain patients taking opioids continued to experience significant pain and dysfunction.[17] In the study, middle-aged women, a target market for the opioid industry, experienced especially poor outcomes.

18. One of the most serious adverse outcomes associated with prolonged exposure to opioids, especially at high doses, is addiction. Any individual who takes opioids daily for more than a few days will be at high risk for developing opioid addiction. The reason for use, whether medical, recreational, or self-medicating, has less influence on the development of addiction than the duration of use. Although the opioid industry promoted the false notion that only a small subset of the population is at risk for developing opioid addiction (See Section VI (E) (6) (b) below), health officials and public health advocates have tried to clarify that opioids are inherently addictive – that the problem is "risky drugs, not risky patients."[18]

19. In a study of more than 500,000 patients with chronic pain, dose and duration were found to be the greatest risk factors for development of opioid addiction.[19] The study found that a person taking a relatively low dose of prescribed opioids was 15 times more likely to develop opioid use disorder than a person who was not prescribed opioids. The risk continues to rise as doses increase; at high doses (≥ 120 mg MED) of opioids, the person's risk of developing OUD is 122 times that of a person who has not been prescribed opioids (Figure 1).[20]

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[16] Centers for Disease Control and Prevention. Vital signs: Overdoses of prescription opioid pain relievers and other drugs among women—United States, 1999–2010. *MMWR* Morb Mortal Wkly Rep 2013, 62(26), 537–542; Baldini A. et al. (2012). A review of potential adverse effects of long-term opioid therapy: A practitioner's guide. *Prim Care Companion CNS Disord*, 14(3), pii. doi: 10.4088/PCC.11m01326.

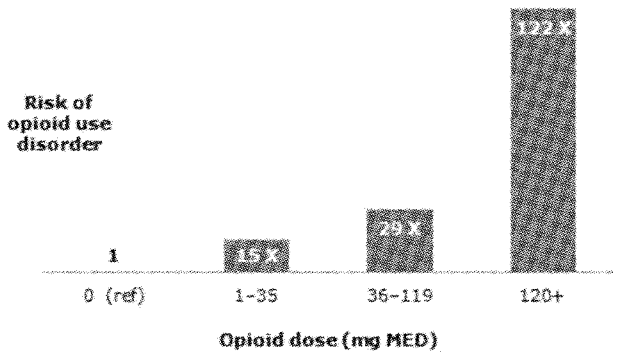
[17] LeResche L. et al. (2015). Sex and Age Differences in Global Pain Status Among Patients Using Opioids Long Term for Chronic Noncancer Pain. *J Womens Health (Larchmt)*, 24(8), 629-635. doi: 10.1089/jwh.2015.5222.

[18] Dowell D, et al. (2013). Opioid Analgesics—Risky Drugs, Not Risky Patients. *JAMA,* 309(21), 2219–2220. doi:10.1001/jama.2013.5794.

[19] Edlund MJ, et al. (2014). The role of opioid prescription in incident opioid abuse and dependence among individuals with chronic noncancer pain: the role of opioid prescription. *Clin J Pain*., 30(7), 557-64. Doi: 10.1097/AJP.0000000000000021.

[20] *Id.*

Figure 1: Risk of Opioid Use Disorder for Different Doses of Prescription Opioids



20. Higher opioid dosages are associated with increased overdose risk. The CDC Guideline review included four well-designed studies that evaluated similar MME/day dose ranges for association with overdose risk.[21]

21. The CDC found that keeping dosages under 50 MME/day reduces overdose risk among a large proportion of patients, that dosages under 50 MME/day are safer than dosages of 50–100 MME/day, and that dosages under 20 MME/day are safer than dosages of 20–50 MME/day. CDC's expert consensus was that increasing dosages to 50 or more MME/day increases overdose risk without necessarily adding benefits for pain control or function.[22]

22. Dose-related serious harms are not limited to risk of overdose. High dose opioids are associated with increased risk for motor vehicle accidents, fractures from falls, immune suppression, and opioid associated androgen deficiency which can cause reduced libido, erectile dysfunction, fatigue, depression, decreased muscle mass, weight gain, osteoporosis and infertility.[23]

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[21] Zedler B, et al. (2014). Risk factors for serious prescription opioid-related toxicity or overdose among Veterans Health Administration patients. *Pain Med*, 15(11), 1911–29. doi: 10.1111/pme.12480, Bohnert AS, et al. (2011). Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA*, 305(13), 1315–21. doi:10.1001/jama.2011.370; Dunn KM, et al. (2010). Opioid prescriptions for chronic pain and overdose: a cohort study. *Ann Intern Med*, 152(2), 85–92. doi: 10.7326/0003-4819-152-2-201001190-00006; Gomes T, et al. (2011). Opioid dose and drug-related mortality in patients with nonmalignant pain. Arch Intern Med, 171(7), 686–91. doi:10.1001/archinternmed.2011.117.

[22] Dowell D, et al. (2016). CDC guideline for prescribing opioids for chronic pain—United States, 2016. *JAMA*, 315(15), 1624-1645. doi:10.1001/jama.2016.1464.

[23] Saunders KW, et al. (2010). Relationship of opioid use and dosage levels to fractures in older chronic pain patients. *J. Gen. Intern. Med.*, 25(4), 310-5. doi: 10.1007/s11606-009-1218-z; Takkouche B, et al. (2007). Psychotropic medications and the risk of fracture: a meta-analysis. *Drug Saf.* 30(2), 171-84. doi: 10.2165/00002018-200730020-00006; Vuong C, et al. (2010). The effects of opioids and opioid analogs on animal and human endocrine systems. *Endocr. Rev.*, 31(1), 98–132. doi: 10.1210/er.2009-0009; Angst MS, Clark JD. (2006). Opioid-induced hyperalgesia: a qualitative systematic review. *Anesthesiology*, 104(3), 570–87. doi: 10.1097/00000542-200603000-00025; Tuteja AK, et al. (2010). Opioid-induced bowel disorders and narcotic bowel syndrome in patients with chronic non-cancer pain. *Neurogastroenterol. Motil.* 22(4), 424-30. doi:

23. Ultra-high dosage unit (UHDU) opioids are formulations that when taken as directed exceed 90 MME/day, a dose the CDC determined to be dangerously high.[24] Examples of UHDU opioids include Opana Immediate Release tablets in the 10mg dosage and Opana Extended Release tablets in the 15 mg, 20 mg, 30 mg, and 40 mg doses. A patient who took Opana Extended Release 40 mg tablets, as prescribed, was consuming 240 MME/day—more than double the dose defined by the CDC as dangerous.

24. UHDU are dangerous and harmful to patients who take them as prescribed but pose even greater risks to individuals without a tolerance to opioids. In 2015, there were 969,000 youths aged 12 to 17 who misused prescription pain relievers, and 3.0 million young adults aged 18 to 25.[25] Specific to Florida for 2015, 5.3% of middle school- and high school-aged youth reported lifetime prescription opioid misuse and 1.8% reported prescription opioid misuse within the last 30 days, representing around 122,000 and 41,500 Floridians respectively.[26] An opioid naive adolescent who makes the mistake of experimenting with an UHDU opioid could easily suffer a fatal overdose. Data from the Florida Medical Examiners shows that 27 adolescents lost their lives to opioid overdoses in 2019.[27] Experimentation with a low dosage opioid is also dangerous and can lead to addiction but is less likely to result in life threatening respiratory depression.

B. There has been a sharp increase in the prevalence of opioid addiction and other opioid-related harms in the United States and in the State of Florida. The increased prevalence of opioid addiction and other opioid-related harms has resulted in an array of health and social problems commonly referred to as the "opioid crisis."

1. In the 1980s and early 1990s, the incidence of opioid addiction in the United States was relatively low and deaths from opioid overdose mainly occurred in poor, urban communities with a high prevalence of heroin addiction.

2. In the 1990s, the incidence of opioid addiction and opioid-related overdose deaths began increasing at an alarming rate, climbing to a level that prompted the CDC to call the crisis

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10.1111/j.1365-2982.2009.01458.x; Thomson MW, et al. (2006). Xerostomia and medications among 32-year-olds. *Acta Odontol Scand.*, 64(4). 249-54. doi: 10.1080/00016350600633243.

[24] Dowell D, et al. (2016). CDC guideline for prescribing opioids for chronic pain United States, 2016. *JAMA*, 315(15), 1624-1645. doi:10.1001/jama.2016.1464.

[25] Hughes, A., et al. Prescription drug use and misuse in the United States: Results from the 2015 National Survey on Drug Use and Health. *NSDUH, available at*, https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR2-2015/NSDUH-FFR2-2015.htm.

[26] Florida Department of Children and Families, "2015 Florida Youth Substance Abuse Survey," 2015, https://www.myflfamilies.com/service-programs/samh/prevention/fysas/2015/docs/2015%20FYSAS%20State%20Report.pdf; Florida Department of Health, "Population Dashboard," n.d., http://www.flhealthcharts.com/ChartsReports/rdPage.aspx?rdReport=PopAtlas.PopulationAtlasDASHBOARD&rdRequestForwarding=Form.

[27] Florida Department of Law Enforcement, "Drugs Identified in Deceased Persons by Florida Medical Examiners," 2020, http://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2019-Annual-Drug-Report.aspx.

the "worst drug overdose epidemic in [US] history" and note that the primary driver was an unprecedented increase in prescription opioid consumption.[28] Indeed, from 1997 to 2012, there was a 900% increase in individuals seeking treatment for addiction to prescription opioids.[29] During this same time frame, the rate of opioid-related overdose deaths nearly quadrupled.[30]

3. The sharp increase in the prevalence of opioid addiction is a key driver of opioid-related mortality. Accidental opioid overdose is a common cause of death in individuals suffering from opioid addiction.[31] Consistent findings in samples of prescription overdose decedents show that deaths are most common in individuals likely to be suffering from opioid addiction.[32] For example, a study of 295 unintentional prescription opioid overdose deaths found that four out of five decedents (80%) had a history of a substance use disorder.[33] In a study of prescription opioid overdose decedents conducted by the State of Utah's health department, 76% of the decedents exhibited evidence of addiction prior to their death.[34] For 92% of the patients, the primary source for the prescription opioids was directly from a healthcare provider.

4. As the number of Americans suffering from opioid addiction increased over the past 25 years, there was a soaring increase in accidental death from opioid overdose. In the 1980s, the rate of opioid-related overdose death in the United States was less than 0.4 per 100,000.[35] But by 2017, after a sharp and steady increase for more than 25 years, the

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[28] Paulozzi, LJ. (2010). *The epidemiology of drug overdoses in the United States*. Grand Rounds Lecture Presented at Maimonides Med. Cent. Dep. Psychiatry, Brooklyn, New York.

[29] SAMHSA (Subst. Abuse Ment. Health Serv. Adm.). 2010. *Center for Behavioral Health Statistics and Quality. Treatment Episode Data Set (TEDS): 2007. Discharges from Substance Abuse Treatment Services*. DASIS Ser.: S-51, HHS Publ. No. (SMA) 10-4479. Rockville, MD: SAMHSA; SAMHSA (Subst. AbuseMent. Health Serv. Adm.). 2013. *Center for Behavioral Health Statistics and Quality.*

Treatment Episode Data Set (TEDS): 2001–2011. National Admissions to Substance Abuse Treatment Services. BHSIS Ser. S-65, DHHS Publ. No. SMA 13-4772. Rockville, MD: SAMHSA.

[30] Chen, LH. et al. (2014). *Drug-Poisoning Deaths Involving Opioid Analgesics: United States, 1999–2011*. NCHS Data Brief No. 166. Hyattsville, MD: Natl. Cent. Health Stat.

[31] Hser YI, Hoffman V, Grella CE, Anglin MD. (2001). A 33-year follow-up of narcotics addicts. *Arch. Gen. Psychiatry*, 58(5), 503–8. doi: 10.1001/archpsyc.58.5.50.

[32] Kolodny, A. et al. (2015). The prescription opioid and heroin crisis: a public health approach to an epidemic of addiction. *Annu Rev Public Health*, 36, 559-574. https://doi.org/10.1146/annurev-publhealth-031914-122957; Hall, AJ. et al. (2008). Patterns of abuse among unintentional pharmaceutical overdose fatalities. *JAMA* 300(22), 2613–20. doi: 10.1001/jama.2008.802; Johnson EM, Lanier WA, Merrill RM, Crook J, Porucznik CA, et al. 2013. Unintentional prescription opioid-related overdose deaths: description of decedents by next of kin or best contact, Utah, 2008–2009. *J. Gen. Intern. Med.*, 28(4), 522–29. doi: 10.1007/s11606-012-2225-z9.

[33] Kolodny, A. et al. (2015). The prescription opioid and heroin crisis: a public health approach to an epidemic of addiction. *Annu Rev Public Health*, 36, 559-574. https://doi.org/10.1146/annurev-publhealth-031914-122957.

[34] Johnson EM, Lanier WA, Merrill RM, et al. Unintentional prescription opioid-related overdose deaths: description of decedents by next of kin or best contact, Utah, 2008-2009. J Gen Intern Med. 2013;28(4):522-529.

[35] Paulozzi LJ, Budnitz DS, Xi Y. Increasing deaths from opioid analgesics in the United States. *Pharmacoepidemiol Drug Saf.* 2006;15(9):618-627. doi:10.1002/pds.1276.

opioid-related death rate increased to 14.9 per 100,000.[36] Since 2005, more than 500,000 lives were lost to opioid overdose.[37]

5. The increased prevalence of prescription opioid use and dependence has also led to a sharp rise in use and availability of heroin and illicitly synthesized heroin. Several studies have shown that prescription opioid use frequently precedes heroin use.[38] Nearly 80 percent of heroin users report using prescription opioids prior to heroin.[39] Based on published research findings and my clinical experience, I believe that the vast majority of heroin users who initiated heroin use during the past 25 years were first addicted to prescription opioids.

6. In turn, the resulting sharp rise in the use of heroin, including injection use, occurred. In recent years, as the illicit opioid supply became more potent, mainly from fentanyl and fentanyl analogues, the United States, including the State of Florida, experienced a soaring increased in opioid overdose deaths. From 2013 to 2019, the age-adjusted rate of deaths involving synthetic opioids other than methadone increased 1,040%.[40]

7. The State of Florida has been hit especially hard by the opioid crisis. In 1997, the rate of admissions to state-licensed Florida treatment programs for primary addiction to prescription opioids was 7 per 100,000.[41] By 2011, after a skyrocketing increase for more than a decade, rate of admissions was 164 per 100,000, an increase of more than 2000% over a 14-year period.[42]

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[36] Wilson N, Kariisa M, Seth P, Smith H IV, Davis NL. Drug and Opioid-Involved Overdose Deaths — United States, 2017–2018. MMWR Morb Mortal Wkly Rep 2020;69:290–297. DOI: http://dx.doi.org/10.15585/mmwr.mm6911a4external icon.

[37] Compton WM, Valentino RJ, DuPont RL. Polysubstance use in the U.S. opioid crisis. Mol Psychiatry. 2021 Jan;26(1):41-50. doi: 10.1038/s41380-020-00949-3. Epub 2020 Nov 13. PMID: 33188253; PMCID: PMC7815508.

[38] Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The changing face of heroin use in the united states: A retrospective analysis of the past 50 years. JAMA Psychiatry. 2014.doi:10.1001/jamapsychiatry.2014.366, at p. E-1.; Muhuri PK, Gfroerer JC, Davies MC. Associations of nonmedical pain reliever use and initiation of heroin use in the united States. CBHSQ Data Rev. 2013;(August):1-16.; Compton WM, Jones CM, Baldwin GT. Relationship between Nonmedical Prescription-Opioid Use and Heroin Use. N Engl J Med. 2016. doi:10.1056/NEJMra1508490.; Lankenau SE, Teti M, Silva K, Bloom JJ, Harocopos A, Treese M. Initiation into prescription opioid misuse amongst young injection drug users. Int J Drug Policy. 2012;23(1):37-44.

[39] NIDA Research report. Prescription Opioids and Heroin Research Report Prescription opioid use is a risk factor for heroin use. January 2018. Available at: https://www.drugabuse.gov/download/19774/prescription-opioids-heroin-research-report.pdf?v=fc86d9fdda38d0f275b23cd969da1a1f

[40] Mattson CL, Tanz LJ, Quinn K, Kariisa M, Patel P, Davis NL. Trends and Geographic Patterns in Drug and Synthetic Opioid Overdose Deaths — United States, 2013–2019. MMWR Morb Mortal Wkly Rep 2021;70:202–207. DOI: http://dx.doi.org/10.15585/mmwr.mm7006a4.

[41] Substance Abuse and Mental Health Services Administration, Office of Applied Studies. Treatment Episode Data Set (TEDS): 1997-2007. National Admissions to Substance Abuse Treatment Services, DASIS Series: S-47, DHHS Publication No. (SMA) 09-4379, Rockville, MD, 2009.

[42] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Treatment Episode Data Set (TEDS): 2005-2015. National Admissions to Substance Abuse Treatment Services.

8. I estimate that the OUD prevalence in Florida is 382,300, representing 2.2% of the population aged 15 and over (methodology further discussed below), though I believe this to be a conservative number. This estimate does not include individuals at risk for OUD among the almost 500,000 Floridians who received six or more prescriptions for an opioid in 2019. Around 13.5% of these nearly 500,000 individuals are likely to develop moderate to severe OUD, requiring long-term medication treatment and intensive ancillary services, and another 28% are likely to develop mild OUD.[43]

9. The high prevalence of Floridians with OUD has contributed to the state being disproportionately impacted by the opioid crisis and has led to a wide range of health and social problems, including a dramatic rise in opioid-related mortality. As seen in the Figure 2 below, from 1999 to 2019 the opioid-related death rate increased from 2.6 per 100,000 people to 18.7 per 100,000 people in Florida, a more than seven-fold rise. The opioid-related death rate was consistently higher than the national average in the 2000s and in 2019 was 21% higher than the national average.[44] Preliminary evidence suggests that 7,579 Floridians died of a drug overdose in 2020, with the large majority opioid-related.[45] This represents a 37% increase from 2019, highlighting an exacerbated public health crisis in a need of an immediate response that is resource-intensive and comprehensive in scope. An analysis of provisional data from the Florida Department of Health suggests that overdose deaths are even higher in 2020, as much as a 60% increase from 2019, with evidence showing that the COVID-19 pandemic contributed to this rise.[46]

BHSIS Series S-91, HHS Publication No. (SMA) 17-5037. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2017.

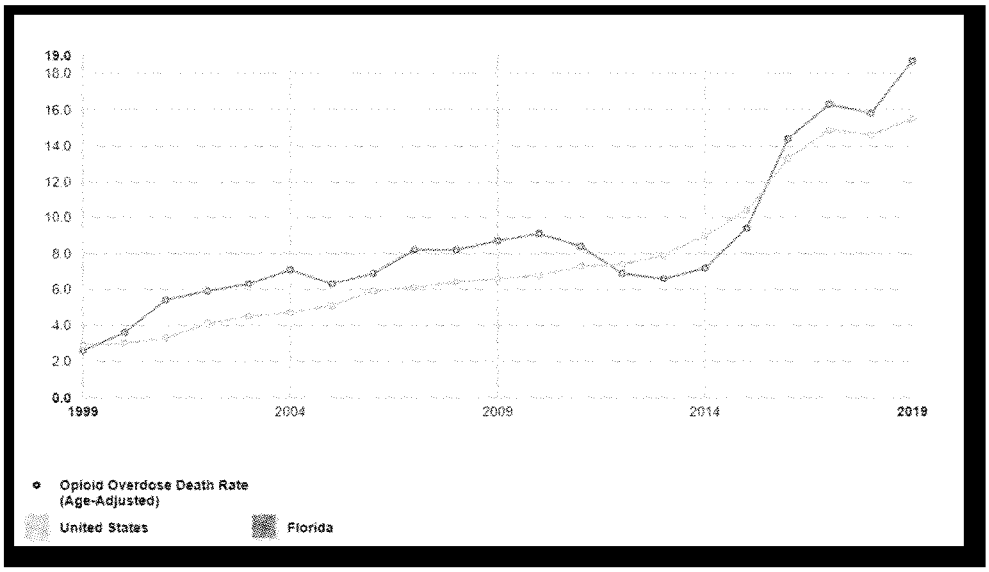
[43] Joseph A. Boscarino, Stuart N. Hoffman, and John J. Han, "Opioid-Use Disorder among Patients on Long-Term Opioid Therapy: Impact of Final DSM-5 Diagnostic Criteria on Prevalence and Correlates," *Substance Abuse and Rehabilitation* 6 (2015): 83–91, https://doi.org/10.2147/SAR.S85667.

[44] Kaiser Family Foundation, "Opioid Overdose Death Rates and All Drug Overdose Death Rates per 100,000 Population (Age-Adjusted)," 2021, https://www.kff.org/other/state-indicator/opioid-overdose-death-rates/.

[45] F.B. Ahmad, L.M. Rossen, and P. Sutton, "Provisional Drug Overdose Death Counts," National Center for Health Statistics, 2021, https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.

[46] Project Opioid, "The COVID-19 Overdose Crisis: A Pandemic Fueling an Epidemic in Florida in 2020," n.d., https://projectopioid.org/wp-content/uploads/2020/12/PO-2020-Data-Study-Final_New-Section.pdf.

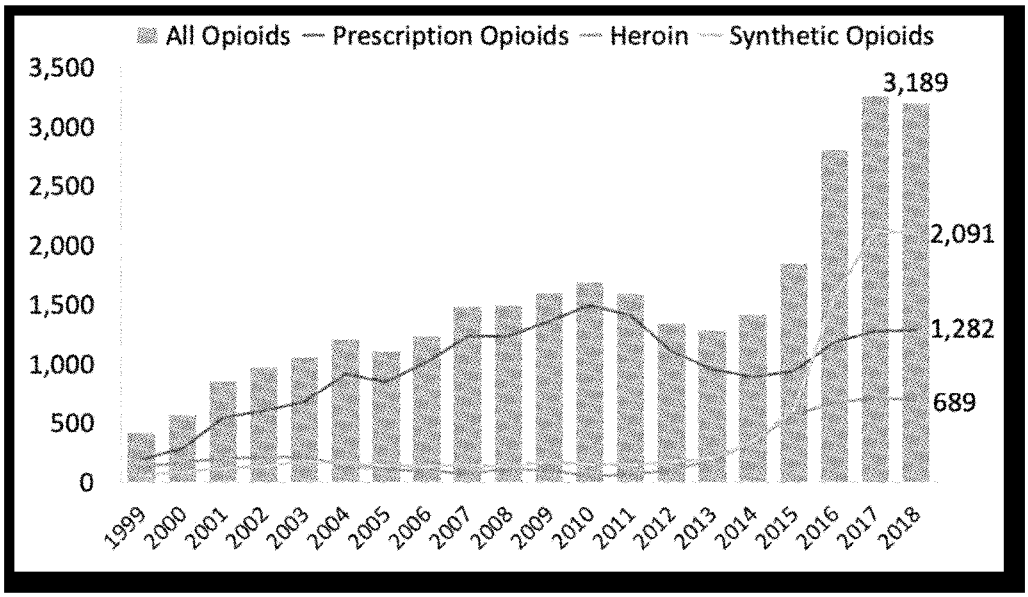
Figure 2: Opioid-Related Overdose Death Rate for Florida and United States



Source: Kaiser Family Foundation (2021)

10. Overdose deaths involving prescription opioids in Florida steadily increased from 1999 to 2010, and prescription opioids were the most common opioid involved in an opioid overdose death until 2016, as seen in the Figure 3 below.[47] Middle-aged individuals (aged 35 to 44) have historically been the most impacted by opioid-related overdose deaths though a younger cohort (aged 25 to 34) now has the highest rate of these deaths,[48] underscoring an increased personal and societal burden from premature fatalities of young adults.[49]

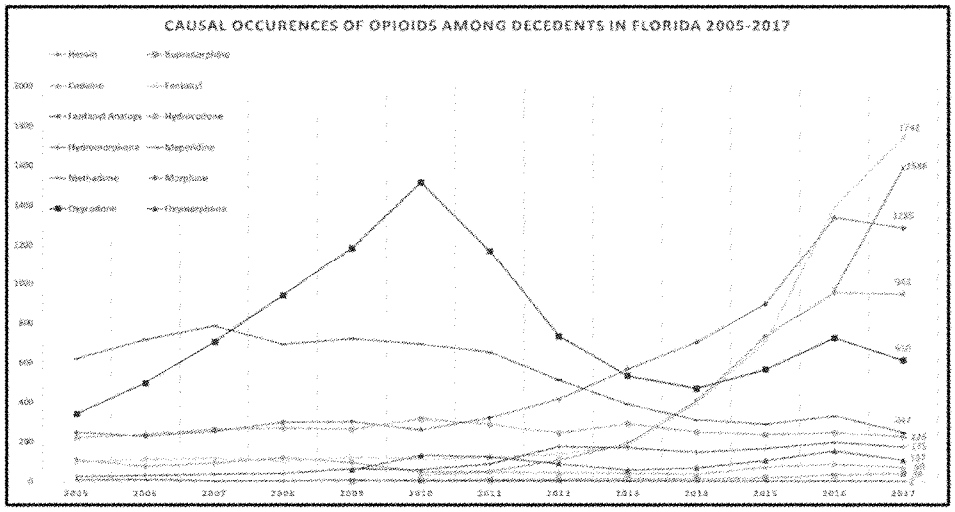
Figure 3: Types of Opioids Involved in Opioid-Related Overdose Deaths, Florida



Source: CDC (2021)

11. When the prescription opioids category is further broken down into different types, a steep rise in oxycodone-related overdose deaths stands out from 2005-2010 as seen in Figure 4 below.[50] This is reflective of the overprescribing of Oxycontin and other oxycodone formulations during this time period.

Figure 4: Types of Prescription Opioids Involved in Opioid-Related Overdose Deaths



Source: Florida Department of Children and Families (2018)

12. In addition to the lives lost, there has been a significant economic impact of the opioid crisis on Florida. I understand that another expert, James McClave, will address the economic costs to Florida of the opioid crisis.

13. In addition to mortality, the impact of opioid-related morbidity is substantial and has been increasing in the state. As seen in Figure 5 below, opioid-related hospitalizations doubled from 2005 to 2011.[51] Opioid-related emergency department visits increased 43% during this same time period and, as of 2017, there has been a seven-fold rise compared to 2005.[52] Provisional data from the Florida Department of Health suggests continued rises in opioid-

[47] National Institute on Drug Abuse, "Florida: Opioid-Involved Deaths and Related Harms," 2020, https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/florida-opioid-involved-deaths-related-harms.

[48] Kaiser Family Foundation, "Opioid Overdose Deaths by Age Group," 2021, https://www.kff.org/other/state-indicator/opioid-overdose-deaths-by-age-group/.

[49] O. Trent Hall et al., "Assessment of Excess Mortality Associated With Drug Overdose in Ohio From 2009 to 2018," *JAMA Network Open* 3, no. 4 (April 1, 2020): e202183, https://doi.org/10.1001/jamanetworkopen.2020.2183.

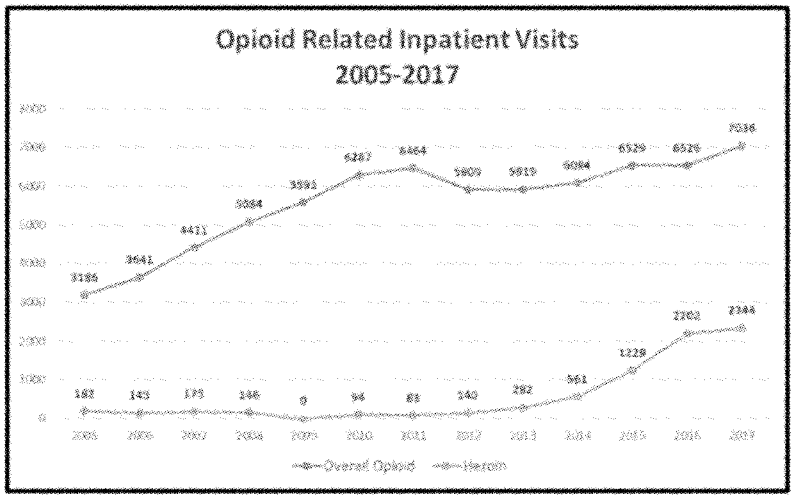
[50] Florida Department of Children and Families, "Patterns and Trends of the Opioid Epidemic in Florida," 2018, https://www.myflfamilies.com/service-programs/samh/publications/docs/Florida%20SEOW%20Annual%20Report%202018.pdf.

[51] Florida Department of Children and Families, "Patterns and Trends of the Opioid Epidemic in Florida."

[52] Florida Department of Children and Families.

related morbidity, with suspected nonfatal overdoses increasing by 104%, opioid-related emergency department visits increasing by 149%, and opioid-related hospitalizations increasing by 11% from 2015 to 2019.[53] This is also a national trend, as costs to Medicaid associated with OUD have more than tripled from 1999-2013 owing to the 378% increase in OUD prevalence among the entire US Medicaid population.[54] Specifically in Florida, there has been a heavy economic burden on the state government as 53% and 13% of all opioid-related emergency department visits involved uninsured patients and Medicaid patients respectively in 2017.[55]

Figure 5: Opioid-Related Hospitalizations in Florida



Source: Florida Department of Children and Families (2018)

14. Another health consequence of the opioid crisis has been a substantial increase in opioid-related infectious diseases, particularly Hepatitis C Virus (HCV), HIV, endocarditis, and soft tissue infections. According to the CDC, acute cases of HCV have increased more than three-fold nationally from 2010-2016, reflecting rising rates of injection drug use, and injection drug use contributed to around 20% of recorded HIV cases in 2016.[56] As explained above, rates of injection drug use rose dramatically because of the rise in OUD fueled by the oversupply of prescription opioids. The rate of reported new cases of HCV in Florida has been rapidly increasing and has been consistently higher than the national

[53] Florida Department of Health, "Substance Use Dashboard."

[54] Douglas L. Leslie et al., "The Economic Burden of the Opioid Epidemic on States: The Case of Medicaid," *The American Journal of Managed Care* 25, no. 13 Suppl (July 2019): S243–49.

[55] Florida Department of Children and Families, "Patterns and Trends of the Opioid Epidemic in Florida."

[56] Centers for Disease Control and Prevention, "2016 Surveillance Data for Viral Hepatitis in U.S.," 2018, https://www.cdc.gov/hepatitis/statistics/2016surveillance/commentary.htm; National Institute on Drug Abuse, "Drug Use and Viral Infections (HIV, Hepatitis) DrugFacts," 2020, https://www.drugabuse.gov/publications/drugfacts/drug-use-viral-infections-hiv-hepatitis.

average since 2008, notably more than double the national rate in 2018.[57] The estimated prevalence of those living with HCV in Florida is 151,000, or about 0.95% of the adult population.[58] A study done in Miami at the IDEA Exchange, Florida's first syringe service program (SSP), highlights the extent of infectious diseases as a result of injection drug use. The prevalence of HCV and HIV was 44.4% and 10.2% respectively among 837 participants accessing the SSP for the first time.[59] Though there is now curative treatment for HCV, it comes at an average wholesale acquisition cost of $26,400 per treatment regimen,[60] and lifetime costs for treating HIV average more than $326,000 per person.[61] Drug-related cases of endocarditis have doubled nationally from 2002 to 2016 at a median reimbursement of around $45,000 per case.[62]

15. Rates of Neonatal Abstinence Syndrome (NAS) in Florida increased nearly sixteen-fold in a 15-year period, rising from 0.4 per 1000 live births in 1999 to 6.3 per 1000 live births in 2013, with rates higher than the national average in 2013.[63] Rates have continued to rise among Medicaid beneficiaries, increasing 51% from 2012 to 2016.[64] Infants born with NAS often require treatment for withdrawal symptoms and a longer stay in the hospital, with an average cost five-fold higher compared to an infant without NAS.[65] Among Florida Medicaid beneficiaries exposed to prescription opioids during pregnancy, rates of NAS increased from 1.6 to 25.2 per 1000 live births from 2000 to 2010, while maternal prescription opioid use remained relatively stable during this time period, suggestive of a

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[57] Florida Alcohol and Drug Abuse Association and Florida Department of Children and Families, "Parallel Hepatitis C & Opioid Epidemics: A Change in Recommendations," 2020, https://cdn.ymaws.com/www.fadaa.org/resource/resmgr/files/resource_center/FADAA_TrendAlert_2020-04.pdf.

[58] HepVu, "Local Data: Florida," 2021, https://hepvu.org/local-data/florida/.

[59] Tyler S. Bartholomew et al., "Baseline Prevalence and Correlates of HIV and HCV Infection among People Who Inject Drugs Accessing a Syringe Services Program; Miami, FL," *Harm Reduction Journal* 17, no. 1 (June 10, 2020): 40, https://doi.org/10.1186/s12954-020-00385-0.

[60] Moosa Tatar et al., "Cost-Effectiveness of Universal and Targeted Hepatitis C Virus Screening in the United States," *JAMA Network Open* 3, no. 9 (September 1, 2020): e2015756, https://doi.org/10.1001/jamanetworkopen.2020.15756.

[61] Bruce R. Schackman et al., "The Lifetime Medical Cost Savings from Preventing HIV in the United States," *Medical Care* 53, no. 4 (April 2015): 293–301, https://doi.org/10.1097/MLR.0000000000000308.

[62] Mohamad Alkhouli et al., "Clinical and Economic Burden of Hospitalizations for Infective Endocarditis in the United States," *Mayo Clinic Proceedings* 95, no. 5 (May 2020): 858–66, https://doi.org/10.1016/j.mayocp.2019.08.023; Amer N. Kadri et al., "Geographic Trends, Patient Characteristics, and Outcomes of Infective Endocarditis Associated With Drug Abuse in the United States From 2002 to 2016," *Journal of the American Heart Association* 8, no. 19 (October 2019): e012969, https://doi.org/10.1161/JAHA.119.012969.

[63] Jean Y. Ko et al., "Incidence of Neonatal Abstinence Syndrome - 28 States, 1999-2013," *MMWR. Morbidity and Mortality Weekly Report* 65, no. 31 (August 12, 2016): 799–802, https://doi.org/10.15585/mmwr.mm6531a2.

[64] Megan Weiland and Ruchi Rhodes, "Neonatal Abstinence Syndrome (NAS) in Florida," https://www.hsag.com/contentassets/11ff77afc77e4148bacea64829198fee/eqronov8nasnogrphcsupdtdfnl508.pdf.

[65] Tyler NA Winkelman et al., "Incidence and Costs of Neonatal Abstinence Syndrome among Infants with Medicaid: 2004–2014," *Pediatrics* 141, no. 4 (2018).

steep rise in OUD.[66] Indeed, rates of maternal OUD at delivery in Florida rose more than thirteen-fold, increasing from 0.5 per 1000 deliveries in 1999 to 6.6 per 1000 deliveries in 2014, with rates higher than the national average in 2014.[67] The current evidence suggests that there may be long-term consequences of NAS to affected infants, though more research is needed.[68]

16. In addition to the high rate of infants born with NAS, the opioid crisis has had a disastrous and intergenerational impact on children and families in Florida. From 2002 to 2017, the number of children in the United States living with an adult that had an OUD increased by 30% and children living with an adult that used heroin increased by 200%.[69] Nationally, around half of opioid overdose deaths occurred in individuals aged 25-44 from 1999-2019, representing key parenting years, which has contributed to the increase in grandchildren living with grandparents, rising 22% from 2000 to 2011.[70] Foster care entries attributable to parental drug use in the United States has increased 147% from 2000 to 2017, with the percentage of these entries among all foster care entries increasing from 14.5% to 26.2% in the same time period.[71] Opioid-related indicators suggest that the opioid crisis is driving these trends. Nationally, county-level rates of opioid-related hospitalizations and drug overdose deaths have been found to be associated with increased foster care entry and child maltreatment.[72] In Florida, a study using data at the county level found an association between the rate of child removals and the opioid prescribing rate, specifically reporting that a one-standard-deviation increase in the opioid prescription rate within a county during the study period (2012-2015) was associated with a 32% increase in the removal rate for

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[66] Xi Wang et al., "Trends of Neonatal Abstinence Syndrome Epidemic and Maternal Risk Factors in Florida," *Pharmacotherapy* 37, no. 7 (July 2017): 806–13, https://doi.org/10.1002/phar.1947.

[67] Sarah C. Haight et al., "Opioid Use Disorder Documented at Delivery Hospitalization — United States, 1999–2014," *Morbidity and Mortality Weekly Report* 67, no. 31 (August 10, 2018): 845–49, https://doi.org/10.15585/mmwr.mm6731a1.

[68] Sara J. Arter et al., "Longitudinal Outcomes of Children Exposed to Opioids In-Utero: A Systematic Review," *Journal of Nursing Scholarship: An Official Publication of Sigma Theta Tau International Honor Society of Nursing* 53, no. 1 (January 2021): 55–64, https://doi.org/10.1111/jnu.12609; Kathryn Dee Lizcano MacMillan, "Neonatal Abstinence Syndrome: Review of Epidemiology, Care Models, and Current Understanding of Outcomes," *Clinics in Perinatology* 46, no. 4 (December 2019): 817–32, https://doi.org/10.1016/j.clp.2019.08.012.

[69] Lindsey Rose Bullinger and Coady Wing, "How Many Children Live with Adults with Opioid Use Disorder?," *Children and Youth Services Review* 104 (2019): 104381.

[70] Margot Trotter Davis et al., "Parenting a 6-Year Old Is Not What I Planned in Retirement: Trauma and Stress among Grandparents Due to the Opioid Crisis," *Journal of Gerontological Social Work* 63, no. 4 (June 2020): 295–315, https://doi.org/10.1080/01634372.2020.1752872; Kaiser Family Foundation, "Opioid Overdose Deaths by Age Group"; G. Livingston, "At Grandmother's House We Stay," Pew Research Center, 2013, https://www.pewresearch.org/social-trends/2013/09/04/at-grandmothers-house-we-stay/.

[71] Angélica Meinhofer and Yohanis Angleró-Díaz, "Trends in Foster Care Entry among Children Removed from Their Homes Because of Parental Drug Use, 2000 to 2017," *JAMA Pediatrics* 173, no. 9 (2019): 881–83.

[72] Robin Ghertner et al., "The Role of Substance Use in Child Welfare Caseloads," *Children and Youth Services Review* 90 (July 1, 2018): 83–93, https://doi.org/10.1016/j.childyouth.2018.05.015.

parental neglect.[73] Parental drug abuse is the primary reason for child removals in Florida and this rate has steadily increased over the last 15 years, with half of removals in 2021 for this reason, a 57% increase compared with the rate in 2003.[74] It is estimated that 138,000 children in the state were affected by the opioid crisis in 2017, with a rate that is 11% higher than the national average.[75] Societal costs due to increased medical expenses, child welfare, and special education along with the long-term impact of adverse childhood experiences are estimated to be $11.3 billion for the 138,000 children already affected, or $82,000 lifetime cost per child, with costs increasing to $25 billion by 2030 for newly affected children.[76]

17. There is considerable intersection of the opioid crisis and the criminal justice system as 52% of those with prescription drug use disorder and 77% of heroin users (around 80% of whom began on prescription opioids) have a lifetime history of criminal justice involvement.[77] More than half of state prisoners and almost two-thirds of sentenced jailed inmates have a drug use disorder (of which OUD is one type), compared with about 5% of the general population.[78] Evidence-based treatment is rarely provided for those that are incarcerated with OUD, making them especially vulnerable to an opioid overdose upon release.[79] In addition to the economic cost to the state, recently incarcerated individuals transitioning to society will face long-term barriers to employment, housing, and civic opportunities.[80]

18. Employers and the U.S. workforce have experienced detrimental effects from the opioid crisis. Nationally, opioid prescribing is associated with reductions in labor force

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[73] Troy Quast, Eric A. Storch, and Svetlana Yampolskaya, "Opioid Prescription Rates and Child Removals: Evidence from Florida," *Health Affairs* 37, no. 1 (2018): 134–39.

[74] Florida Department of Children and Families, "Florida's Child Welfare Statistics," 2021, https://www.myflfamilies.com/programs/childwelfare/dashboard/index.shtml.

[75] Suzanne C. Brundage, Adam Fifield, and Lee Partridge, "The Ripple Effect: National and State Estimates of the US Opioid Epidemic's Impact on Children" (United Hospital Fund, 2020), https://uhfnyc.org/media/filer_public/6e/80/6e80760f-d579-46a3-998d-1aa816ab06f6/uhf_ripple_effect_national_and_state_estimates_chartbook.pdf.

[76] Brundage, Fifield, and Partridge.

[77] Tyler N. A. Winkelman, Virginia W. Chang, and Ingrid A. Binswanger, "Health, Polysubstance Use, and Criminal Justice Involvement Among Adults With Varying Levels of Opioid Use," *JAMA Network Open* 1, no. 3 (July 6, 2018): e180558, https://doi.org/10.1001/jamanetworkopen.2018.0558.

[78] Jennifer Bronson et al., "Drug Use, Dependence, and Abuse among State Prisoners and Jail Inmates, 2007–2009," *Washington, DC: United States Department of Justice, Office of Juvenile Justice and Delinquency Prevention*, 2017, https://bjs.ojp.gov/content/pub/pdf/dudaspji0709.pdf.

[79] Shabbar I. Ranapurwala et al., "Opioid Overdose Mortality Among Former North Carolina Inmates: 2000–2015," *American Journal of Public Health* 108, no. 9 (September 2018): 1207–13, https://doi.org/10.2105/AJPH.2018.304514.

[80] Olivia K. Sugarman et al., "Interventions for Incarcerated Adults with Opioid Use Disorder in the United States: A Systematic Review with a Focus on Social Determinants of Health," *PLOS ONE* 15, no. 1 (January 21, 2020): e0227968, https://doi.org/10.1371/journal.pone.0227968.

participation and increases in the unemployment rate.[81] This impact on the workforce is related to adverse outcomes. At the county-level, a one percentage point increase in the unemployment rate was associated with a 3.6% increase in the opioid-related death rate and a 7% increase in the opioid-related emergency department utilization rate.[82] For prime age men not in the labor market, it is estimated that 20% are regularly using prescription opioids.[83] Employers in the United States are seeing effects of the opioid crisis in the workplace, as a survey from the National Safety Council revealed that 75% of employers reported that their workplaces have been directly impacted by opioids.[84] Lost productivity typically represents the largest share of financial burden in studies on the economic impact of the opioid crisis.[85] One study valued lost productivity in Florida from OUD and premature fatal overdoses at $6.8 billion in 2017.[86] Beyond lost productivity, a study calculated that losses in tax revenue lost from opioid misuse cost state governments $11.8 billion and federal governments $26 billion from 2000 to 2016.[87]

C. The increased prevalence of opioid addiction and other opioid-related harms were primarily caused by overexposing the United States population, including people in the State of Florida, to prescription opioids.

1. The increase in OUD and opioid deaths was primarily caused by a sharp increase in opioid consumption. The relationship between opioid supply, death and addiction was starkly

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[81] Matthew C. Harris et al., "Prescription Opioids and Labor Market Pains The Effect of Schedule II Opioids on Labor Force Participation and Unemployment," *Journal of Human Resources* 55, no. 4 (2020): 1319–64; Alan B. Krueger, "Where Have All the Workers Gone? An Inquiry into the Decline of the US Labor Force Participation Rate," *Brookings Papers on Economic Activity* 2017, no. 2 (2017): 1.

[82] Alex Hollingsworth, Christopher J. Ruhm, and Kosali Simon, "Macroeconomic Conditions and Opioid Abuse," *Journal of Health Economics* 56 (2017): 222–33.

[83] Krueger, "Where Have All the Workers Gone? An Inquiry into the Decline of the US Labor Force Participation Rate."

[84] National Safety Council, "Poll: 75% of Employers Say Their Workplace Impacted by Opioid Use," 2019, https://www.nsc.org/in-the-newsroom/poll-75-of-employers-say-their-workplace-impacted-by-opioid-use.

[85] Curtis S. Florence et al., "The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013," *Medical Care* 54, no. 10 (October 2016): 901–6, https://doi.org/10.1097/MLR.0000000000000625; Ruixuan Jiang et al., "The Societal Cost of Heroin Use Disorder in the United States," *PloS One* 12, no. 5 (2017): e0177323, https://doi.org/10.1371/journal.pone.0177323.

[86] Luo, Li, and Florence, "State-Level Economic Costs of Opioid Use Disorder and Fatal Opioid Overdose - United States, 2017."

[87] Joel E. Segel et al., "Revenue Losses to State and Federal Government from Opioid-Related Employment Reductions," *Medical Care* 57, no. 7 (2019): 494–97.

illustrated in Figure 6.[88]

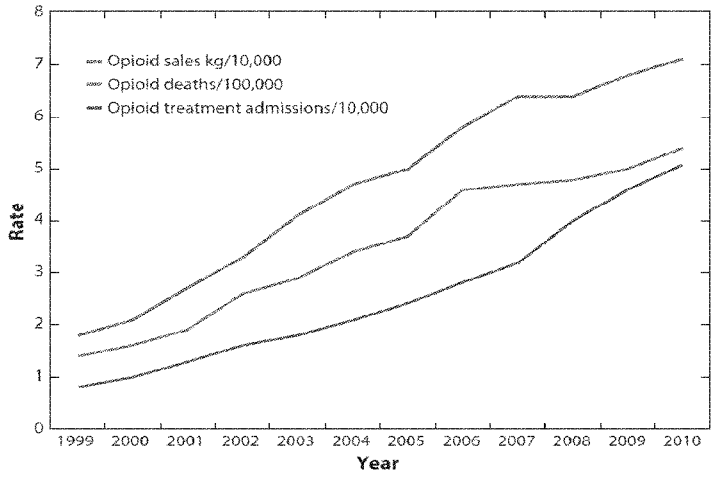

Figure 1

Rates of OPR sales, OPR-related unintentional overdose deaths, and OPR addiction treatment admissions, 1999–2010. Abbreviation: OPR, opioid pain reliever. Source: 10.

2. In the 1990s, opioid consumption in the United States and the State of Florida increased rapidly. United States opioid consumption increased from less than 50 billion MME in the early 1990s to a peak of nearly 250 billion MME in 2011.[89] Around 2012, opioid consumption in the United States started to decline but remains far higher than it was in the early 1990s and, on a per capita basis, far higher than other countries (Figure 7).[90] About 4% of the world's population lives in the United States yet our percentage of global opioid consumption for the following opioid molecules is hydrocodone 99%, oxycodone 63%, morphine 40%, methadone 40%, fentanyl 21%, and codeine 9%.[91] Even when compared to countries with the highest opioid consumption, the United States remains an outlier (Figure 8).[92]

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[88] Centers for Disease Control and Prevention. (2011). Vital signs: overdoses of prescription opioid pain relievers—United States, 1999–2008. *MMWR*, (60), 1487-92; Centers for Disease Control and Prevention. (2013). Vital signs: overdoses of prescription opioid pain relievers—United States, 1999–2010. *MMWR*, (62), 537-42; Centers for Disease Control and Prevention. (2014). QuickStats: rates of drug poisoning deaths involving heroin,* by selected age and racial/ethnic groups—United States, 2002 and 2011. *MMWR*, (63), 595; Opioid Distributors' internal documents cite and acknowledge this correlation. *See e.g.* ABDCMDL08307607; MCK-AGMS-006-0000886; MCKMDL00557252 at 261; CAH_MDL2804_01493700.

[89] IQVIA Institute for Human Data Science. Prescription Opioid Trends in the United States: Measuring and Understanding Progress in the Opioid Crisis. December 2020.

[90] Graph created with oxycodone consumption data from the International Narcotics Control Board.

[91] International Narcotics Control Board. *Narcotic Drugs Estimated World Requirements for 2020 Statistics for 2018*. UNITED NATIONS PUBLICATION ISBN: 978-92-1-148334-5 e-ISBN: 978-92-1-047695-9 ISSN: 1013-3453 https://incb.org/incb/en/narcotic-drugs/Technical_Reports/narcotic_drugs_reports.html.

[92] Degenhardt L, et al. Global patterns of opioid use and dependence: harms to populations, interventions, and future action. Lancet. 2019 Oct 26;394(10208):1560-1579. doi: 10.1016/S0140-6736(19)32229-9. Epub 2019 Oct 23. PMID: 31657732; PMCID: PMC7068135.

Figure 7: United States Oxycodone Consumption

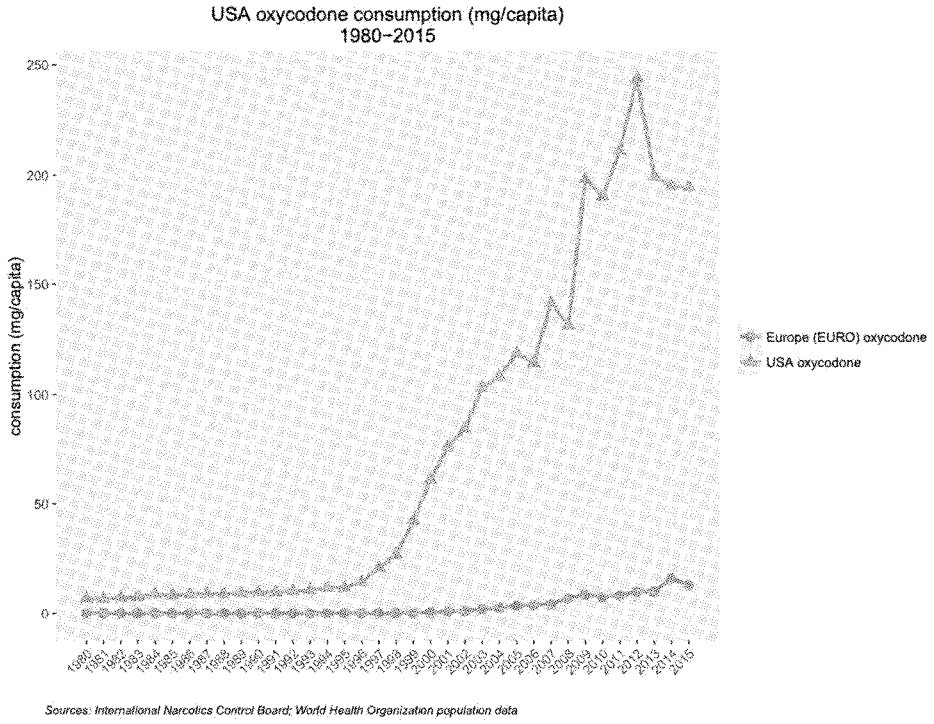
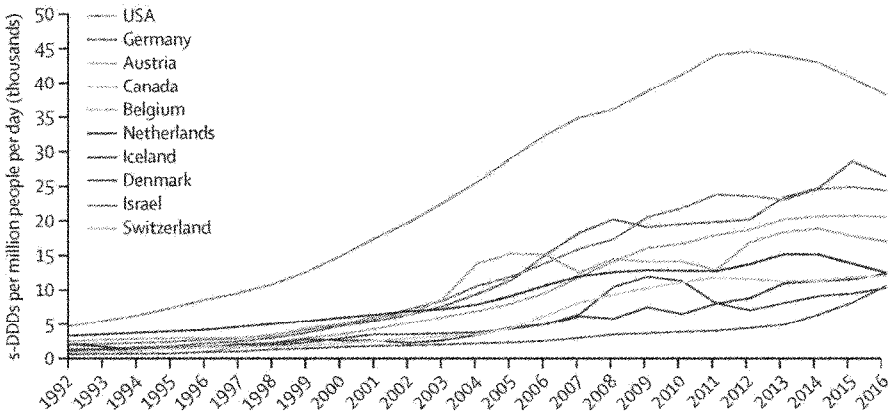


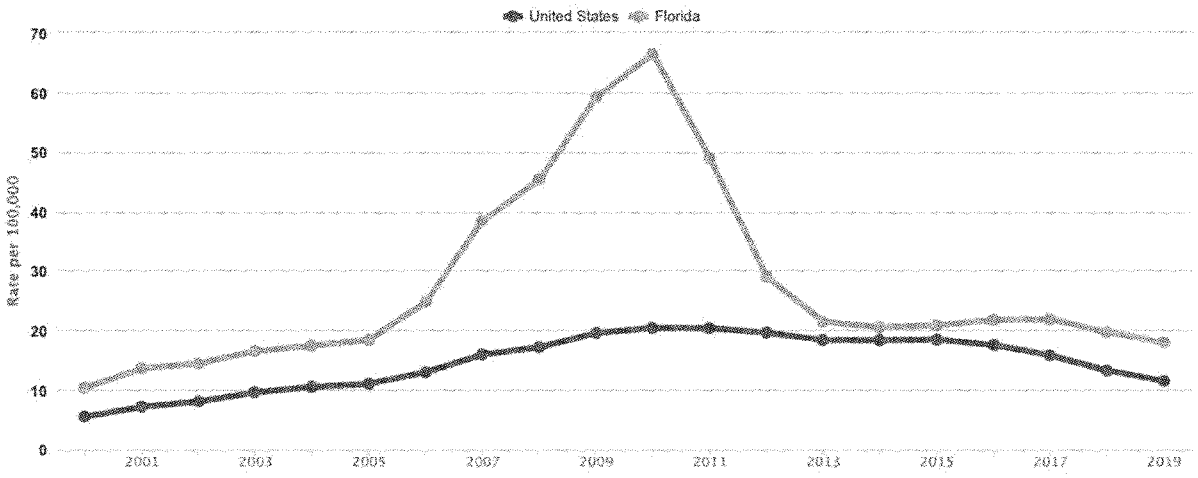
Figure 8: Opioid Consumption in United States vs. Other Developed Countries



3. While oxycodone consumption in the United States far exceeds other developed countries, oxycodone supplied to the State of Florida far exceeded the extremely high U.S. national average. From 2000 to 2010, oxycodone supply to Florida increased more than 500%, from 10.4 kg per 100,000 to 66.4 kg per 100,000 (Figure 9).[93]

[93] SHADAC analysis of U.S. Drug Enforcement Agency's Automated Reports and Consolidated Ordering System (ARCOS) Retail Drug Summary Reports. State Health Compare, SHADAC, University of Minnesota, statehealthcompare.shadac.org, Accessed May 19, 2021.

Figure 9: Oxycodone Sales in Kilograms per 100,000. Florida vs U.S.



4. The oversupply of opioids in Florida resulted in a sharp increase in opioid-related morbidity and mortality described above. The increase in opioid sales in Florida until their peak in 2010 led to parallel increases in opioid-related overdose deaths and opioid-related hospitalizations as seen in Figure 10 below. Opioid-related overdose deaths plateaued in 2011 then slightly decreased in 2012 as sustained reductions in opioid prescribing likely decreased the incidence of prescription opioid overdose deaths. However, deaths in the cohort of opioid-addicted Floridians who mainly used black market opioids increased exponentially after 2014, when illicitly synthesized fentanyl became increasingly more common in the black-market opioid supply. I believe that a large majority of these deaths occurred in individuals who initially developed OUD from prescription opioids.

Figure 10: Opioid Sales, Opioid-Related Overdose Death Rate, and Opioid-Related Hospitalizations in Florida

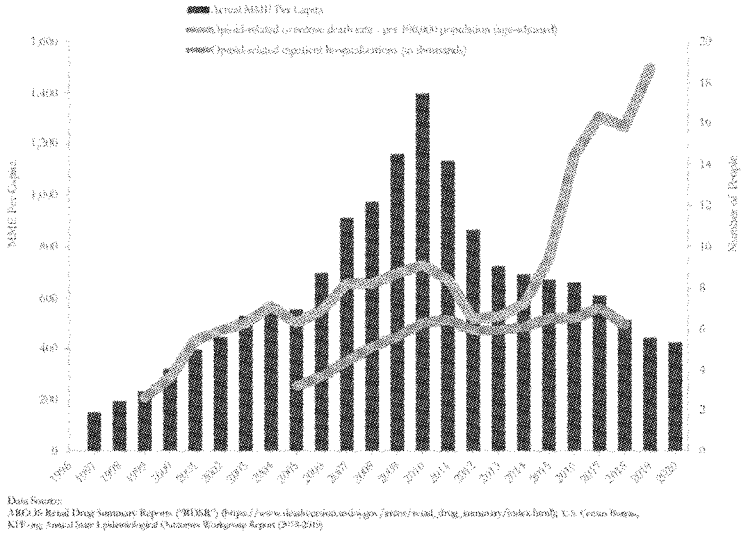


*Figure created by Securities Litigation and Consulting Group, Inc.

D. Overexposure of the population to prescription opioids was a consequence of the Defendants' multi-faceted campaign to increase the sale of opioid analgesics in the United States, including the State of Florida.

1. As explained in more detail in the report of [redacted], in the late 19th Century and early 20th Century, the United States experienced an epidemic of opiate addiction that, like our current opioid crisis, was fueled by excessive prescribing and consumption of opioid analgesics.

2. As explained in the report of [redacted] from America's first opiate crisis the medical community learned an important lesson. Opioids must be prescribed cautiously. Indeed, by 1919, narcotic overprescribing was the hallmark of older, less competent physicians.[94] The younger, better-trained practitioners who replaced them were more circumspect about administering and prescribing opioids.

3. In the 1980s and 1990s, however, a multi-faceted industry-sponsored campaign against conservatism in opioid prescribing was launched. In a 2015 review article about the opioid crisis, I explained the sharp rise in opioid consumption:[95]

> In 1986 a paper describing the treatment of 38 chronic pain patients concluded that OPRs could be prescribed safely on a long-term basis.
>
> Despite its low-quality evidence, the paper was widely cited to support expanded use of opioids for chronic non-cancer pain. Opioid use increased gradually in the 1980s. In 1996, the rate of opioid use began accelerating rapidly. This acceleration was fueled in large part by the introduction in 1995 of OxyContin, an extended-release formulation of oxycodone manufactured by Purdue Pharma.
>
> Between 1996 and 2002, Purdue Pharma funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants and launched a multifaceted campaign to encourage long-term use of OPRs for chronic non-cancer pain. As part of this campaign, Purdue provided financial support to the American Pain Society, the American Academy of Pain Medicine, the Federation of State Medical Boards, the Joint Commission, pain patient groups, and other organizations. In turn, these groups all advocated for more aggressive identification and treatment of pain, especially use of OPRs.
>
> For example, in 1995, the president of the American Pain Society introduced a campaign entitled "Pain is the Fifth Vital Sign" at the society's annual meeting. This campaign encouraged health care professionals to assess pain with the "same zeal" as they do with vital signs and urged more

[94] Blair T. 1919. Is opium the "sheet-anchor of treatment"? Am. J. Clin. Med. 26:829–34.

[95] Kolodny, A. et al. (2015). The prescription opioid and heroin crisis: a public health approach to an epidemic of addiction. *Annu Rev Public Health*, 36, 559, 562-563. https://doi.org/10.1146/annurev-publhealth-031914-122957.

aggressive use of opioids for chronic non-cancer pain. Shortly thereafter, the Veterans' Affairs health system, as well as the Joint Commission, which accredits hospitals and other health care organizations, embraced the Pain is the Fifth Vital Sign campaign to increase the identification and treatment of pain, especially with OPRs. Similarly, the American Pain Society and the American Academy of Pain Medicine issued a consensus statement endorsing opioid use for chronic non-cancer pain. Although the statement cautioned against imprudent prescribing, this warning may have been overshadowed by assertions that the risk of addiction and tolerance was low, risk of opioid-induced respiratory depression was short-lived, and concerns about drug diversion and abuse should not constrain prescribing.

Prior to the introduction of OxyContin, many physicians were reluctant to prescribe OPRs on a long-term basis for common chronic conditions because of their concerns about addiction, tolerance, and physiological dependence. To overcome what they claimed to be "opiophobia," physician-spokespersons for opioid manufacturers published papers and gave lectures in which they claimed that the medical community had been confusing addiction with "physical dependence." They described addiction as rare and completely distinct from so-called "physical dependence," which was said to be "clinically unimportant". They cited studies with serious methodological flaws to highlight the claim that the risk of addiction was less than 1%.

In addition to minimizing risks of OPRs, the campaign advanced by opioid manufacturers and pain organizations exaggerated the benefits of long-term OPR use. In fact, high-quality, long-term clinical trials demonstrating the safety and efficacy of OPRs for chronic non-cancer pain have never been conducted. Surveys of patients with chronic non-cancer pain receiving long-term OPRs suggest that most patients continued to experience significant chronic pain and dysfunction. The CDC and some professional societies now warn clinicians to avoid prescribing OPRs for common chronic conditions.

Although increased opioid consumption over the past two decades has been driven largely by greater ambulatory use for chronic non-cancer pain, opioid use for acute pain among hospitalized patients has also increased sharply. A recent study found that physicians prescribed opioids in more than 50% of 1.14 million nonsurgical hospital admissions from 2009 to 2010, often in high doses. The Joint Commission's adoption of the Pain is the Fifth Vital Sign campaign and federally mandated patient satisfaction surveys asking patients to rate how often hospital staff did "everything they could to help you with your pain" are noteworthy, given the association with increased hospital use of OPRs (internal footnotes and citations omitted).

4. I experienced the campaign to increase opioid prescribing first-hand in my medical training. As I explained in a 2010 interview, "[i]f patients have legitimate pain, we were

taught that they don't become addicted to these medicines, and that instead of allowing people to suffer needlessly, we should be much more liberal in our prescribing of opioids."[96]

E. Opioid manufacturer Defendants worked with opioid industry partners to change the culture of opioid prescribing in the United States by participating in a deceptive, multi-faceted, unbranded campaign, as well as branded marketing, that downplayed the serious risks of opioids and exaggerated the benefits of long-term use.

1. I understand that the expert report of Matthew Perri, will address in detail how the opioid Defendants, led by the manufacturers, dramatically expanded the overall market for opioids. The multi-faceted misinformation campaign they co-sponsored with other opioid manufacturers involved the creation of an artificial medical "consensus" through paid and co-opted "experts" and organizations to give the false impression that high doses of opioids are safe and effective for long-term use. My expert opinion will focus on misleading statements at the heart of that campaign, and why they were misleading.

2. To increase opioid consumption in the United States, the opioid manufacturer Defendants, including Endo, Johnson & Johnson, Allergan, Teva, and Actavis, working with industry partners including Walgreens and CVS, falsely redefined important reasons to be cautious with opioids, like risk of addiction, as "barriers" to appropriate treatment of pain. For example, "educational" materials for prescribers, pharmacists, and patients, underwritten with payments from the Defendants, characterized "fear of addiction" to opioids as an inappropriate "barrier" to treatment of pain.[97]

3. Johnson & Johnson (J&J) benefitted uniquely from the unbranded campaign to increase opioid sales. J&J was uniquely positioned to benefit from the unbranded campaign to increase opioid prescribing because it sold its own opioids and supplied other opioid manufacturers with opioids and opium.[98] From about 1980 until 2016, J&J owned a subsidiary called Noramco which refined opium, also called "raw narcotic material" for the development of pharmaceutical opioids and it owned a subsidiary in Tasmania called Tasmanian Alkaloids which produced opium.[99] Tasmanian Alkaloids paid contractors to

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[96] Interview with Kolodny, A. (October 30, 2011), https://www.youtube.com/watch?v=DgyuBWN9D4w.

[97] JAN-MS-00326044, JAN-MS-01192118; ENDO_OPIOID_DEPMAT-000034757 (Barriers to Effective Pain Management, describing "fear of addiction" as a "patient barrier[s] to pain relief" on page ENDO_OPIOID_DEPMAT-000034768); Teva_MDL_A_00002020, at 00002065 (Cephalon, Fentora Learning System: Introduction to Pain); Allergan_MDL_00063928 (Actavis Internal and Training Materials, KADIAN Learning System); WAGMDL00766955 (Endo-sponsored Pharmacy Education calling "fears and prejudices" and "concerns about addictive behaviors," "opiophobia").

[98] JAN-OK-00149992.

[99] *Id.* Whoriskey P. How Johnson & Johnson companies used a 'super poppy' to make narcotics for America's most abused opioid pills. Washington Post. March 26, 2020. Available at https://www.washingtonpost.com/graphics/2020/business/opioid-crisis-johnson-and-johnson-tasmania-poppy/.

grow and harvest genetically modified opium poppies, then extracted and processed thebaine-rich opium from the poppies for export to the United States.

4. From the opium that J&J produced in Tasmania and imported into the United States, J&J synthesized natural, semi-synthetic and synthetic opioids that it sold to its opioid industry partners, including Purdue, Teva, Endo, and Mallinckrodt for the production of branded products, including OxyContin, Xartemis, Exalgo, Hysingla, Targniq, Opana, and Butrans.[100]

5. In 2000, J&J and Purdue discussed coordinating an opioid-related "co-promotion arrangement" including a goal to jointly grow the market, terming their collaboration "a powerful combination."[101] They called the exploration of a joint pain franchise "Project Pearl."[102] As the public health crisis caused by overprescribing of OxyContin began to gain national attention, J&J instructed its employees not to use OxyContin's bad press to its competitive advantage as it would hurt the overall cause.[103]

6. To increase sales of opioids, the opioid manufacturer Defendants, along with distributors and pharmacies, disseminated deceptive messages that downplayed the risks of long-term opioid use and exaggerated the benefits. These messages were promoted directly, in presentations, websites and materials created and disseminated to health care providers, front-line pharmacists, and the public, and they were promoted indirectly by way of front groups, key opinion leaders, and sponsored research and medical and pharmacy education. These mechanisms for promoting the messages are discussed in the expert report of Matthew Perri. All Defendants in this case engaged in these types of false and deceptive messages, as illustrated by the examples below. Deceptive and false messages included the following:

    a. ***Long-term, daily use of opioids effectively improves function and quality of life in patients with chronic pain***.[104]

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[100] JAN-OK-00149992.

[101] JAN-MS-01052128; JAN-MS-00456087 (Pain and Inflammation Franchise Plan, touting "co-promotion" as a "Top-line Recommendation" of an "external opportunit[y]" that J&J should "invest in" "to generate revenue for 2005."; JAN-MS-01006283; JAN-MS-00246903; JAN-MS-01052181; JAN-MS-01051754; JAN-MS-01052165; JAN-MS-00456093 (a January 3, 2001 PPT about co-promotional opportunities with Purdue states: "Reviewing how we can work together to help each company achieve maximum sales potential of existing and future products").

[102] JAN-MS-04290083, at 04290087.

[103] JAN-MS-00307337 ("It is not our policy to advance language that would attack a competitor's product," and noting that abuse discussion can damage the whole market).

[104] JAN-MS-00476773 (Finding Relief: Pain Management for Older Adults); JAN-MS-00747492; National Pain Education Council, *Appropriate Opioid Pharmacotherapy for Chronic Pain Management: A Multimedia CME Program* (June 17, 2002); ENDO-OPIOID_MDL-02765931 (CME called Opioid Prescribing); ENDO-OPIOID_MDL-02212377 (American Pain Foundation, Roundtable Materials, Prescribing Patterns and Perceptions); Allergan_MDL_00063928, 00064017; TEVA_FL_00013521 (Pain Matters).

As discussed above, long-term opioid use has not been proven effective. Evidence suggests that opioids are ineffective for long-term use and can even worsen pain by causing hyperalgesia. Evidence also suggests that many patients on long-term opioids experience significant pain and dysfunction. The false claim that opioids improve function in chronic pain patients led the FDA to issue warning letters to opioid manufacturer Defendants.[105] I understand that the expert report of Daniel Clauw discusses this set of misrepresentations in greater detail.

b. ***Long-term daily use of opioids rarely leads to addiction.***[106]

As discussed above, opioids are highly addictive, and OUD is common in patients receiving long-term opioids for chronic pain.

c. ***Fear of addiction is an inappropriate barrier to treatment of chronic pain and results in undertreatment of pain.***[107]

As discussed above, addiction is not rare when opioids are used long-term. It is appropriate for clinicians to be fearful of causing iatrogenic opioid addiction.

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[105] JAN-MS-00747492; ENDO-OPIOID_MDL-02765931; ENDO_FLAG-00463408.

[106] JAN-MS-00068759; JAN-MS-01192118; JAN-MS-00303825; JAN-MS-00476773; National Pain Education Council, *Appropriate Opioid Pharmacotherapy for Chronic Pain Management: A Multimedia CME Program* (June 17, 2002); ENDO_FLAG-00463408; Allergan_MDL_00063928, at 00064003; Teva_MDL_A_00002020, at 00002061; TEVA_MDL_A_00765208; APF, A Reporter's Guide: Covering Pain and Its Management, available at https://www.scribd.com/document/52592265/Pain-from-the-Consumer-s-Perspective-A-Reporter-s-Guide-Will-Rowe (promotes the false concept of pseudoaddiction and claims that "the potential for addiction is low for the vast majority of patients using opioids for the long-term management of chronic pain"); END00174281, at 00174284 (Opana ER website, "[m]ost doctors who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted"); ENDO-OPIOID_MDL-05968444, at 05968448 (www.Painaction.com, Endo misleadingly represented that "[m]ost chronic pain patients do not become addicted to the opioid medications that are prescribed for them"); ENDO-OPIOID_MDL-00381676; ENDO-CHI_LIT-00537916; ENDO-OPIOID_MDL-00367697.

[107] McCarberg B, et al. OPTIMIZING CHRONIC PAIN MANAGEMENT: INTEGRATING PHARMACOKINETICS AND PHARMACODYNAMICS. Clinical Courier. Vol.27, No.3, June 2009 ISSN 0264-6684, available at https://www.cecentral.com/assets/2100/pen09166-02_content_FINALwebV2.pdf; McCarberg BH, Nicholson BD, Todd KH, Palmer T, Penles L. The impact of pain on quality of life and the unmet needs of pain management: results from pain sufferers and physicians participating in an Internet survey, Am J Ther. 2008;15(4):312-320; McCarberg B. Tramadol extended-release in the management of chronic pain. Ther. Clin Risk Manag. 2007;3(3):401-410.; Fishman SM. Healthcare professional's perception vs patient's experience of pain.; JAN-MS-00326044; JAN-MS-01192118; National Pain Education Council, *Appropriate Opioid Pharmacotherapy for Chronic Pain Management: A Multimedia CME Program* (June 17, 2002); ENDO_FLAG-00463408; ENDO_OPIOID_DEPMAT-000034087, at Endo_OPIOID_DEPMAT-000034149 (characterizing fears as opioiphobia); Allergan_MDL_00063928, at 00063955; Teva_MDL_A_00002020, at 00002065; APF, A Reporter's Guide: Covering Pain and Its Management, available at https://www.scribd.com/document/52592265/Pain-from-the-Consumer-s-Perspective-A-Reporter-s-Guide-Will-Rowe; CVS-MDLT3-000001481, at 1529; WAGMDL00766955 (Endo-sponsored Pharmacy Education calling "fears and prejudices" and "concerns about addictive behaviors," "opiophobia").

d. ***There is no ceiling dose or upper limit on opioid dosages.***[108]

As discussed above, as opioid doses increase, so do opioid-related adverse effects, including addiction and overdose.

e. ***Physical dependence is benign and distinct from addiction.***[109]

As discussed above, after prolonged use of opioids, physiological dependence can result in severe withdrawal symptoms when discontinuation is attempted, which is a key reason why opioids are highly addictive. The negative symptoms of withdrawal, including pain hypersensitivity, cause patients to continue using opioids despite harmful effects.

f. ***Patients who are physiologically dependent on opioids can be easily tapered off.***[110]

As discussed above, the truth is that after prolonged use of opioids patients often experience severe and disabling withdrawal symptoms. Even after the acute withdrawal symptoms resolve, patients can experience several months of insomnia, fatigue, depression and cravings.

g. ***Patients who appear to be suffering from opioid addiction may have "pseudoaddiction" defined as drug seeking behavior caused by "undertreatment of pain." These patients should have their opioid dose increased."***[111]

Patients who appear to be addicted to opioids because they are running out of medication too early or are asking for higher doses should be urgently and carefully assessed for opioid addiction. Clinicians who increase opioid doses because they assume this behavior is caused by under treated pain are likely to cause serious harm to their patients, including death.

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[108] JAN00124243; JAN-MS-00023677; National Pain Education Council, *Appropriate Opioid Pharmacotherapy for Chronic Pain Management: A Multimedia CME Program* (June 17, 2002); ENDO_FLAG-00463408; Teva_MDL_A_02868041; ENDO_OPIOID_DEPMAT-000019591; ENDO_OPIOID_DEPMAT-000006093 (Endo brochure, *Understanding Your Pain: Taking Oral Opioid Analgesics*).

[109] National Pain Education Council, *Appropriate Opioid Pharmacotherapy for Chronic Pain Management: A Multimedia CME Program* (June 17, 2002); ENDO_FLAG-00463408; Teva_MDL_A_00002020; Allergan_MDL_00063928, at 00063955; ENDO_OPIOID_DEPMAT-000006137 (Endo pamphlet, *Information on Taking a Long-Acting Opioid: What Does It Mean to Me?*); WAGMDL00766955.

[110] JAN-MS-00653426; KOLODNY_SUB_000005898; ENDO_FLAG-00463408; ENDO-CHI_LIT-00053284; Allergan_MDL_00063928, at 00064002; Teva_MDL_A_00002020; CVS-MDLT3-000001481, at CVS-MDLT3-000001490.

[111] JAN-MS-00310473, JAN-MS-00408610, JAN-MS-04269270; KOLODNY_SUB_000005898; ENDO_FLAG-00463408; Allergan_MDL_00063928, at 00063934; Teva_MDL_A_00003279, at 00003282; ENDO_OPIOID_DEPMAT-000040854 (*Responsible Opioid Prescribing*, Fishman, M.D., S.); END00006930 (*Avoiding Opioid Abuse While Managing Pain*, Webster, M.D., L et al.); CVS-MDLT3-000001481 at 1513 (CVS, Opioid Prescriber Toolkit, discussing pseudoaddiction, tolerance); WAGMDL00766955.

h. ***Doctors can prevent addiction in patients on opioids by using "risk assessment tools" and by close monitoring.***[112]

The truth is that effective so-called "screening" "tools" that can predict in advance who will or will not become addicted to opioids do not exist.[113] And so-called "close monitoring strategies" cannot prevent patients from becoming addicted.

i. ***The adverse effects of over-the-counter analgesics (i.e. Advil & Tylenol) are more dangerous than opioids.***[114]

The truth is that over-the-counter analgesics are generally safer than opioid analgesics. Opioids are responsible for more deaths annually than any other class of drug. ENDO_FLAG-00463408.

j. ***Treatment of acute pain with opioids can prevent chronic pain.***[115]

Evidence that treating acute pain with opioids can prevent chronic pain does not exist. To the contrary, evidence suggests that aggressive use of opioids for acute pain increases the likelihood of long-term opioid use for chronic pain.[116]

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[112] McCarberg B, et al. OPTIMIZING CHRONIC PAIN MANAGEMENT: INTEGRATING PHARMACOKINETICS AND PHARMACODYNAMICS. Clinical Courier. Vol.27, No.3, June 2009 ISSN 0264-6684, available at https://www.cecentral.com/assets/2100/pen09166-02_content_FINALwebV2.pdf.; JAN-MS-00016322; JAN-MS-00016265 (prescriberesponsibly.com); ENDO_FLAG-00463408; Teva_MDL_A_00005098; Teva_FL_00001413; Allergan_MDL_01466431; Allergan_MDL_00001525, at 1541; ENDO_OPIOID_DEPMAT-000034308; ENDO_OPIOID_DEPMAT-000034308, at ENDO_OPIOID_DEPMAT-000034330; EPI001474323; CVS-MDLT3-000001481, at 000001489 (CVS Toolkit discussing APS-AAPM Guidelines) and at MDLT3-000001501 (promoting ORT and other "risk tools").

[113] Chou R, Hartung D, Turner J, Blazina I, Chan B, Levander X, McDonagh M, Selph S, Fu R, Pappas M. Opioid Treatments for Chronic Pain. Comparative Effectiveness Review No. 229. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2015-00009-I.) AHRQ Publication No. 20-EHC011. Rockville, MD: Agency for Healthcare Research and Quality; April 2020. DOI: 10.23970/AHRQEPCCER229. ENDO_FLAG-00463408.

[114] McCarberg B, et al. OPTIMIZING CHRONIC PAIN MANAGEMENT: INTEGRATING PHARMACOKINETICS AND PHARMACODYNAMICS. Clinical Courier. Vol.27, No.3, June 2009 ISSN 0264-6684, available at https://www.cecentral.com/assets/2100/pen09166-02_content_FINALwebV2.pdf; JAN-MS-03010750, JAN-MS-01192118; https://www.medpagetoday.com/Geriatrics/PainManagement/32971; JAN-MS-02522610.; Allergan_MDL_00063928; Teva_MDL_A_02866420; ENDO-OPIOID_MDL-00459650 (Endo supported the case study *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* to prescribers. It described a patient who was using NSAIDs for pain management as having "a massive upper gastrointestinal bleed believed to be related to his protracted use of NSAIDs," "over eight years"); CVS-MDLT3-000001481, at 1520-1521.

[115] McCarberg B, et al. OPTIMIZING CHRONIC PAIN MANAGEMENT: INTEGRATING PHARMACOKINETICS AND PHARMACODYNAMICS. Clinical Courier. Vol.27, No.3, June 2009 ISSN 0264-6684, available at https://www.cecentral.com/assets/2100/pen09166-02_content_FINALwebV2.pdf.

[116] Shah A, Hayes CJ, Martin BC. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use - United States, 2006-2015. MMWR Morb Mortal Wkly Rep. 2017 Mar 17;66(10):265-269. doi: 10.15585/mmwr.mm6610a1. PMID: 28301454; PMCID: PMC5657867.; Allergan_MDL_00063928, at 00063945; Teva_FL_00013521; Teva_FL_00017230.

k. ***Patients already taking extended-release opioids should be prescribed additional opioids for treatment of so-called "breakthrough pain."***[117]

Use of the term "breakthrough pain" to describe pain experienced by a patient already taking opioids was popularized by Dr. Rusell Portenoy, a KOL with extensive financial ties to opioid manufacturers.[118] In reality, long-term use of opioids can result in increased pain hypersensitivity and should not be managed by routinely prescribing additional opioids.

l. ***Veterans and the Elderly are appropriate targets for opioids.***[119]

In reality older adults and veterans are especially vulnerable to the risks of opioids. Unfortunately, efforts to target these groups were effective. Opioid prescribing for older adults has exceeded all other age groups and opioid use within the Veterans Affairs Administration increased at an especially alarming rate.[120] Not surprisingly, veterans and seniors have been more likely that other groups to be hospitalized for an opioid overdose or experience a fatal opioid overdose.[121]

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[116] Allergan_MDL_00063928, at 00064088; Teva_MDL_A_06666094; TEVA_FL_00013555.

[117] ENDO_OPIOID_DEPMAT-000006093 (Endo brochure, *Understanding Your Pain: Taking Oral Opioid Analgesics*); WAGMDL00766955; Breakthrough pain is also discussed at TEVA_MDL_A_00323250; TEVA_MDL_A_00339098; TEVA_MDL_A_00501883, at 00501834.

[118] Portenoy RK, Bennett DS, Rauck R, Simon S, Taylor D, Brennan M, Shoemaker S. Prevalence and characteristics of breakthrough pain in opioid-treated patients with chronic noncancer pain. J Pain. 2006 Aug;7(8):583-91. doi: 10.1016/j.jpain.2006.02.003. PMID: 16885015.; Portenoy RK, Hagen NA. Breakthrough pain: definition, prevalence and characteristics. Pain. 1990 Jun;41(3):273-281. doi: 10.1016/0304-3959(90)90004-W. PMID: 1697056.; Catan T, Perez E. A pain-drug champion has second thoughts. 2012 Available at https://www.wsj.com/articles/SB10001424127887324478304578173342657044604#printMode

[119] JAN-MS-00476773 *(Finding Relief: Pain Management for Older Adults,* which was sponsored by Janssen, with AGS and AAPM as "partners"); TEVA_MDL_A_01090496 (*Treatment Options: A Guide for People Living with Pain*, which was sponsored by Purdue, Cephalon, and others and published by APF); ENDO-OPIOID_MDL-00583052 (2009 *Guidelines for the Pharmacological Management of Persistent Pain in Older Persons*, which misrepresented that the risk of addiction was "exceedingly low in older patients with no current or past history of substance abuse); TEVA_MDL_A_06610743 (McGinnis, D., *Exit Wounds* (book)); CVS-MDLT3-000001481, at 1493..

[120] SUBCOMMITTEE ON HEALTH, COMMITTEE ON VETERANS' AFFAIRS U.S. HOUSE OF REPRESENTATIVES, 113th Congress. BETWEEN PERIL AND PROMISE: FACING THE DANGERS OF VA'S SKYROCKETING USE OF PRESCRIPTION PAINKILLERS TO TREAT VETERANS, OCTOBER 10, 2013; Han B, Compton WM, Blanco C, Crane E, Lee J, Jones CM. Prescription Opioid Use, Misuse, and Use Disorders in U.S. Adults: 2015 National Survey on Drug Use and Health. Ann Intern Med. 2017 Sep 5;167(5):293-301. doi: 10.7326/M17-0865. Epub 2017 Aug 1. PMID: 28761945

[121] West NA, et al. Trends in abuse and misuse of prescription opioids among older adults. Drug Alcohol Depend. 2015 Apr 1;149:117-21. doi: 10.1016/j.drugalcdep.2015.01.027. Epub 2015 Jan 31. PMID: 25678441.; Owens PL, et al. Hospital Inpatient Utilization Related to Opioid Overuse Among Adults, 1993–2012: Statistical Brief #177. 2014 Aug. In: Healthcare Cost and Utilization Project (HCUP) Statistical Briefs [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2006 Feb–. PMID: 25275208.; Bohnert AS, et al. Accidental poisoning mortality among patients in the Department of Veterans Affairs Health System. Med Care. 2011 Apr;49(4):393-6. doi: 10.1097/MLR.0b013e318202aa27. PMID: 21407033.

F. Despite overwhelming evidence that an oversupply of opioids was fueling a public health crisis, Defendants attempted to preserve the massive oversupply by misleading regulators and policymakers.

1. Within the first few years of the release of OxyContin, serious public health problems related to its use, especially in Appalachia and New England, began to emerge.[122] To prevent policymakers, the medical community and the public from responding appropriately to this newly emerging public health crisis, Purdue Pharma and its industry partners would adopt a public relations strategy that falsely framed the problem. "We have to hammer on the abusers in every way possible," Purdue's Richard Sackler wrote in a confidential email in 2001. "They are the culprits and the problem. They are reckless criminals."[123]

2. The strategy that Sackler was describing, Purdue Pharma would adopt, was deceptive. They falsely framed all of the harms caused by the soaring increase in opioid supply as limited to a small subset of "abusers" while claiming that the increasing supply was helping millions of people with chronic pain. Purdue hired Dezenhall Resources, a crisis management public relations firm (also hired by the Healthcare Distribution Alliance), to attack fair media coverage of the crisis and to push this false narrative.[124] When Kathy Foley, a prominent opioid industry key opinion leader, suggested the formation of the Pain Care Forum (PCF) in an email to Richard Sackler, it was evident that she had a media strategy in mind:

> "…we should call a meeting, bring together representatives from all of the companies, ideally high level representatives, like presidents or major leaders and strategize about the way to play the media issues."[125]

3. The Pain Care Forum formed shortly after this email from Dr. Foley was sent. Its membership included opioid manufacturer Defendants, including the manufacturer Defendants in this case, industry-funded pain organizations, front groups, the Federation of State Medical Boards, and representatives for opioid distributors and retailers. In opposing state and federal interventions that might reduce the massive oversupply of opioids, the Pain Care Forum consistently claimed it was defending the interests of patients with chronic pain.[126] Efforts that might result in a decreased supply were described by Pain Care Forum members as harmful to pain patients. In blocking efforts to limit opioids, such as an effective Risk Evaluation and Mitigation Strategies (REMS) program, hydrocodone up-scheduling, CDC guidelines or when pushing through legislation to weaken the DEA's

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[122] Meir B. 2003. Pain Killer: A "Wonder" Drug's Trail of Addiction and Death. Rodale Inc.

[123] PDD8801133516.

[124] Armstrong D. Inside Purdue Pharma's Media Playbook: How It Planted the Opioid "Anti-Story": OxyContin's makers delayed the reckoning for their role in the opioid crisis by funding think tanks, placing friendly experts on leading outlets, and deterring or challenging negative coverage. Propublica Nov. 19, 2019.

[125] PPLPC037000008901.

[126] Perrone, M. et al. (2016): Pro-painkiller echo chamber shaped policy amid drug epidemic. https://publicintegrity.org/state-politics/pro-painkiller-echo-chamber-shaped-policy-amiddrug-epidemic/.

enforcement authority over the Defendants, the need to "ensure access" for patients with chronic pain was always claimed. This was deceptive because, in reality, opioids have never been proven safe nor effective for chronic pain and people suffering with pain have been disproportionately harmed by aggressive opioid use.

4. Unfortunately, this tactic was successful. Interventions and polices that might have helped bring the opioid crisis under control were avoided or delayed because of fear of impeding access to opioids for patients suffering from pain. But for the PCF's activities, the crisis would not have been as severe. Meanwhile, millions of Americans were becoming addicted to opioids, thousands were losing their lives to opioid-related overdoses and the devastating epidemic of opioid addiction continued unabated.

5. Between 2006 and 2015, the Pain Care Forum's members, including the Defendants in this case, spent nearly $900 million to influence government on issues critical to their industry, including measures to prevent state and federal policymakers from taking actions that might limit the supply of opioids.[127]

6. In 2007, Congress gave the FDA a new authority over pharmaceutical companies that manufacture dangerous medications.[128] The law allowed the FDA to require these companies to operate programs called Risk Evaluation and Mitigation Strategies to reduce the risks associated with these drugs.

7. In 2008, while contemplating a REMS program requirement for manufacturers of extended-release and long-acting (ER/LA) opioids,[129] the FDA asked the companies making these products to form an Industry Working Group (IWG) to coordinate their position.[130] These Industry Working Group meetings would be on the record and attended by antitrust counsel.[131] The FDA's proposed IWG did not include key players such as Healthcare Distribution Alliance, Defendants and various front groups.[132]

8. In a March 2009 meeting with manufacturers of ER/LA opioids, the FDA outlined its plan for the REMS programs.[133] The FDA's proposal included a requirement for prescribers to obtain a certification to prescribe ER/LA opioids."[134] The FDA proposal also called for certifications for pharmacists that would "reflect that persons dispensing the drug (e.g., pharmacists or hospital personnel) are familiar with educational materials, risks of the drug

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[127] http://data.ap.org/projects/2016/cpi_ap_opioids/indexcpiap.html.

[128] PPLPC051000064077 (Food and Drug Administration Amendments Act of 2007).

[129] Burt Rosen [Purdue] Deposition (Jan. 16, 2019), at 191:1-9.

[130] EPI000066634 (IWG Submission to FDA Docket detailing FDA's request to form IWG); EPI001059511.

[131] PPLP004299456 (Meeting minutes of first IWG meeting); Rosen Deposition at 237:12-16 (IWG meetings were attended by antitrust counsel).

[132] Rosen Deposition at Ex. 27 at 6 (IWG presentation listing IWG members).

[133] PPLP004065860-878 (Slide presentation by FDA on proposed Risk Evaluation and Mitigation Strategies).

[134] *Id.*

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[127] http://data.ap.org/projects/2016/cpi_ap_opioids/indexcpiap.html.

[128] PPLPC051000064077 (Food and Drug Administration Amendments Act of 2007).

[129] Burt Rosen [Purdue] Deposition (Jan. 16, 2019), at 191:1-9.

[130] EPI000066634 (IWG Submission to FDA Docket detailing FDA's request to form IWG); EPI001059511.

[131] PPLP004299456 (Meeting minutes of first IWG meeting); Rosen Deposition at 237:12-16 (IWG meetings were attended by antitrust counsel).

[132] Rosen Deposition at Ex. 27 at 6 (IWG presentation listing IWG members).

[133] PPLP004065860-878 (Slide presentation by FDA on proposed Risk Evaluation and Mitigation Strategies).

[134] *Id.*

and conditions for safe use." Lastly, the proposal included a plan for a "database of all enrolled entities including prescribers, pharmacies, practitioners and healthcare settings."

9. As an advocate for more cautious opioid use, I recall applauding the FDA's proposed plan because I believed it would reduce the supply of these ER/LA opioids. I expected that many clinicians would opt-out from getting certified, thus reducing the pool of clinicians able to prescribe these products and I believed it would be helpful to ensure that those who did prescribe or dispense were trained in opioid risks. I also believed that the proposed database would help prevent diversion.

10. The opioid industry, through the Pain Care Forum, immediately set out to "coordinate strategy and address the FDAs REMS proposals."[135] The Pain Care Forum and its members, formed its own working group (the "internal IWG)" to address the threat to industry that a robust REMS would pose.[136] This internal IWG had a very different goal than protecting public health, revealed in internal documents stating that the FDA's goal for REMS was to "[r]educe serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of long acting and extended-release opioids while maintaining patient access to these medications" and that this goal "*differs* from the goal proposed by the Industry Working Group (IWG)."[137]

11. The Pain Care Forum's strategy included a plan to push media stories to "highlight the blurring of responsibilities between the FDA and other agencies, and the impact this may have on patient care and access to appropriate medications" and "that the abuse and diversion problem should not, and could not, be solved on the backs of people with pain."[138]As in other efforts by the Pain Care Forum, there was agreement that industry players should operate behind the scene with a public plan that "should be driven by the not-for-profit community, potentially with multiple industry sponsors."[139]

12. Defendant members of the PCF were able to use the PCF broad membership to present what appeared to be a diverse group of stakeholders, including professional organizations, "grass roots" patients groups and health care providers all submitting separate but similar comments to a federal docket on the proposed REMS from prepared "recommendations."[140] When one PCF member raised concern that the FDA "may feel it was rather duplicitous of the [industry members] to meet with [the [redacted]

[135] Rosen Deposition at 191:1-9.

[136] EPI001059511 (2008 Will Rowe email RE: PCF REMS Task Force with recipients from organizations including APHA, PPSG, Allergan, Endo, Purdue, J&J, NHPCO, Cephalon, HDMA, and APF); Rosen Deposition at Ex. 23, Ex. 24, and Ex. 25 (PCF emails re REMS Task Force, including email from HDMA commenting on proposed letter to FDA).

[137] *See also* Rosen Deposition at Ex. 27 at 10.

[138] PPLP004298301-303 (Summary of Pain Care Forum Media Committee).

[139] *Id.*

[140] *See* Rosen Deposition at Ex. 27 at 12, 28.

and not mention that these were in the works," he was told, "It's the way things work" and there was a "need to keep silent on the congressional and media strategies."[141]

13. The effort by the PCF to weaken the opioid REMS was highly effective. The FDA responded to their efforts by removing from its REMS proposal all elements that would have reduced the supply of opioids. The FDA's revised final plan was so weak that when it was presented to an external expert Advisory Committee, the plan was voted down 25-10.[142] When asked at the meeting to explain their vote against the FDA proposal, multiple committee members explained that the REMS "lacked teeth."[143]

14. A PCF effort, led by the National Association of Chain Pharmacies (of which CVS and Walgreens were members), attempted to block an effort by the DEA to up-schedule hydrocodone combination products.[144]

15. In late 2016, as the CDC was finalizing a guideline calling for more cautious prescribing, the opioid industry mounted an effort to block its release.[145] As it became clear that their efforts would fail, PCF adopted a new strategy. It successfully lobbied for legislation that create a government task force stacked with front group members, to issue a competing guideline.[146]

16. The effort was successful. Section 101 of the Comprehensive Addiction and Recovery Act of 2016 called for a task force on pain management which in 2019 issued opioid prescribing recommendations that contradicted guidance from the CDC.[147]

G. There are evidence-based solutions that can be implemented, albeit over time and with the right resources, that can turn the tide of the epidemic in Florida and should be implemented.

(a) DATA SOURCES AND METHODOLOGY FOR ABATEMENT PLAN

1. In preparing this part of my report I reviewed material from several sources, including: the peer-reviewed literature, national and state reports, opioid-specific public documents, reports and data from public health authorities, and documents from other opioid litigation

[141] PPLP003985888; PPLP004051807 at 808.

[142] Transcript of the Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC) & Drug Safety and Risk Management Advisory Committee (DSaRM), July 23, 2010 12, 8:00 a.m. to 3:30 p.m.

[143] *Id.*

[144] ENDO_FLAG-00367151

[145] Perrone, M. et al. (2016): Pro-painkiller echo chamber shaped policy amid drug epidemic. https://publicintegrity.org/state-politics/pro-painkiller-echo-chamber-shaped-policy-amiddrug-epidemic/.

[146] Lurie J. Big Pharma Has a Big Role on the Federal Committee Tasked With Curbing Opioid Abuse. May 19, 2019.

[147] *Id.*

cases. I am also relying on my training and experience in the fields of addiction treatment and public health.

2. I relied on published reports regarding the opioid crisis in Florida and meetings with key stakeholders to contextualize an abatement plan that would be most effective for this state. The salient state-level reports that I reviewed included but are not limited to: Findings and Recommendations of the Statewide Task Force on Opioid Abuse; the Statewide Drug Policy Advisory Council 2020 Annual Report; the Annual State Epidemiological Outcomes Workgroup Report; the Florida's State Opioid Response Project 2019 Annual Report; the Florida Substance Abuse and Mental Health Plan: Fiscal Years 2019-2022; and state grant applications and reports. These and additional state reports and documents are cited herein and included in Schedule 3.

3. The efforts needed to abate the opioid crisis in Florida are vast. A wide range of interventions are needed in all parts of the continuum of care, which include the areas of prevention, harm reduction, early intervention, treatment, and recovery.

4. My recommendations for abating the opioid crisis in Florida are consistent with a variety of other proposals and recommendations for abating the consequences of the opioid crisis. There is widespread consensus on many of the clinical and public health interventions to reduce opioid-related morbidity and mortality.

5. The common themes on a comprehensive response to the opioid crisis include correcting misinformation that led to an oversupply of prescription opioids and mitigating the health and social problems that have evolved over time as a result of a sharp increase in opioid use disorder. This type of response intends to do three things: prevent future cases of OUD; identify and treat active cases of OUD; and attenuate opioid-related harm. There is an evidence base to guide the selection of interventions within these three domains for the state of Florida to abate the opioid crisis.

6. Standalone interventions will not be enough to abate this public health emergency. An array of policies and interventions are needed to reduce opioid-related morbidity and mortality.[148] For example, interventions to reduce prescription opioid use and misuse (defined as either non-medical use or medical use in a manner or dose other than prescribed) without simultaneously increasing access to OUD treatment could have the unintended effect of putting people with OUD at higher risk for overdose in the short-

[148] Jack Homer and Wayne Wakeland, "A Dynamic Model of the Opioid Drug Epidemic with Implications for Policy," *The American Journal of Drug and Alcohol Abuse* 47, no. 1 (January 2, 2021): 5–15, https://doi.org/10.1080/00952990.2020.1755677; Michael A. Irvine et al., "Modelling the Combined Impact of Interventions in Averting Deaths during a Synthetic-Opioid Overdose Epidemic," *Addiction* 114, no. 9 (2019): 1602–13, https://doi.org/10.1111/add.14664; Benjamin P. Linas et al., "Projected Estimates of Opioid Mortality After Community-Level Interventions," *JAMA Network Open* 4, no. 2 (February 1, 2021): e2037259, https://doi.org/10.1001/jamanetworkopen.2020.37259; Allison L. Pitt, Keith Humphreys, and Margaret L. Brandeau, "Modeling Health Benefits and Harms of Public Policy Responses to the US Opioid Epidemic," *American Journal of Public Health* 108, no. 10 (October 2018): 1394–1400, https://doi.org/10.2105/AJPH.2018.304590.

term.[149] Alternatively, a combination of interventions can have a synergistic effect. For example, statewide and stakeholder-focused initiatives to decrease stigma may increase the demand for treatment among those with OUD, so increasing access to OUD treatment concurrently is likely to reduce opioid-related harms.

7. Some interventions to address the opioid crisis have been evaluated. For example, medication treatment with either methadone or buprenorphine has been extensively studied and the findings from these studies have established these treatment modalities as the gold standard for OUD treatment.[150] However, there is a large treatment gap for individuals with active OUD, contributing to opioid-related overdose deaths continuing to rise.[151] A treatment gap refers to the difference between the total number of individuals with OUD in a given population and the number of individuals with OUD currently receiving treatment. The treatment gap is substantial: the large majority of people with OUD are not receiving any type of treatment.[152] In responding to the complexities of the opioid crisis and the challenges in identifying and treating individuals with OUD, new interventions have emerged. These innovative approaches are currently being evaluated and are both evidence-informed and based on a sound scientific rationale, and states and localities should not wait for rigorous evidence before implementing these promising strategies. In a comprehensive response to an evolving opioid crisis, it is essential that evidence-based treatment modalities are scaled up and promising models are piloted and evaluated, then expanded if found effective.

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[149] Qiushi Chen et al., "Prevention of Prescription Opioid Misuse and Projected Overdose Deaths in the United States," *JAMA Network Open* 2, no. 2 (February 1, 2019): e187621, https://doi.org/10.1001/jamanetworkopen.2018.7621.

[150] Luis Sordo et al., "Mortality Risk during and after Opioid Substitution Treatment: Systematic Review and Meta-Analysis of Cohort Studies," *BMJ (Clinical Research Ed.)* 357 (April 26, 2017): j1550, https://doi.org/10.1136/bmj.j1550; Jun Ma et al., "Effects of Medication-Assisted Treatment on Mortality among Opioids Users: A Systematic Review and Meta-Analysis," *Molecular Psychiatry* 24, no. 12 (December 2019): 1868–83, https://doi.org/10.1038/s41380-018-0094-5; Thomas Santo et al., "Association of Opioid Agonist Treatment With All-Cause Mortality and Specific Causes of Death Among People With Opioid Dependence: A Systematic Review and Meta-Analysis," *JAMA Psychiatry*, June 2, 2021, https://doi.org/10.1001/jamapsychiatry.2021.0976; Marc R. Larochelle et al., "Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association With Mortality: A Cohort Study," *Annals of Internal Medicine* 169, no. 3 (August 7, 2018): 137–45, https://doi.org/10.7326/M17-3107; Sarah E. Wakeman et al., "Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder," *JAMA Network Open* 3, no. 2 (February 5, 2020): e1920622, https://doi.org/10.1001/jamanetworkopen.2019.20622.

[151] Li-Tzy Wu et al., "Prevalence and Correlates of Treatment Utilization among Adults with Cannabis Use Disorder in the United States," *Drug and Alcohol Dependence* 177 (August 2017): 153–62, https://doi.org/10.1016/j.drugalcdep.2017.03.037; Saloner et al., "A Public Health Strategy for the Opioid Crisis"; Arthur Robin Williams et al., "Development of a Cascade of Care for Responding to the Opioid Epidemic," *The American Journal of Drug and Alcohol Abuse* 45, no. 1 (January 2, 2019): 1–10, https://doi.org/10.1080/00952990.2018.1546862.

[152] Li-Tzy Wu, He Zhu, and Marvin S. Swartz, "Treatment Utilization among Persons with Opioid Use Disorder in the United States," *Drug and Alcohol Dependence* 169 (December 2016): 117–27, https://doi.org/10.1016/j.drugalcdep.2016.10.015; Arthur Robin Williams et al., "Development of a Cascade of Care for Responding to the Opioid Epidemic," *The American Journal of Drug and Alcohol Abuse* 45, no. 1 (January 2, 2019): 1–10, https://doi.org/10.1080/00952990.2018.1546862.

8. There are three FDA-approved medications to treat OUD: methadone, buprenorphine, and extended-release naltrexone. Selection of these different types of treatment, termed medications for opioid use disorder (MOUD), should be tailored to the particular needs of the individual with OUD. Each medication has unique characteristics:

    - Methadone – Has a mechanism of action as an opioid agonist (fully activates opioid receptors in the brain), which can help control cravings, prevent withdrawal symptoms, and block the euphoric effects of other opioids. This type of MOUD must generally be administered in a federally regulated Opioid Treatment Program (OTP), limiting its use in broader settings.

    - Buprenorphine – Is a partial opioid agonist (partially activates opioid receptors in the brain), which can help control cravings, prevent withdrawal symptoms, and block the effects of other opioids. Its unique pharmacological effects minimize the risk of overdose. Healthcare professionals must complete a federal waiver application to be eligible to prescribe buprenorphine which, until recently, included a mandatory training requirement. It is available in oral formulations and in long-acting forms (injection or implant).

    - Naltrexone – Has a mechanism of action as an opioid antagonist (blocks opioid receptors in the brain), which prevents individuals with OUD from feeling the effects of opioids. Formulations include a daily pill or a monthly injection. The monthly injection is the preferred formulation and should be used in highly motivated and carefully selected patients due to the increased risk of overdose if relapse should occur.[153] This medication can be prescribed without any special training.

9. Initiating buprenorphine and naltrexone for individuals with OUD is more challenging than initiating methadone, due to the unique pharmacological profiles of each medication. Initiating naltrexone may require a complete detoxification from opioids and initiating buprenorphine, for example in the emergency room after an opioid-related visit, may precipitate opioid withdrawal. These potential complexities contribute to providers' hesitancy to deliver OUD treatment without proper training. Interventions recommended below aim to overcome these and other barriers to treatment.

10. In addition to medications to treat OUD, this report will discuss naloxone, which is a medication used to reverse an opioid overdose if given in enough time and at the appropriate dose. Naloxone is an opioid antagonist that counters the effect of opioid agonists at mu-opioid receptors. The most common formulations of naloxone used in community settings are an intramuscular injection and an intranasal spray (brand name Narcan). Increasing the accessibility and availability of naloxone should be an important component of an abatement plan to address the opioid crisis.

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[153] Ingrid A Binswanger and Jason M. Glanz, "Potential Risk Windows for Opioid Overdose Related to Treatment with Extended-Release Injectable Naltrexone," *Drug Safety* 41, no. 10 (October 2018): 979–80, https://doi.org/10.1007/s40264-018-0705-8.

11. Due to the complexity of the opioid crisis and the need for a set of interventions that address a wide array of health and social problems across multiple sectors, collaboration and coordination among stakeholders is crucial. In local communities, these stakeholders may include first responders, healthcare professionals, representatives from the criminal justice system, policymakers, employers, faith-based organizations, educators, and social service agencies. Many times, this cross-sector collaboration is facilitated by community coalitions or task forces. Taking together the devastating impact on communities and the persisting legacy of the opioid crisis along with the need for collaboration, community-level interventions are recommended in addition to individual-level interventions.

12. Some interventions I recommend will need to be in place for several decades, whereas others may have the necessary effect over a shorter time period. For example, some individuals with OUD may need to be on medications for the rest of their lives and may need lifelong medical care for comorbidities resulting from OUD, such as HIV and Hepatitis C. In addition, the legacy of the opioid crisis is likely to persist for generations. By contrast, counter detailing (a type of academic detailing), which consists of interventions to reverse the false and misleading education disseminated by opioid manufacturers that changed the culture of opioid prescribing, and entails retraining prescribers to understand the significant risks and limited indications for prescription opioids, likely is only required for a shorter period. Research is still inconclusive on the long-term impact of neonatal abstinence syndrome and childhood trauma due to the opioid crisis. Therefore, some abatement approaches may be framed in the context of looking forward a decade whereas others may need to be in place for fifty years or more.

13. Many of the interventions that I recommend have already been implemented in the State of Florida to some degree. Most require expansion to adequately address the opioid crisis in the state, and some have been recently implemented as pilot programs. Where appropriate, the abatement recommendations leverage existing initiatives and provider infrastructures. Based upon a review of existing programs, I recommend expansion and new program development.

14. This abatement portion of this report is organized through a framework of the different levels of prevention that each intervention best represents.[154] This type of framework has been previously employed to mount epidemiologic responses to communicable and noncommunicable disease epidemics.[155] Primary prevention aims to reduce the incidence of OUD – defined as the new cases. Secondary prevention aims to identify and treat OUD early in the course of the disease. Tertiary prevention aims to effectively treat cases of OUD and reduce opioid-related harms, including nonfatal and fatal overdoses. Abating the devastating and extensive impact of the opioid crisis in the context of primary, secondary,

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[154] Andrew Kolodny et al., "The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction," *Annual Review of Public Health* 36 (March 18, 2015): 559–74, https://doi.org/10.1146/annurev-publhealth-031914-122957.

[155] Barbara A. Bowman et al., "Translating the Science of Primary, Secondary, and Tertiary Prevention to Inform the Public Health Response to Diabetes," *Journal of Public Health Management and Practice* 9 (2003): S8–14; Anis Rassi, Joao Carlos Pinto Dias, and Jose Antonio Marin-Neto, "Challenges and Opportunities for Primary, Secondary, and Tertiary Prevention of Chagas' Disease," *Heart* 95, no. 7 (2009): 524–34.

and tertiary prevention highlights that a diverse array of interventions are needed to comprehensively address this public health emergency in Florida.

15. A perennial issue in describing the scope of the opioid crisis is the need to quantify the population who have developed opioid addiction and thus the cohorts of people that needs to be treated. Historically, the National Survey on Drug Use and Health (NSDUH) has been used to establish the prevalence of OUD. It is my opinion that estimations derived from this national survey underestimate the prevalence of OUD, namely because it does not include those who are incarcerated or experiencing homelessness in the sample frame, does not capture those in OUD remission who are on medications, and many people with severe OUD would be unlikely to participate in this survey.

16. I am not alone in this line of thinking, as one study suggests that including those who are incarcerated into the NSDUH sample frame would increase the prevalence of drug use disorder, of which OUD is one type, by 25%,[156] and another study estimates that the NSDUH underestimates frequent heroin users by 75%.[157] Measuring OUD prevalence using other methods has highlighted this underestimation of OUD prevalence. One study used multiple administrative databases and employed a capture-recapture methodology to estimate the OUD prevalence in Massachusetts to be 4.6% in 2015 among those aged 11 years and older.[158] For comparison, the 2015 NSDUH estimated that 1.0% of the US population aged 12 and over had an OUD. Though Massachusetts has a higher OUD prevalence than the national average,[159] this is nearly five times higher than the national prevalence reported by NSDUH. Other studies have used claims data to estimate OUD prevalence, which was found to be 5% among Medicaid beneficiaries in 2016,[160] and 1.6% among Medicare beneficiaries in 2018,[161] both higher than the general population estimate from the NSDUH, though claims data is only capturing those who have been *clinically diagnosed* with OUD. Given these limitations, using the NSDUH to quantify the number of people in Florida that have OUD will provide an ultra-conservative estimate of the

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[156] Wilson M. Compton et al., "The Effect of Inmate Populations on Estimates of DSM-IV Alcohol and Drug Use Disorders in the United States," *American Journal of Psychiatry* 167, no. 4 (April 2010): 473–74, https://doi.org/10.1176/appi.ajp.2009.09081087.

[157] Peter Reuter, Jonathan P. Caulkins, and Greg Midgette, "Heroin Use Cannot Be Measured Adequately with a General Population Survey," *Addiction (Abingdon, England)*, March 2, 2021, https://doi.org/10.1111/add.15458.

[158] Joshua A. Barocas et al., "Estimated Prevalence of Opioid Use Disorder in Massachusetts, 2011-2015: A Capture-Recapture Analysis," *American Journal of Public Health* 108, no. 12 (December 2018): 1675–81, https://doi.org/10.2105/AJPH.2018.304673.

[159] Christopher M. Jones et al., "National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment," *American Journal of Public Health* 105, no. 8 (August 2015): e55–63, https://doi.org/10.2105/AJPH.2015.302664.

[160] Julie Donohue, Peter Cunningham, and Lauryn Walker, "Opioid Use Disorder among Medicaid Enrollees: Snapshot of the Epidemic and State Responses" (Kaiser Family Foundation, 2019), https://www.kff.org/medicaid/issue-brief/opioid-use-disorder-among-medicaid-enrollees-snapshot-of-the-epidemic-and-state-responses/.

[161] Carla Shoff, Tse-Chuan Yang, and Benjamin A. Shaw, "Trends in Opioid Use Disorder Among Older Adults: Analyzing Medicare Data, 2013-2018," *American Journal of Preventive Medicine*, March 4, 2021, https://doi.org/10.1016/j.amepre.2021.01.010.

population that needs many of the abatement strategies described in this section, possibly informing an inadequate response.

17. My method for estimating OUD prevalence in Florida involves applying a treatment gap to the number of Floridians who initiated at least one of the three types of MOUD in 2019. Sixty-six OTPs in the state served 19,436 clients in 2019, predominantly with methadone (93%).[162] According to data from the prescription drug monitoring program (PDMP) in Florida, known as E-FORCSE, 85,347 unique individuals filled a prescription for buprenorphine in 2019.[163] Non-OTP treatment facilities started 2,261 individuals on extended-release naltrexone in 2019,[164] though this is a conservative number as it does not include injections received at private doctor's offices. In total, at least 107,044 Floridians initiated MOUD in 2019.

18. A study was done among Florida Medicaid beneficiaries that reports the treatment gap between individuals with OUD and those initiating MOUD in 2017-2018.[165] Of those who had a clinically diagnosed OUD documented in claims data, only 28% initiated MOUD. This study also reported a 25.5% treatment gap for those who met criteria for OUD according to the NSDUH. For comparison, there was an 18% treatment gap for initiating MOUD nationally among those who met criteria for OUD according to the NSDUH in 2019.[166] Given the limitations of the NSDUH that were previously mentioned, I decided to use the percentage of people with clinically diagnosed OUD who initiated MOUD as an estimate of the treatment gap for all individuals with OUD in Florida. Using this gap is likely to lead to a conservative estimate of OUD prevalence for two reasons. First, this treatment gap represents only those who have been *clinically diagnosed* with OUD, meaning that an individual would have to be documented by a healthcare system as having OUD. Secondly, other studies show that the treatment gap is not as large for the Medicaid population compared to the general population.[167] Applying this treatment gap to the number of Floridians who initiated MOUD in 2019 yields an OUD prevalence estimate of 382,300. This includes 107,044 individuals who used MOUD at some point in 2019 and

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[162] SAMHSA, "National Survey of Substance Abuse Treatment Services (N-SSATS): 2019. Data on Substance Abuse Treatment Facilities," 2020, https://wwwdasis.samhsa.gov/dasis2/nssats/NSSATS_2019/2019-NSSATS-R.pdf.

[163] Florida PDMP analysis by Securities Litigation and Consulting Group, Inc., 2021. The queries and code used to search the PDMP is included in the backup materials for Dr. McCann's report.

[164] SAMHSA.

[165] Kimberly Johnson et al., "Treatment for Opioid Use Disorder in the Florida Medicaid Population: Using a Cascade of Care Model to Evaluate Quality," *The American Journal of Drug and Alcohol Abuse*, October 15, 2020, 1–9, https://doi.org/10.1080/00952990.2020.1824236.

[166] SAMHSA, "Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health" (Rockville, MD: Center for Behavioral Health Statistics and Quality, 2020), https://www.samhsa.gov/data/.

[167] Donohue, Cunningham, and Walker, "Opioid Use Disorder among Medicaid Enrollees"; Gwen Lapham, "Prevalence and Treatment of Opioid Use Disorders among Primary Care Patients in Six Health Systems," *Drug and Alcohol Dependence*, 2020, 9.

275,256 individuals who were not treated with MOUD. The overall estimated number of Floridians with OUD represents 2.2% of the state population aged 15 and older.[168]

19. Other methods have been used in the peer-reviewed literature to estimate OUD prevalence. In an economic costing study, Murphy[169] uses an adjustment factor that aligns the observed OUD prevalence from the NSDUH with the actual OUD prevalence. The adjustment factor, or "multiplier", is derived from a clinical validation study of the NSDUH that calculated the positive and negative predictive values of cocaine use disorder.[170] Although a multiplier for OUD was not calculated, the Murphy argues that using the adjustment factor for cocaine use disorder would be most reasonable. Applying this multiplier (3.06) to the estimated numbers of Floridians with OUD in 2016-2017 according to the NSDUH,[171] yields an OUD prevalence of 428,400. Another method estimates OUD from the total number of drug overdose deaths using a "mortality multiplier."[172] The mortality multiplier can be derived from the overdose-related mortality rate among regular or dependent users of opioids, which was estimated as 0.65 per 100 person-years through a systematic review.[173] Importantly, this mortality rate was derived from a time period before the emergence of fentanyl in 2013. Taking the total number of drug overdose deaths in Florida in 2012 (2,597)[174] and dividing that by the overdose-related mortality rate (0.65 per 100 person-years) among regular or dependent users of opioids yields an OUD prevalence of 399,538. I highlight these other methods to show that they result in a similar yet elevated OUD prevalence to the method that I use.

20. Another reason that the estimated prevalence of OUD is conservative is that I do not account for current cases of OUD among those on long-term opioid therapy. Also, I do not account for new cases of OUD that are certain to occur among those on long-term opioid therapy as well as individuals receiving a new prescription for opioids. As discussed above,

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[168] Florida Department of Health, "Population Dashboard," n.d., http://www.flhealthcharts.com/ChartsReports/rdPage.aspx?rdReport=PopAtlas.PopulationAtlasDASHBOARD&rdRequestForwarding=Form.

[169] Sean M. Murphy, "The Cost of Opioid Use Disorder and the Value of Aversion," *Drug and Alcohol Dependence* 217 (December 1, 2020): 108382, https://doi.org/10.1016/j.drugalcdep.2020.108382.

[170] B. Kathleen Jordan et al., "A Clinical Validation of the National Survey on Drug Use and Health Assessment of Substance Use Disorders," *Addictive Behaviors* 33, no. 6 (June 2008): 782–98, https://doi.org/10.1016/j.addbeh.2007.12.007.

[171] Feijun Luo, Mengyao Li, and Curtis Florence, "State-Level Economic Costs of Opioid Use Disorder and Fatal Opioid Overdose - United States, 2017," *MMWR. Morbidity and Mortality Weekly Report* 70, no. 15 (April 16, 2021): 541–46, https://doi.org/10.15585/mmwr.mm7015a1.

[172] Hayley E. Jones et al., "Estimating the Prevalence of Problem Drug Use from Drug-Related Mortality Data," *Addiction (Abingdon, England)* 115, no. 12 (December 2020): 2393–2404, https://doi.org/10.1111/add.15111.

[173] Louisa Degenhardt et al., "Mortality among Regular or Dependent Users of Heroin and Other Opioids: A Systematic Review and Meta-Analysis of Cohort Studies," *Addiction (Abingdon, England)* 106, no. 1 (January 2011): 32–51, https://doi.org/10.1111/j.1360-0443.2010.03140.x.

[174] Kaiser Family Foundation, "Drug Overdose Death Rate (per 100,000 Population)," 2021, https://www.kff.org/other/state-indicator/drug-overdose-death-rate-per-100000-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

many individuals on long-term opioid therapy have or will develop an OUD, and opioid prescribing is still much higher than pre-1997 levels. I expect that new cases of OUD will, at the very least, balance out deaths from natural causes and fatal opioid overdoses in the population with OUD along with those who go into long-term OUD remission without the use of medications. However, these new cases are likely to outweigh these other trajectories, leading to a conservative estimate of the OUD prevalence going forward.

(b) PRIMARY PREVENTION

The goal of primary prevention is to reduce the incidence of OUD by preventing new cases.[175] This disease typically follows a chronic course that is difficult to treat and associated with high rates of morbidity and mortality. Preventing new cases of OUD from developing is required to attenuate the opioid crisis. In addition, there is tremendous societal benefit to preventing just one case of OUD, estimated at $2.2 million.[176] This potential cost savings underscores the immense toll that the sharp rise in OUD has taken on Florida. Generally, the primary prevention interventions recommended in this report will reduce the widespread oversupply of prescription opioids, while also simultaneously decreasing the demand for prescription opioids. Supply-side measures range from addressing how clinicians treat pain to the diversion of opioids throughout the supply chain, and demand-side measures range from strengthening families and communities to addressing risk factors for opioid misuse.

The primary prevention interventions that I recommend take two forms. Universal interventions, such as initiatives to encourage more cautious opioid prescribing or broad strategies to increase community resilience and collaboration, are designed for an entire population without regard to individual risk factors, whereas selective interventions, such as strategies to decrease youth prescription opioid misuse, are targeted to specific subpopulations and communities at greater risk for OUD. Primary prevention interventions address both the medical and non-medical use of prescription opioids. Addressing just one of these types of prescription opioid use is necessary but not sufficient to comprehensively respond to the opioid crisis.

A robust primary prevention campaign utilizing the abatement strategies discussed below is likely to be most impactful over a ten-year period, although community coalitions that facilitate a comprehensive response to the opioid crisis will need to be sustained for at least twenty years.

(i) Educational interventions to promote cautious prescribing

As discussed at length above, opioid prescribing in the United States dramatically increased after 1996 and remains much higher than pre-1997 levels. The United States is as an outlier when its high levels of prescription opioid consumption are compared to other developed countries. Florida is no exception to this high rate of opioid prescribing. Although prescription opioids can be useful during end-of-life care or when used within a few days after major surgery

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[175] Andrew Kolodny et al., "The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction," *Annual Review of Public Health* 36 (March 18, 2015): 559–74, https://doi.org/10.1146/annurev-publhealth-031914-122957.

[176] Sean M. Murphy, "The Cost of Opioid Use Disorder and the Value of Aversion," *Drug and Alcohol Dependence* 217 (December 1, 2020): 108382, https://doi.org/10.1016/j.drugalcdep.2020.108382.

or a serious accident, 479,679 Floridians received six or more opioid prescriptions in 2019 (excluding those who also received a prescription for buprenorphine) and 285,061 were on 90 MME or more per day at some point during the calendar year according to PDMP data as calculated by Dr. McCann,[177] suggesting that many are on long-term opioid therapy for chronic conditions despite limited evidence on effectiveness and increased risk of harm.[178] In addition, some 2.9 million Floridians filled an opioid prescription in 2019. In order to reverse the impact of the opioid industry on the culture of opioid prescribing, healthcare professionals must be retrained to prescribe opioids more cautiously and patients who could potentially receive opioids must have an accurate understanding of the significant risks and limited benefits. Therefore, interventions to reverse the campaign by the opioid industry should consist of counter detailing, provider education, and patient education.

1. Academic detailing provides direct training to healthcare professionals. It consists of an in-person educational outreach visit by trained personnel to promote optimal prescribing and improve the quality of patient care. One systematic review found that passive approaches to provider education are generally ineffective, but educational outreach for prescribing, an active approach, was promising.[179] Another systematic review looking specifically at educational outreach visits found that this intervention alone has a consistently positive effect on prescribing behavior.[180] This intervention has been shown to reduce the rate of opioid prescribing and MME per prescription as part of a quality improvement study in a regional healthcare system,[181] and increased knowledge among prescribers and reduced high-dose opioid prescribing in a borough in New York City.[182] The latter academic detailing campaign had three simple but effective messages: a 3-day supply of opioids is usually sufficient for acute pain, avoid prescribing opioids for chronic non-cancer pain, and avoid high-dose opioid prescriptions. There should be a large-scale academic detailing campaign targeting all opioid prescribers in Florida for a ten-year period. Known as counter detailing, this approach would be reversing the detailing of opioid manufacturers that changed the

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[177] Florida PDMP analysis by Securities Litigation and Consulting Group, Inc. The queries and code used to search the PDMP is included in the backup materials for Dr. McCann's report..

[178] Roger Chou et al., "The Effectiveness and Risks of Long-Term Opioid Therapy for Chronic Pain: A Systematic Review for a National Institutes of Health Pathways to Prevention Workshop," *Annals of Internal Medicine* 162, no. 4 (February 17, 2015): 276–86, https://doi.org/10.7326/M14-2559; Roger Chou et al., "The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain," *Evidence Report/Technology Assessment*, no. 218 (September 2014): 1–219, https://doi.org/10.23970/AHRQEPCERTA218.

[179] J. M. Grimshaw et al., "Changing Provider Behavior: An Overview of Systematic Reviews of Interventions," *Medical Care* 39, no. 8 Suppl 2 (August 2001): II2-45.

[180] M. A. O'Brien et al., "Educational Outreach Visits: Effects on Professional Practice and Health Care Outcomes," *The Cochrane Database of Systematic Reviews*, no. 4 (October 17, 2007): CD000409, https://doi.org/10.1002/14651858.CD000409.pub2.

[181] Barry R. Meisenberg et al., "Assessment of Opioid Prescribing Practices Before and After Implementation of a Health System Intervention to Reduce Opioid Overprescribing," *JAMA Network Open* 1, no. 5 (September 28, 2018), https://doi.org/10.1001/jamanetworkopen.2018.2908.

[182] Jessica A. Kattan et al., "Public Health Detailing—A Successful Strategy to Promote Judicious Opioid Analgesic Prescribing," *American Journal of Public Health* 106, no. 8 (August 2016): 1430–38, https://doi.org/10.2105/AJPH.2016.303274.

culture around opioid prescribing. A simple and effective message would be similar to the NYC academic detailing campaign highlighted above. In addition to educational outreach to reduce opioid prescribing and increase knowledge of non-opioid alternatives, detailers should also capitalize on this opportunity to educate prescribers on the screening, identification, and treatment of OUD, along with overdose prevention. According to PDMP data, there were 147,652 prescribers of controlled substances in Florida in 2020,[183] which serves as a good proxy for opioid prescribers. These prescribers may include physicians, dentists, nurse practitioners, physician assistants, optometrists, and podiatrists. I also suggest targeted academic detailing to high prescribers in the secondary prevention section, discussed further below.

2. In the past, medical education on opioid prescribing has been heavily influenced by opioid manufacturers.[184] In addition to detailing, medical education after residency is oftentimes delivered through continuing medical education (CME). While not a replacement for improved education in medical school and residency training, CME, when produced and disseminated by faculty and organizations without financial ties to pharmaceutical companies and device manufacturers, can help improve provider knowledge and practice. Florida's House Bill 21, implemented in July 2018, requires that each person registered with the DEA and authorized to prescribe controlled substances must take a board-approved two-hour continuing education course on prescribing controlled substances. The course must be repeated prior to each subsequent license renewal. Nurse practitioners and physician assistants already have to take a three-hour course on controlled substance prescribing. House Bill 21 also implemented a 3-day restriction of opioid prescriptions for acute pain, and this law is associated with decreased opioid use and with changes in initial prescribing decisions.[185] Florida also provides feedback to providers through PDMP data. Feedback to providers on their patients' outcomes,[186] and how they compare with their peers,[187] has been shown to reduce opioid prescribing. Florida should continue providing feedback to providers through the PDMP quarterly reports. In addition, the required CME for physician and non-physician prescribers should be free of conflicts of interest, as one systematic review found that nearly one in five of the evaluated CME programs on opioid prescribing or overdose prevention in the peer-reviewed literature

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[183] Florida Department of Health, "Prescription Drug Monitoring Program Annual Report: Fiscal Year 2019-2020," 2020.

[184] Art Van Zee, "The Promotion and Marketing of Oxycontin: Commercial Triumph, Public Health Tragedy," *American Journal of Public Health* 99, no. 2 (February 2009): 221–27, https://doi.org/10.2105/AJPH.2007.131714.

[185] Juan M. Hincapie-Castillo et al., "Changes in Opioid Use After Florida's Restriction Law for Acute Pain Prescriptions," *JAMA Network Open* 3, no. 2 (February 5, 2020): e200234, https://doi.org/10.1001/jamanetworkopen.2020.0234.

[186] Jason N. Doctor et al., "Opioid Prescribing Decreases after Learning of a Patient's Fatal Overdose," *Science (New York, N.Y.)* 361, no. 6402 (August 10, 2018): 588–90, https://doi.org/10.1126/science.aat4595.

[187] Sean S. Michael et al., "Effect of a Data-Driven Intervention on Opioid Prescribing Intensity Among Emergency Department Providers: A Randomized Controlled Trial," *Academic Emergency Medicine: Official Journal of the Society for Academic Emergency Medicine* 25, no. 5 (May 2018): 482–93, https://doi.org/10.1111/acem.13400.

had direct or indirect opioid manufacturer involvement.[188] A diverse CME curriculum should explicitly correct past misinformation and include the following topics: non-opioid pain management, non-pharmacological pain treatments, cautious opioid prescribing, screening, identification, and treatment of OUD, and overdose prevention. All prescribers (physicians and non-physicians) should be trained using this specially designed CME class to address the opioid crisis within the first two years followed by every four years for an overall duration of ten years. These trainings should be done in-person across Florida at no cost to healthcare professionals and be delivered in engaging environments (e.g. no more than 150 people per class). Appropriate provider education to future healthcare professionals, delivered through training in medical school and residency programs, is also crucial to reverse the culture of opioid prescribing. Comprehensive education to these populations, including identifying and treating OUD, is discussed in the tertiary prevention section below.

3. Misrepresentation of the risks of prescription opioid use has also affected patients' perceived risk of initiating opioid therapy. Therefore, patient education by the provider is important in conveying the known risk and realistic benefits of opioid therapy as well as delivering information on safe storage and disposal. Patient education has been recommended by the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain and the Veterans Affairs/Department of Defense Clinical Practice Guideline for Opioid Therapy for Chronic Pain.[189] A review of the literature suggests that patient education in clinical settings shows promise for increasing knowledge and awareness of opioid-related harms and decreasing substance misuse.[190] One randomized control study showed that, among patients receiving a new opioid prescription, a video-based educational intervention increased knowledge about opioid-related risks.[191] Patient education has also been shown to double the proportion of patients who disposed of their unused opioids.[192] All opioid-naïve patients for whom an opioid prescription is

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[188] Abhimanyu Sud, Graziella R. Molska, and Fabio Salamanca-Buentello, "Evaluations of Continuing Health Provider Education Focused on Opioid Prescribing: A Scoping Review," *Academic Medicine: Journal of the Association of American Medical Colleges*, June 1, 2021, https://doi.org/10.1097/ACM.0000000000004186.

[189] Department of Veterans Affairs and Department of Defense, "VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain," 2017, https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPGPocketCard022817.pdf; Deborah Dowell, Tamara M. Haegerich, and Roger Chou, "CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016," *MMWR. Recommendations and Reports: Morbidity and Mortality Weekly Report. Recommendations and Reports* 65, no. 1 (March 18, 2016): 1–49, https://doi.org/10.15585/mmwr.rr6501e1.

[190] Tamara M. Haegerich et al., "Evidence for State, Community and Systems-Level Prevention Strategies to Address the Opioid Crisis," *Drug and Alcohol Dependence* 204 (November 1, 2019): 107563, https://doi.org/10.1016/j.drugalcdep.2019.107563.

[191] Bharath Chakravarthy et al., "Randomized Pilot Trial Measuring Knowledge Acquisition of Opioid Education in Emergency Department Patients Using a Novel Media Platform," *Substance Abuse* 39, no. 1 (January 2, 2018): 27–31, https://doi.org/10.1080/08897077.2017.1375061.

[192] Jessica M. Hasak et al., "Empowering Post-Surgical Patients to Improve Opioid Disposal: A Before and After Quality Improvement Study," *Journal of the American College of Surgeons* 226, no. 3 (March 2018): 235-240.e3, https://doi.org/10.1016/j.jamcollsurg.2017.11.023.

considered should receive informed consent about opioid risks and benefits to increase health literacy around prescription opioids, especially the risk of addiction.

4. Education of other healthcare professionals, such as pharmacists and emergency first responders, is also vital in facilitating the delivery of evidence-based care in the healthcare system. Educational interventions for these stakeholders are incorporated in tertiary prevention recommendations discussed below.

(ii) Community-level interventions to educate and strengthen local communities

Many communities have been devastated by the opioid crisis. However, due to its complexity, regions, states, and communities have been impacted differently. For example, some areas may have historically had higher opioid prescribing rates whereas others have been disproportionately infiltrated with fentanyl in the illicit drug supply. In addition, some states and local communities may have made large investments in particular areas to address the opioid crisis. For example, some areas may have focused on the oversupply of prescription opioids whereas others may have focused on naloxone distribution. Because of these community-level differences, there will not be a one-size-fits-all approach to an abatement plan. For this abatement plan to be most effective, it should be contextualized to the State of Florida while also acknowledging that there are likely to be different needs and approaches within the state. This next subsection will provide recommendations to ensure a robust network of coalitions that can assess the needs of the community at the county level, facilitate and foster vital partnerships, and tailor interventions to community-level factors. It is also important to educate communities, as recommended through a mass media campaign.

5. Community-based prevention and education is an essential component of primary prevention. These interventions can increase protective factors and reduce risk factors for opioid misuse and OUD. Prevention coalitions are one way to deliver community-based prevention and education. Selecting, implementing, and monitoring these interventions can be enhanced through a Communities that Care (CTC) model, which is a system that trains and supports prevention coalitions to make science-based and data-driven decisions about local prevention efforts. These prevention efforts, informed by the CTC model, are targeted to early adolescents (aged 10-14 years), though community-based prevention and education interventions can universally impact the entire community, including both youth and adults. Long-term rigorous studies on the impact of the CTC model suggest that it decreases substance use, and this reduction is sustained over time.[193] Funding should be provided for every Florida county (n = 67) to build or sustain a prevention coalition under the CTC model. In addition, counties should enhance their capacity to universally deliver community-based prevention services. This enhancement should include a local health educator specifically trained

[193] Sabrina Oesterle et al., "Long-Term Effects of the Communities That Care Trial on Substance Use, Antisocial Behavior, and Violence Through Age 21 Years," *American Journal of Public Health* 108, no. 5 (May 2018): 659–65, https://doi.org/10.2105/AJPH.2018.304320; J. David Hawkins et al., "Sustained Decreases in Risk Exposure and Youth Problem Behaviors after Installation of the Communities That Care Prevention System in a Randomized Trial," *Archives of Pediatrics & Adolescent Medicine* 166, no. 2 (February 2012): 141–48, https://doi.org/10.1001/archpediatrics.2011.183.

to deliver opioid education in each county's health department. Also, each county should also have a Certified Prevention Professional, as recommended by the Statewide Task Force on Opioid Abuse, whose role is to work with individuals, families, and communities to create environments and conditions that support wellness and the ability of individuals to withstand changes.[194] Both the health educator and the Certified Prevention Professional will have roles in other interventions recommended below. These positions and the CTC model should be sustained for at least ten years.

6. Although federal- and state-level responses are a vital part of addressing the opioid crisis, many initiatives and response plans are implemented at the county-level or within local communities. Community engagement can improve the design and implementation of these initiatives and response plans. Coalition building is a way to build this community engagement. Coalitions and task forces, essentially similar models, can facilitate collaboration and coordination among stakeholders in local communities and counties, which are essential for mounting an effective and comprehensive response to the opioid crisis. Although evidence for coalition building to address the opioid crisis is emerging, a network of coalitions in California shows promise in building partnerships and improving the dissemination of evidence-based practices.[195] Coalitions have also been shown to increase the flexibility of communities to quickly adapt to circumstances, such as the case of sustaining naloxone distribution during COVID-19.[196] The creation of a coalition/task force to address the opioid crisis can be facilitated by community forums that bring together a diverse group of stakeholders to talk about the issue in their community.[197] Florida already has several coalitions and task forces, many at the county level, to address the opioid crisis. To foster the necessary community-level infrastructure to facilitate community engagement, assessment of community needs, and improve the uptake and sustainability of evidence-based practices, funding should be provided for every Florida county (n = 67) to build or sustain an opioid-specific coalition/task force. A good model of this type of coalition, the Opioid Task Force in Franklin County,

[194] Florida Statewide Task Force on Opioid Abuse, "Findings and Recommendations of the Statewide Task Force on Opioid Abuse," 2020, https://doseofrealityfl.com/pdfs/opioid-task-force-findings-recommendations-opioid-abuse.pdf.

[195] A. Max, R. Garrow, and M. Willis, "Tackling an Epidemic: An Assessment of the California Opioid Safety Coalitions Network" (Public Health Institute, 2017), http://www.phi.org/wp-content/uploads/migration/uploads/application/files/bt93oju0nrnbsmjhpdw692ljgu0d27ttdpzxmbclj7cxq99alz.pdf.

[196] Matthew W. Courser and Holly Raffle, "With Crisis Comes Opportunity: Unanticipated Benefits Resulting from Pivots to Take-Home Naloxone (THN) Programs during the COVID-19 Pandemic," *Journal of Substance Abuse Treatment* 122 (March 2021): 108220, https://doi.org/10.1016/j.jsat.2020.108220.

[197] Laura C. Palombi et al., "A Community Partnership to Respond to the Heroin and Opioid Abuse Epidemic," *The Journal of Rural Health: Official Journal of the American Rural Health Association and the National Rural Health Care Association* 33, no. 1 (January 2017): 110–13, https://doi.org/10.1111/jrh.12180; Laura Palombi et al., "Community Forums to Address the Opioid Crisis: An Effective Grassroots Approach to Rural Community Engagement," *Substance Abuse: Research and Treatment* 13 (2019): 1178221819827595, https://doi.org/10.1177/1178221819827595.

Massachusetts, has an operating budget of $300,000 per year.[198] In addition to providing the essential functions of a coalition, the Opioid Task Force is also able to give pilot funding to promising local initiatives. This is likely to be an important component of a coalition/task force in Florida given the large size of the counties. These coalitions/task forces should be sustained for at least 20 years due to their multifaceted role in prevention, treatment, recovery, and harm reduction.

7. Research has demonstrated that health communication campaigns can effectively address important public health issues such as HIV/AIDS prevention and smoking cessation.[199] Specific to the opioid crisis, a health communication campaign would disseminate known risks of prescription opioids, thus increasing perceived risk. Research has found that youth who perceive less risk with taking opioids for nonprescribed reasons are more likely to misuse them, while youth who believe that it is unsafe are at less risk of doing so.[200] Florida Department of Legal Affairs operates a website called Dose of Reality, with the goal of preventing prescription opioid misuse and OUD in Florida through education.[201] Also, the state has a legacy in launching a successful tobacco counter marketing campaign.[202] Both of these can be leveraged to deliver an effective counter marketing campaign directed at prescription opioids. In parallel with the recommendations of the Drug Policy Advisory Council (created by the Florida legislature) and the Statewide Task Force for Opioid Abuse (created by the governor of Florida), community education should be delivered through a mass media campaign. Florida should enhance and sustain Dose of Reality to facilitate this campaign. The state should implement a mass media campaign targeting all Floridians with three main aims: increasing the perceived risk of using prescription opioids; safe storage and disposal of prescription opioids; and disseminating knowledge about the Dose of Reality resource. According to CDC guidelines, a one-year communication campaign should reach 75-85% of the target audience (all Floridians aged 12 and over) quarterly.[203] These interventions can be effective in changing health behavior if

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[198] Opioid Task Force of Franklin County and the North Quabbin Region, "July 1, 2016 - June 30, 2017 Annual Report," n.d., https://opioid-resource-connector.org/sites/default/files/2019-11/OTF_AnnualReport2016_17-FINAL_lores.pdf.

[199] Malgorzata M. Bala, Lukasz Strzeszynski, and Roman Topor-Madry, "Mass Media Interventions for Smoking Cessation in Adults," *The Cochrane Database of Systematic Reviews* 11 (November 21, 2017): CD004704, https://doi.org/10.1002/14651858.CD004704.pub4; John O. Olawepo, Jennifer R. Pharr, and Axenya Kachen, "The Use of Social Marketing Campaigns to Increase HIV Testing Uptake: A Systematic Review," *AIDS Care* 31, no. 2 (February 2019): 153–62, https://doi.org/10.1080/09540121.2018.1533631.

[200] Jason A. Ford and Khary K. Rigg, "Racial/Ethnic Differences in Factors That Place Adolescents at Risk for Prescription Opioid Misuse," *Prevention Science: The Official Journal of the Society for Prevention Research* 16, no. 5 (July 2015): 633–41, https://doi.org/10.1007/s11121-014-0514-y.

[201] Florida Department of Legal Affairs, "Dose of Reality: Prevent Prescription Painkiller Abuse in Florida," n.d., https://doseofrealityfl.com/.

[202] Jeff Niederdeppe, Matthew C. Farrelly, and M. Lyndon Haviland, "Confirming 'Truth': More Evidence of a Successful Tobacco Countermarketing Campaign in Florida," *American Journal of Public Health* 94, no. 2 (2004): 255–57.

[203] Centers for Disease Control and Prevention, "Best Practices for Comprehensive Tobacco Control Programs—2014," 2021, https://www.cdc.gov/tobacco/stateandcommunity/best_practices/index.htm.

designed with a thoughtful approach.[204] Therefore, the campaign needs to have a simple yet effective message that has been developed by communication and content experts and that has been piloted and pretested using methods such as focus groups.

(iii) Youth prevention of opioid misuse and opioid use disorder

Young people are more susceptible to the harmful effects of substance use.[205] One study found that the rate of prescription opioid use disorder was higher among adolescents compared with young adults after initiating prescription opioid use, potentially highlighting a faster transition to OUD in adolescents.[206] According to data from the National Survey on Drug Use and Health from 2002 to 2010, between 6.2-7.7% of adolescents (aged 12-17) and between 11.1-12.4% of young adults (aged 18-25) reported non-medical use of pain relievers in the past year, amounting to millions of young people nationwide, though this number has been trending downwards in parallel with opioid prescribing.[207] In Florida, 7.0% of high school-aged youth reported prescription drug misuse during the past 30 days in 2002 while 2.7% reported this type of misuse in 2020.[208] Prevention and early identification of opioid misuse and OUD in adolescents should be prioritized to minimize short- and long-term consequences. It is also important to note that interventions to promote cautious opioid prescribing will also prevent future cases of opioid misuse and OUD in youth as one study found that legitimate prescription opioid use before high school graduation was independently associated with a 33% increase in the risk of future opioid misuse after high school.[209]

8. Several school-based and family-based prevention programs have successfully delayed or prevented initiation or escalation of substance use in youths. These prevention programs are typically targeted toward specific ages. A systematic review of school-based interventions showed that including social competence and social influence approaches consistently increases protective factors and prevents illicit drug use.[210] Florida has already implemented school-based prevention programs for some students.

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[204] Melanie A. Wakefield, Barbara Loken, and Robert C. Hornik, "Use of Mass Media Campaigns to Change Health Behaviour," *Lancet (London, England)* 376, no. 9748 (October 9, 2010): 1261–71, https://doi.org/10.1016/S0140-6736(10)60809-4.

[205] Ken C. Winters and Amelia Arria, "Adolescent Brain Development and Drugs," *The Prevention Researcher* 18, no. 2 (2011): 21–24.

[206] Nora D. Volkow et al., "Prevalence of Substance Use Disorders by Time Since First Substance Use Among Young People in the US," *JAMA Pediatrics* 175, no. 6 (June 1, 2021): 640–43, https://doi.org/10.1001/jamapediatrics.2020.6981.

[207] SAMHSA, "Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings," 2011, https://atforum.com/documents/NSDUH2010.pdf.

[208] Bert Rothenbach, "2020 Florida Youth Substance Abuse Survey Annual Presentation" (Florida Department of Children and Families, 2020), https://www.myflfamilies.com/service-programs/samh/prevention/fysas/2020/docs/2020%20FYSAS%20Annual%20Presentation%20per%20Section%20C2-2.6.pdf.

[209] Richard Miech et al., "Prescription Opioids in Adolescence and Future Opioid Misuse," *Pediatrics* 136, no. 5 (November 2015): e1169-1177, https://doi.org/10.1542/peds.2015-1364.

[210] Fabrizio Faggiano et al., "Universal School-Based Prevention for Illicit Drug Use," *The Cochrane Database of Systematic Reviews*, no. 12 (2014): CD003020, https://doi.org/10.1002/14651858.CD003020.pub3.

As part of the first year of the State Opioid Response (SOR) grant, 13,522 youth were engaged in prevention programs, of which most (73%) participated in LifeSkills Training.[211] In line with the recommendations from the Drug Policy Advisory Council,[212] Florida should enhance the implementation of age-appropriate, evidence-based prevention programs to reach all grade school children in the state. Based on a review of school-based prevention interventions for opioid misuse and OUD among adolescents,[213] along with evaluations of these programs, I recommend programs such as the Good Behavior Game[214] for elementary school age, Lifeskills Training[215] plus Strengthening Families Program for middle school age[216] (the latter is family-based and can be delivered by Certified Prevention Professionals), and Project Toward No Drug Abuse[217] for high school age. Also, Florida should increase the number of school counselors to meet the standard recommended by the American School Counselor Association, which is a 250:1 student-to-counselor ratio.[218] This would allow optimal identification and intervention for risk factors of opioid misuse. Currently, the student-to-counselor ratio in Florida is 485:1.[219] These interventions should be sustained for ten years, at which point the availability of prescription opioids for non-medical use should be substantially reduced through other primary prevention strategies.

9. Safe storage and disposal of prescription opioids is an important intervention to address the opioid crisis, especially in reducing non-medical use. It is common for patients to fill an opioid prescription and have pills leftover. One study found that more than half

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[211] Florida Department of Children and Families, "Florida's State Opioid Response Project: Annual Report 2019," 2020, https://www.myflfamilies.com/service-programs/samh/docs/opioid/FL%20SOR%20Annual%20Report%20Year%201%202019_UPDATED%20January%202020.pdf.

[212] Drug Policy Advisory Council, "Statewide Drug Policy Advisory Council 2020 Annual Report," 2020, http://www.floridahealth.gov/provider-and-partner-resources/dpac/DPAC_11-30-20.pdf.

[213] Christal Ramos, Lisa Clemans-Cope, and HSJL Basurto, "Evidence-Based Interventions for Adolescent Opioid Use Disorder" (Urban Institute, 2018).

[214] Sheppard G. Kellam et al., "Effects of a Universal Classroom Behavior Management Program in First and Second Grades on Young Adult Behavioral, Psychiatric, and Social Outcomes," *Drug and Alcohol Dependence* 95 Suppl 1 (June 1, 2008): S5–28, https://doi.org/10.1016/j.drugalcdep.2008.01.004.

[215] D. Max Crowley et al., "Can We Build an Efficient Response to the Prescription Drug Abuse Epidemic? Assessing the Cost Effectiveness of Universal Prevention in the PROSPER Trial," *Preventive Medicine* 62 (May 2014): 71–77, https://doi.org/10.1016/j.ypmed.2014.01.029.

[216] Richard Spoth et al., "Longitudinal Effects of Universal Preventive Intervention on Prescription Drug Misuse: Three Randomized Controlled Trials with Late Adolescents and Young Adults," *American Journal of Public Health* 103, no. 4 (April 2013): 665–72, https://doi.org/10.2105/AJPH.2012.301209.

[217] Wei Sun et al., "Project Towards No Drug Abuse: Long-Term Substance Use Outcomes Evaluation," *Preventive Medicine* 42, no. 3 (March 2006): 188–92, https://doi.org/10.1016/j.ypmed.2005.11.011.

[218] American School Counselor Association, "The School Counselor and Use of Support Staff in School Counseling Programs," 2019, https://schoolcounselor.org/Standards-Positions/Position-Statements/ASCA-Position-Statements/The-Professional-Counselor-and-Use-of-Support-Staf.

[219] National Association for College Admission Counseling, "State-by-State Student-to-Counselor Ratio Report: 10-Year Trends," 2015, https://www.nacacnet.org/globalassets/documents/publications/research/state-by-state-ratio-report.pdf.

of the opioids prescribed for dental surgery were unused three weeks after surgery,[220] and a systematic review estimates that 67-92% of patients reported having unused prescription opioids after surgery.[221] However, more than 70% of people report not locking up opioids and most do not receive information on safe storage and disposal.[222] These unused prescription opioids are a common source of non-medical use among adolescents and young adults, as 56% of these individuals reported getting the opioid from a family or friend.[223] There is also further evidence for ensuring safe storage and disposal of prescription opioids as living in a household with a prescription opioid user is associated with an increased risk of prescription opioid use,[224] and having a family member who is prescribed opioids was associated with increased risk for prescription opioid overdose among youths.[225]

10. Patient education, as discussed above, will help increase rates of safe storage and disposal. The mass media campaign discussed above will also promote safe storage and disposal. Still, patients need to know where to bring their unused opioids. In addition, medication disposal locations and drug take-back days have the potential to raise awareness of the risks of prescription opioid use. In 2019, national drug take-back days resulted in 71,963 pounds of drugs collected in Florida alone—nearly a 20% increase from the amount collected in 2018.[226] In parallel with recommendations from both the Drug Policy Advisory Council and the Statewide Task Force on Opioid Abuse,[227] Florida should create a robust network of medication disposal locations (permanent sites) that are easily accessible to all Floridians and increase the number of prescription

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[220] Brandon C. Maughan et al., "Unused Opioid Analgesics and Drug Disposal Following Outpatient Dental Surgery: A Randomized Controlled Trial," *Drug and Alcohol Dependence* 168 (November 1, 2016): 328–34, https://doi.org/10.1016/j.drugalcdep.2016.08.016.

[221] Mark C. Bicket et al., "Prescription Opioid Analgesics Commonly Unused After Surgery: A Systematic Review," *JAMA Surgery* 152, no. 11 (November 1, 2017): 1066–71, https://doi.org/10.1001/jamasurg.2017.0831.

[222] Alene Kennedy-Hendricks et al., "Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults," *JAMA Internal Medicine* 176, no. 7 (July 1, 2016): 1027–29, https://doi.org/10.1001/jamainternmed.2016.2543.

[223] Joel D. Hudgins et al., "Prescription Opioid Use and Misuse among Adolescents and Young Adults in the United States: A National Survey Study," *PLoS Medicine* 16, no. 11 (November 2019): e1002922, https://doi.org/10.1371/journal.pmed.1002922.

[224] Marissa J. Seamans et al., "Association of Household Opioid Availability and Prescription Opioid Initiation Among Household Members," *JAMA Internal Medicine* 178, no. 1 (January 1, 2018): 102–9, https://doi.org/10.1001/jamainternmed.2017.7280.

[225] Anh P. Nguyen et al., "Association of Opioids Prescribed to Family Members With Opioid Overdose Among Adolescents and Young Adults," *JAMA Network Open* 3, no. 3 (March 2, 2020): e201018, https://doi.org/10.1001/jamanetworkopen.2020.1018.

[226] Florida Statewide Task Force on Opioid Abuse, "Findings and Recommendations of the Statewide Task Force on Opioid Abuse."

[227] Drug Policy Advisory Council, "Statewide Drug Policy Advisory Council 2020 Annual Report"; Florida Statewide Task Force on Opioid Abuse, "Findings and Recommendations of the Statewide Task Force on Opioid Abuse."

drug take-back programs (episodic sites) across the state. Using chain pharmacies as sites could create this robust network of medication disposal locations.

(c) SECONDARY PREVENTION

The goal of secondary prevention is to identify OUD after its onset but before it causes serious complications, and to link individuals with OUD to appropriate levels of treatment.[228] Abatement strategies that fall under secondary prevention include interventions that screen for and identify OUD early in the course of the disease, link people with less severe forms of OUD to treatment, and address chronic pain patients on long-term opioid therapy who may have developed an OUD. Efforts to identify OUD and provide early intervention are likely to reduce the risk of opioid overdose, slow down the progression of OUD, and decrease transition to injection drug use and its related medical complications. The proposed secondary prevention interventions are likely to have the most impact within the next 20 years.

1. Early identification of OUD and linkage to treatment can reduce opioid-related morbidity and mortality. One way to do this is through universal screening for opioid misuse and OUD in a variety of clinical settings. This is typically done through a technique called Screening, Brief Intervention, and Referral to Treatment (SBIRT). This technique uses validated instruments in a medical setting, usually in the emergency department (I will refer to the emergency department, or emergency room, as an "ED") or in primary care, to screen people for substance use disorders (of which OUD is one type), provide a brief intervention for positive screens, and refer the person to further treatment if deemed the appropriate next step. Screening tools need to be time-efficient, easy to use, have a very high rate of the proportion of positives that are correctly identified (i.e. sensitivity), and have a high rate of the proportion of negatives that are correctly identified (i.e. specificity). Though there are several OUD screening tools available,[229] limitations in validity and reliability suggest that there is no clear tool to use.[230] In screening for OUD in the primary care setting, the Screen of Drug Use was found to be 100% sensitive and 86% specific.[231] Thus, this may be a good screening tool to use among the general population. However, specialized screening tools should be used for individuals on long-term opioid therapy for chronic pain, as discussed below. The United States Preventative Task Force recommends that all adults should be screened for OUD when services for accurate diagnosis, effective

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[228] Andrew Kolodny et al., "The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction," *Annual Review of Public Health* 36 (March 18, 2015): 559–74, https://doi.org/10.1146/annurev-publhealth-031914-122957.

[229] Herbert C. Duber et al., "Identification, Management, and Transition of Care for Patients With Opioid Use Disorder in the Emergency Department," *Annals of Emergency Medicine* 72, no. 4 (October 2018): 420–31, https://doi.org/10.1016/j.annemergmed.2018.04.007.

[230] Preet Kaur Sahota et al., "Screening Emergency Department Patients for Opioid Drug Use: A Qualitative Systematic Review," *Addictive Behaviors* 85 (October 2018): 139–46, https://doi.org/10.1016/j.addbeh.2018.05.022.

[231] Quyen Q. Tiet, Yani E. Leyva, and Rudolf H. Moos, "Screen of Drug Use: Diagnostic Accuracy for Opioid Use Disorder," *Drug and Alcohol Dependence* 198 (May 1, 2019): 176–79, https://doi.org/10.1016/j.drugalcdep.2019.01.044.

treatment, and appropriate care can be offered or referred.[232] If other abatement strategies in this report are implemented, this contingency should be met. For pediatric patients, the American Academy of Pediatrics recommends screening for unhealthy substance use,[233] with one randomized controlled trial showing positive outcomes three years after adolescents were provided SBIRT.[234] Therefore, the availability of universal screening for all Floridians aged 12 and over is recommended, in line with the recommendations from the Statewide Task Force on Opioid Abuse and the Drug Policy Advisory Council,[235] and this screening should be made available at least once a year for each state resident. The increasing prevalence of OUD has meant that healthcare professionals in a variety of clinical settings care for patients with OUD. This means that education about how to conduct the screenings should not be limited to specialists. Screening for OUD should take place in a wide range of clinical settings, including primary care practices, emergency departments, and obstetrics-gynecology (OB-GYN) practices. In addition to early identification of OUD, SBIRT has the added benefit of identifying and addressing opioid misuse. The rate of prescription opioid misuse in Florida was 3.7% based on 2018-2019 data,[236] and this population could benefit from a brief intervention. The SBIRT model with universal screening will likely be most impactful in the first ten years of this proposed abatement plan. In subsequent years, as a result of other abatement strategies, the healthcare system should be in a better position to deliver care through an integrated model, where medications are initiated in the same setting as the screening.

2. Although universal screening for the early identification of OUD through widespread implementation of SBIRT is promising, a newer approach that incorporates initiation of OUD medication in the same setting as the screening, called Screening, Treatment Initiation, and Referral (STIR),[237] has shown superiority over SBIRT in the ED setting

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[232] US Preventive Services Task Force et al., "Screening for Unhealthy Drug Use: US Preventive Services Task Force Recommendation Statement," *JAMA* 323, no. 22 (June 9, 2020): 2301–9, https://doi.org/10.1001/jama.2020.8020.

[233] American Academy of Pediatrics, "Substance Use Screening and Intervention Implementation Guide," 2019, https://www.aap.org/en-us/Documents/substance_use_screening_implementation.pdf.

[234] Stacy Sterling et al., "Health Care Use Over 3 Years After Adolescent SBIRT," *Pediatrics* 143, no. 5 (May 2019): e20182803, https://doi.org/10.1542/peds.2018-2803.

[235] Drug Policy Advisory Council, "Statewide Drug Policy Advisory Council 2020 Annual Report," 2020, http://www.floridahealth.gov/provider-and-partner-resources/dpac/DPAC_11-30-20.pdf; Florida Statewide Task Force on Opioid Abuse, "Findings and Recommendations of the Statewide Task Force on Opioid Abuse," 2020, https://doseofrealityfl.com/pdfs/opioid-task-force-findings-recommendations-opioid-abuse.pdf.

[236] SAMHSA, "2018-2019 National Survey on Drug Use and Health: Model-Based Prevalence Estimates (50 States and the District of Columbia)," 2020, https://www.samhsa.gov/data/sites/default/files/reports/rpt32805/2019NSDUHsaeExcelPercents/2019NSDUHsaeExcelPercents/2019NSDUHsaePercents.pdf.

[237] Steven L. Bernstein and Gail D'Onofrio, "Screening, Treatment Initiation, and Referral for Substance Use Disorders," *Addiction Science & Clinical Practice* 12, no. 1 (August 7, 2017): 18, https://doi.org/10.1186/s13722-017-0083-z.

when measured by treatment retention after 30 days.[238] However, providers and healthcare systems must be appropriately trained and resourced to implement STIR, and there must be substantial integration of behavioral health services within medical settings to most effectively provide comprehensive care. Given the wide treatment gap and the high mortality risk for individuals with OUD, the long-term goal for OUD screening in Florida is that all primary care practices, OB-GYN practices, and emergency departments have the capacity for STIR, which should be more feasible after implementation of the abatement strategies laid out in this report.

3. While universal screening is critical in identifying OUD early in the course of the disease, healthcare professionals must be adequately trained to administer the screening. Although 81% of primary care physicians reported being somewhat or very comfortable screening for OUD according to one survey,[239] results from another survey have shown that only 6% of primary care physicians included substance use disorder as a differential diagnosis when given a vignette describing early symptoms of the disease.[240] A positive screen must be followed up with a brief intervention, which only 9% of general internists felt very well prepared to implement.[241] In order to ensure the effectiveness of universal screening among all Floridians in a clinical setting, there should be an SBIRT practice dissemination program that is accessible to all primary care practices, OB-GYN practices, and emergency departments. This dissemination program should provide education, training, and support implementation and may include academic detailing, continuing medical education, electronic medical record integration consultation, and strategies to strengthen relationships with referral partners.[242] In addition to the recent elimination of the training requirement for buprenorphine waivers,[243] several of the abatement strategies recommended in this report will help providers appropriately manage individuals diagnosed with OUD, such as Project ECHO and the statewide consultation service. The dissemination program should be in a five-year cycle where the first year initiates a new campaign and the subsequent four years represent operational costs of continued

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[238] Gail D'Onofrio et al., "Emergency Department-Initiated Buprenorphine/Naloxone Treatment for Opioid Dependence: A Randomized Clinical Trial," *JAMA* 313, no. 16 (April 28, 2015): 1636–44, https://doi.org/10.1001/jama.2015.3474.

[239] Kathryn Foti et al., "Primary Care Physicians' Preparedness to Treat Opioid Use Disorder in the United States: A Cross-Sectional Survey," *Drug and Alcohol Dependence* 225 (August 1, 2021): 108811, https://doi.org/10.1016/j.drugalcdep.2021.108811.

[240] Josiah Macy et al., *Missed Opportunity: CASA National Survey of Primary Care Physicians and Patients on Substance Abuse* (National Center on Addiction and Substance Abuse at Columbia University, 2000).

[241] Sarah E. Wakeman, Genevieve Pham-Kanter, and Karen Donelan, "Attitudes, Practices, and Preparedness to Care for Patients with Substance Use Disorder: Results from a Survey of General Internists," *Substance Abuse* 37, no. 4 (December 2016): 635–41, https://doi.org/10.1080/08897077.2016.1187240.

[242] Kelli Thoele et al., "Strategies to Promote the Implementation of Screening, Brief Intervention, and Referral to Treatment (SBIRT) in Healthcare Settings: A Scoping Review," *Substance Abuse Treatment, Prevention, and Policy* 16, no. 1 (May 11, 2021): 42, https://doi.org/10.1186/s13011-021-00380-z.

[243] U.S. Department of Health and Human Services, "Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder" (Federal Register, 2021), https://www.federalregister.gov/documents/2021/04/28/2021-08961/practice-guidelines-for-the-administration-of-buprenorphine-for-treating-opioid-use-disorder.

dissemination. Improving medical education around OUD and increasing the number of specialists who can treat OUD should shift the screening paradigm from SBIRT to STIR and diminish the need for this dissemination program after ten years.

4. Several vulnerable populations may disproportionately benefit from screening for OUD compared with the general population. Both the American College of Obstetrics and Gynecology (ACOG) and the federal Substance Abuse and Mental Health Services Administration (SAMHSA) recommend universally screening pregnant women for OUD, with ACOG making this recommendation specifically as part of obstetric prenatal care visits.[244] This is a stated goal of Florida's opioid response, as the Department of Health continues to pursue system changes to support universal screening of all pregnant women.[245] This intervention is especially important because in Florida, as further discussed above, the rate of mothers with OUD at delivery hospitalization increased more than thirteen-fold from 1999-2014 and the rate of neonatal abstinence syndrome increased sixteen-fold from 1999-2013, with pregnancy-related deaths due to drugs increasing 88% from 2008 to 2017.[246] Florida has made strides in expanding universal screening for pregnant women in hospitals. The Maternal Opioid Recovery Effort (MORE) is a hospital-based quality improvement initiative that has been implemented in 34 hospitals that have the highest NAS burden in Florida.[247] In addition to screening, MORE is training providers to initiate treatment and refer for continuing treatment, similar to a STIR model implemented in an ED discussed below. Given the dramatic rise in the incidence of NAS since 1999, the MORE initiative should be expanded to ensure that all birth centers in the state have undergone this quality improvement initiative (n = 31).[248] Screenings done at delivery hospitalization are vital opportunities to identify OUD in pregnant women,

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[244] SAMHSA, "Clinical Guidance for Treating Pregnant and Parenting Women With Opioid Use Disorder and Their Infants," 2018, https://store.samhsa.gov/product/Clinical-Guidance-for-Treating-Pregnant-and-Parenting-Women-With-Opioid-Use-Disorder-and-Their-Infants/SMA18-5054; The American College of Obstetrics and Gynecology, "Opioid Use and Opioid Use Disorder in Pregnancy," Committee Opinion, 2017, https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/08/opioid-use-and-opioid-use-disorder-in-pregnancy.

[245] Florida Department of Health, "Department of Health Opioid Response Activities," 2021.

[246] Jean Y. Ko, "Incidence of Neonatal Abstinence Syndrome — 28 States, 1999–2013," *MMWR. Morbidity and Mortality Weekly Report* 65 (2016), https://doi.org/10.15585/mmwr.mm6531a2; Sarah C. Haight, "Opioid Use Disorder Documented at Delivery Hospitalization — United States, 1999–2014," *MMWR. Morbidity and Mortality Weekly Report* 67 (2018), https://doi.org/10.15585/mmwr.mm6731a1; Florida Alcohol and Drug Abuse Association, "Drug-Related Death Leading Cause of Pregnancy-Associated Death in Florida," 2020, https://cdn.ymaws.com/www.fadaa.org/resource/resmgr/files/resource_center/FADAA_June_2020_TrendAlert6.pdf.

[247] Florida Perinatal Quality Collaborative, "Florida Maternal Opioid Recovery Effort Tool Kit: A Quality Improvement Initiative" (Tampa, FL: The Chiles Center at University of South Florida College of Public Health, 2020), https://health.usf.edu/-/media/Files/Public-Health/Chiles-Center/FPQC/MOREToolKitvFeb2020.ashx?la=en&hash=66873DB7D018E3499C1B7E41F121248780DBD462.

[248] "Facility/Provider Search Results," FloridaHealthFinder.gov, 2021, https://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx.

especially since overdose risk is highest postpartum,[249] but a more effective early intervention would be to provide universal screening at the first prenatal visit. However, a recent study showed that 61% of OB-GYN practitioners consider screening for unhealthy opioid use a high priority and only 37% felt confident in providing OUD treatment, highlighting the importance of the SBIRT practice dissemination program discussed below. The tertiary prevention section of this report provides recommendations on comprehensive treatment for women who screen positive for OUD as part of tertiary prevention.

5. Another important vulnerable population to provide universal screening for is incarcerated individuals, who have rates of OUD tenfold or higher than the general population.[250] One study estimates that between 2675 and 5557 overdose deaths would be prevented per year if universal screening for OUD were implemented in prisons and jails in the United States along with clinically-indicated medication treatment while incarcerated and sustained treatment retention post-release.[251] Assuming a homogeneous effect throughout the U.S. population, this translates to between 175 and 364 overdose deaths prevented in Florida, representing 5.5-11.4% of the opioid overdose deaths in the state in 2018.[252] Given the burden of not identifying OUD in these settings, all jails and prisons should have the capacity and the availability of funding to screen individuals for OUD upon incarceration. In the tertiary prevention section below recommendations on next steps after a positive screen in this population are discussed.

6. The emergency department (ED) is a vital touchpoint to address the opioid crisis and is uniquely positioned to help individuals with OUD. Although healthcare professionals working in EDs may see many opioid overdoses, they are also likely to see other opioid-related complications and individuals with OUD seeking care for reasons unrelated to OUD. Thus, the ED can serve as a setting for secondary and tertiary prevention, identifying cases of mild OUD as well as more severe forms of the disease. Emergency department-initiated buprenorphine (EDIB) has emerged as an evidence-based best practice according to SAMHSA and a recent systematic review.[253] The intervention also seems versatile with

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[249] Davida M. Schiff et al., "Fatal and Nonfatal Overdose Among Pregnant and Postpartum Women in Massachusetts," *Obstetrics and Gynecology* 132, no. 2 (August 2018): 466–74, https://doi.org/10.1097/AOG.0000000000002734.

[250] Nickolas Zaller et al., "Screening for Opioid Use Disorder in the Largest Jail in Arkansas: A Brief Report," *Journal of Correctional Health Care: The Official Journal of the National Commission on Correctional Health Care* 25, no. 3 (July 2019): 214–18, https://doi.org/10.1177/1078345819852133; Jennifer Bronson et al., "Drug Use, Dependence, and Abuse among State Prisoners and Jail Inmates, 2007–2009," *Washington, DC: United States Department of Justice, Office of Juvenile Justice and Delinquency Prevention*, 2017, https://bjs.ojp.gov/content/pub/pdf/dudaspji0709.pdf.

[251] Alexandria Macmadu et al., "Estimating the Impact of Wide Scale Uptake of Screening and Medications for Opioid Use Disorder in US Prisons and Jails," *Drug and Alcohol Dependence* 208 (March 1, 2020): 107858, https://doi.org/10.1016/j.drugalcdep.2020.107858.

[252] National Institute on Drug Abuse, "Florida: Opioid-Involved Deaths and Related Harms," 2020, https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/florida-opioid-involved-deaths-related-harms.

[253] SAMHSA, "Use of Medication-Assisted Treatment in Emergency Departments," 2021; Janusz Kaczorowski et al., "Emergency Department-Initiated Interventions for Patients With Opioid Use Disorder: A Systematic

respect to geographic region, with one study in a rural hospital showing that 81% of patients undergoing EDIB showed up for their first outpatient appointment and, among these patients, 86% were retained in treatment after 30 days and 66% were retained in treatment after 90 days.[254] EDIB involves implementing a STIR model in the emergency room and initiating buprenorphine treatment for individuals who screen positive for OUD, and then referring these individuals to an outpatient setting to continue treatment. Once a patient is initiated on buprenorphine, the linking mechanism to continuing care is crucial for high treatment retention rates.[255] Some programs have successfully used social workers[256] to provide a warm handoff to outpatient treatment while others have used peers.[257] A "warm handoff" means either introducing the patient to a treatment provider or making an appointment with the individual and taking supportive measures to ensure they attend the appointment. In the context of interventions to address OUD, a "peer" refers to a person who has lived experience with OUD or addiction in general. In addition to EDIB, best practices should also include providing take-home naloxone to the patient and family members or friends, as a systematic review has shown that this intervention gets naloxone into the hands of those highly likely to witness an opioid overdose.[258] Peers also have the potential to deliver other harm reduction services in addition to naloxone distribution.[259]

7. Despite the evidence for EDIB, there are barriers to implementing this intervention that must be addressed. One study found that 34% of non-waivered emergency room physicians (i.e. not specially trained to prescribe buprenorphine) felt comfortable initiating buprenorphine compared with 96% of waivered physicians, underscoring the importance

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Review," *Academic Emergency Medicine: Official Journal of the Society for Academic Emergency Medicine* 27, no. 11 (November 2020): 1173–82, https://doi.org/10.1111/acem.14054.

[254] Frank J. Edwards et al., "Treating Opioid Withdrawal With Buprenorphine in a Community Hospital Emergency Department: An Outreach Program," *Annals of Emergency Medicine* 75, no. 1 (January 1, 2020): 49–56, https://doi.org/10.1016/j.annemergmed.2019.08.420.

[255] Randi Sokol et al., "Linking MATTERS: Barriers and Facilitators to Implementing Emergency Department-Initiated Buprenorphine-Naloxone in Patients with Opioid Use Disorder and Linkage to Long-Term Care," *Substance Use & Misuse* 56, no. 7 (2021): 1045–53, https://doi.org/10.1080/10826084.2021.1906280.

[256] Timothy Kelly et al., "A Novel Social Work Approach to Emergency Department Buprenorphine Induction and Warm Hand-off to Community Providers," *The American Journal of Emergency Medicine* 38, no. 6 (June 2020): 1286–90, https://doi.org/10.1016/j.ajem.2019.12.038.

[257] Carolyn Bogan et al., "Implementation of Emergency Department-Initiated Buprenorphine for Opioid Use Disorder in a Rural Southern State," *Journal of Substance Abuse Treatment* 112S (March 2020): 73–78, https://doi.org/10.1016/j.jsat.2020.02.007; Lindsey K. Jennings et al., "Retention in Treatment after Emergency Department-Initiated Buprenorphine," *The Journal of Emergency Medicine*, June 25, 2021, https://doi.org/10.1016/j.jemermed.2021.04.007.

[258] Yanjin Chen et al., "A Systematic Review of Opioid Overdose Interventions Delivered within Emergency Departments," *Drug and Alcohol Dependence* 213 (May 23, 2020): 108009, https://doi.org/10.1016/j.drugalcdep.2020.108009.

[259] Alice E. Welch et al., "Relay: A Peer-Delivered Emergency Department-Based Response to Nonfatal Opioid Overdose," *American Journal of Public Health* 109, no. 10 (October 2019): 1392–95, https://doi.org/10.2105/AJPH.2019.305202.

of education in this setting.[260] Another study found that only 27% of emergency room physicians felt prepared to initiate buprenorphine and 29% felt prepared to connect patients to outpatient treatment.[261] In addition to the educational interventions recommended as part of tertiary prevention in this report, adoption of EDIB has been facilitated by a user-centered computerized clinical decision support system. One study showed that this system increased buprenorphine imitation, naloxone distribution, and was well-received by providers in the ED.[262] Another barrier is that the seminal study on EDIB, a randomized controlled trial, found that treatment retention at six months was no better than SBIRT with referral to outpatient buprenorphine treatment, emphasizing the importance of continuity of care after initiation of this intervention. Employing peers and social workers in these settings holds promise,[263] as does referring patients to bridge clinics that are co-located with hospitals, further discussed below.

8. In Florida, it was reported that 79% of all opioid-related emergency department visits were discharged under routine care (self-care) from 2016 to 2018 and only 3.5% were transferred to care in other settings.[264] This statistic has been highlighted by the Statewide Task Force on Opioid Abuse as a reason for implementing interventions in the ED as a goal for Florida's response to the opioid crisis. Specifically, the task force recommends the expansion of hospital bridges. Hospital bridge programs are essentially EDIB initiatives that identify and treat OUD with buprenorphine in the ED setting, then refer the patient to an outpatient setting for continuing treatment. In other words, they generally use a STIR model. Both the Statewide Task Force on Opioid Abuse and the Drug Policy Advisory Council recommend distributing take-home naloxone kits in this setting.[265] A portion of the state's SOR grant (a federal grant from SAMHSA intended to help states address the opioid crisis) has been earmarked to implement these programs. Currently, several program model approaches initiate buprenorphine and use peers in the ED to provide a warm handoff to treatment. Brandon Regional Hospital in the Tampa area has a model program

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[260] Matthew Zuckerman et al., "Physician Attitudes on Buprenorphine Induction in the Emergency Department: Results from a Multistate Survey," *Clinical Toxicology (Philadelphia, Pa.)* 59, no. 4 (April 2021): 279–85, https://doi.org/10.1080/15563650.2020.1805461.

[261] Margaret Lowenstein et al., "Barriers and Facilitators for Emergency Department Initiation of Buprenorphine: A Physician Survey," *The American Journal of Emergency Medicine* 37, no. 9 (September 2019): 1787–90, https://doi.org/10.1016/j.ajem.2019.02.025.

[262] Wesley C. Holland et al., "Interrupted Time Series of User-Centered Clinical Decision Support Implementation for Emergency Department-Initiated Buprenorphine for Opioid Use Disorder," *Academic Emergency Medicine: Official Journal of the Society for Academic Emergency Medicine* 27, no. 8 (August 2020): 753–63, https://doi.org/10.1111/acem.14002.

[263] Bogan et al., "Implementation of Emergency Department-Initiated Buprenorphine for Opioid Use Disorder in a Rural Southern State"; Sokol et al., "Linking MATTERS."

[264] Florida Department of Children and Families, "Patterns and Trends of the Opioid Epidemic in Florida," 2020, https://www.myflfamilies.com/service-programs/samh/publications/docs/Florida%20SEOW%20Annual%20Report%202019.pdf.

[265] Florida Statewide Task Force on Opioid Abuse, "Findings and Recommendations of the Statewide Task Force on Opioid Abuse"; Drug Policy Advisory Council, "Statewide Drug Policy Advisory Council 2020 Annual Report."

to initiate buprenorphine in the ED and provide a warm handoff to treatment.[266] Project Saves Lives, operating in five EDs in Jacksonville, employs a recovery coach to provide a warm handoff to treatment and recovery services, and reports a decrease in overdoses among its participants.[267] In line with the goals of leaders in Florida, hospital bridges should be expanded to all EDs in Florida who are willing to adopt such a program, and these programs should have access to a computerized clinical decision support system to facilitate implementation. Given the evidence for EDIB and take-home naloxone, these bridge programs should have the capacity to initiate buprenorphine and distribute naloxone to patients and their friends or family members. Taking into account the importance of linking people to treatment after initiating buprenorphine in the ED, bridge clinics should be present in the largest hospitals, as discussed below, and peers should be employed in these EDs to ensure a warm handoff to outpatient treatment. Other interventions discussed in the treatment retention subsection of the tertiary prevention section of this report will improve treatment retention for those that initiate buprenorphine in EDs.

9. Helplines, also known as quitlines, are an efficient and immediate source of information for individuals affected by substance use disorders and their families. This resource not only delivers information but can also link individuals to treatment. Empirical evidence suggests that helplines are effective for tobacco cessation[268] and gambling problems.[269] Although Florida does not have a helpline dedicated to addiction treatment, the state has the 211 Network, which serves as a coordination center for information and referral for a wide range of health and human services. This statewide service fielded over one million phone calls, texts, and emails in 2018, with "mental health and addiction" as one of the top categories for caller needs. More than 3,500 contacts were specifically related to OUD treatment.[270] West Virginia has a helpline specific to addiction treatment, HELP4WV, where peer support specialists field many of the calls.[271] Indiana's 211 Network has collaborated with a software platform to integrate real-time treatment availability into their services.[272] In line with the recommendations from the Statewide Task Force on Opioid

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[266] National Council for Mental Wellbeing, "Addressing Opioid Use Disorder in Emergency Departments: Expert Panel Findings," n.d., https://www.thenationalcouncil.org/wp-content/uploads/2021/02/NCBH_TEP_Opioid_Toolkit_v5_021021.pdf?daf=375ateTbd56.

[267] City of Jacksonville, "Project Saves Lives Status Report," 2020, http://myfloridalegal.com/webfiles.nsf/WF/SSWN-BSLN5S/$file/Project+Save+Lives+and+JFRD+Overdose+Status+Report+August+17+2020.pdf.

[268] Edward Lichtenstein, Shu-Hong Zhu, and Gary J. Tedeschi, "Smoking Cessation Quitlines: An Underrecognized Intervention Success Story.," *American Psychologist* 65, no. 4 (2010): 252.

[269] Simone N. Rodda, Nerilee Hing, and Dan I. Lubman, "Improved Outcomes Following Contact with a Gambling Helpline: The Impact of Gender on Barriers and Facilitators," *International Gambling Studies* 14, no. 2 (2014): 318–29.

[270] Florida Statewide Task Force on Opioid Abuse, "Findings and Recommendations of the Statewide Task Force on Opioid Abuse."

[271] West Virginia Department of Health & Human Resources, "HELP4WV," n.d., https://www.help4wv.com/.

[272] Indiana Family & Social Services Administration, "Indiana Announces New Partnership to Connect Hoosiers with Drug Treatment," 2018, https://www.in.gov/fssa/files/FINAL-OpenBeds-211-press-release.pdf.

Abuse,[273] Florida should leverage the 211 Network and expand its role to include an addiction treatment helpline that provides quality information on access to treatment and linkage to treatment. Specific services that could be provided through a special helpline specific to addiction treatment include brief education on topics related to OUD, real-time information on treatment availability, service referral and navigation support, crisis and de-escalation support, and follow-up services. The 211 Network addiction helpline should be available 24/7 to Floridians and be primarily staffed by the peer workforce. A media campaign and other communication channels should be utilized to increase awareness of this statewide service.

10. Prescription drug monitoring programs (PDMPs) are electronic databases that can be used to collect and disseminate information about controlled substance prescribing within a state. As a secondary prevention intervention, PDMPs can be used to identify individuals with high-risk prescription opioid use by providing prescribers and dispensers access to information regarding a patient's controlled substance history. PDMPs also have the potential to play a role in primary prevention by reducing overall opioid prescribing to the general population. A systematic review concluded that PDMPs reduce prescriptions for schedule II controlled substances and decrease the number of multiple provider episodes,[274] with one study showing a 30% reduction in schedule II controlled substances after implementation of a PDMP.[275] Clinical decision support systems (CDSS) have been implemented to facilitate electronic health record integration and make this information actionable. This system may consist of automated alerts, reminders, prompts, templates, or care guidelines that are designed to provide providers, patients, or other members of the care team with customized, real-time information to improve health care quality. In the context of the opioid crisis, this may include a CDSS that provides actionable information from integration of electronic health records with the PDMP. Although there is an absence of rigorous studies on CDSS and opioid prescribing,[276] in general, systematic reviews have

[273] Florida Statewide Task Force on Opioid Abuse, "Findings and Recommendations of the Statewide Task Force on Opioid Abuse."

[274] Maria N. Wilson et al., "Effectiveness of Prescription Monitoring Programs in Reducing Opioid Prescribing, Dispensing, and Use Outcomes: A Systematic Review," *The Journal of Pain* 20, no. 12 (December 2019): 1383–93, https://doi.org/10.1016/j.jpain.2019.04.007.

[275] Yuhua Bao et al., "Prescription Drug Monitoring Programs Are Associated With Sustained Reductions In Opioid Prescribing By Physicians," *Health Affairs (Project Hope)* 35, no. 6 (June 1, 2016): 1045–51, https://doi.org/10.1377/hlthaff.2015.1673.

[276] Sheryl Spithoff et al., "Clinical Decision Support Systems for Opioid Prescribing for Chronic Non-Cancer Pain in Primary Care: A Scoping Review," *Journal of the American Board of Family Medicine: JABFM* 33, no. 4 (August 2020): 529–40, https://doi.org/10.3122/jabfm.2020.04.190199.

shown that CDSSs improve prescriber performance[277] and improve the quality of patient care when certain features are implemented.[278]

11. The PDMP in Florida, called the Electronic-Florida Online Reporting of Controlled Substance Evaluation Program (E-FORSCE), was implemented in 2011.[279] Implementation of these laws was associated with a modest decrease in opioid prescribing and MMEs per prescription generally,[280] large relative reductions in prescription opioid utilization among high-risk patients,[281] decreases in opioid-related hospitalizations and ED visits,[282] and a 25% decrease in oxycodone-related mortality.[283] Since its initial implementation, Florida has made great strides in creating a robust PDMP. Currently, there are mandatory checks of the E-FORCSE by the prescriber and the dispenser before prescribing or dispensing a prescription opioid. Florida also has a limit on the number of days a prescription opioid can be given for acute pain (3-7 days). These changes have corresponded with an 87% decrease in multiple provider episodes, a proxy for doctor shopping, from 2012 to 2020, and a steady decrease in opioid prescribing, with a 5.5% decrease in prescriptions for controlled substances and a 14.6% decrease in the average daily MMEs per prescription in fiscal year 2020 alone compared to the previous year.[284] The E-FORSCE generates quarterly reports for prescribers that provides feedback on how their prescribing compares with other healthcare professionals in their field.

12. The E-FORSCE is largely an informational database that provides information to healthcare professionals to guide their decisions in prescribing and dispensing controlled substances. The database is housed and analyzed by an outside vendor. The E-FORSCE should be funded so that the program has the administrative and data professional staff to house and analyze the PDMP data without having to contract with an outside vendor. The

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[277] Amit X. Garg et al., "Effects of Computerized Clinical Decision Support Systems on Practitioner Performance and Patient Outcomes: A Systematic Review," *JAMA* 293, no. 10 (March 9, 2005): 1223–38, https://doi.org/10.1001/jama.293.10.1223.

[278] Kensaku Kawamoto et al., "Improving Clinical Practice Using Clinical Decision Support Systems: A Systematic Review of Trials to Identify Features Critical to Success," *BMJ (Clinical Research Ed.)* 330, no. 7494 (April 2, 2005): 765, https://doi.org/10.1136/bmj.38398.500764.8F.

[279] Florida Department of Health, "Prescription Drug Monitoring Program Annual Report: Fiscal Year 2019-2020," 2020.

[280] Lainie Rutkow et al., "Effect of Florida's Prescription Drug Monitoring Program and Pill Mill Laws on Opioid Prescribing and Use," *JAMA Internal Medicine* 175, no. 10 (October 2015): 1642–49, https://doi.org/10.1001/jamainternmed.2015.3931.

[281] Hsien-Yen Chang et al., "Impact of Florida's Prescription Drug Monitoring Program and Pill Mill Law on High-Risk Patients: A Comparative Interrupted Time Series Analysis," *Pharmacoepidemiology and Drug Safety* 27, no. 4 (April 2018): 422–29, https://doi.org/10.1002/pds.4404.

[282] Gery P. Guy and Kun Zhang, "Effect of State Policy Changes in Florida on Opioid-Related Overdoses," *American Journal of Preventive Medicine* 58, no. 5 (May 2020): 703–6, https://doi.org/10.1016/j.amepre.2019.11.008.

[283] Chris Delcher et al., "Abrupt Decline in Oxycodone-Caused Mortality after Implementation of Florida's Prescription Drug Monitoring Program," *Drug and Alcohol Dependence* 150 (May 1, 2015): 63–68, https://doi.org/10.1016/j.drugalcdep.2015.02.010.

[284] Florida Department of Health, "Prescription Drug Monitoring Program Annual Report: Fiscal Year 2019-2020."

data from Florida's PDMP should be used to target educational interventions towards high-risk prescribers, as discussed above regarding academic detailing. The E-FORSCE should also be funded to integrate with public and private electronic health record systems given that this integration of systems has been shown to improve patient outcomes.[285] This will allow the full implementation of a CDSS that can provide alerts and prompts to prescribers and dispensers of prescription opioids. This is just one of the benefits of creating a data warehouse in Florida that integrates data from multiple state agencies.

13. Many of the primary prevention interventions already discussed are likely to shift healthcare professionals from managing pain with prescription opioids to treating pain with non-opioid pain management therapies, thereby reducing the incidence of individuals placed on high doses of prescription opioids long-term for non-cancer chronic pain. However, there is already a cohort of people who are opioid dependent from this type of treatment. This population is complex. One study estimates that lifetime prevalence of OUD among individuals on long-term opioid therapy is 41%.[286] Additionally, it is estimated that around half of individuals in pain management programs have comorbid depression,[287] and nearly two-thirds of those with OUD also have a chronic pain condition as documented by claims data.[288] Therefore, a comprehensive set of interventions is needed for individuals who are opioid dependent as a result of chronic pain treatment. These interventions should include screening for opioid misuse and OUD, interdisciplinary pain management, intensive and holistic support if undergoing a tapering protocol, and transition to buprenorphine if warranted.

14. As previously noted, rates of lifetime OUD among individuals on long-term opioid therapy are high. Therefore, screening and monitoring is crucial to mitigate opioid-related harms in this population. All patients in Florida who are currently on long-term opioid therapy need to be screened frequently for opioid misuse and OUD and monitored using urine drug testing at least annually.

15. Discontinuation of long-term opioid therapy (i.e. tapering) is often slow, difficult and intensive process for patients and can affect multiple domains of their lives.[289] Therefore, supportive interventions should be delivered to individuals undergoing tapering. A randomized controlled trial, supporting this type of care, found that a 22-week program

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[285] Lucy Xiaolu Wang, "The Complementarity of Drug Monitoring Programs and Health IT for Reducing Opioid-Related Mortality and Morbidity," *Health Economics*, May 27, 2021, https://doi.org/10.1002/hec.4360.

[286] Joseph A. Boscarino, Stuart N. Hoffman, and John J. Han, "Opioid-Use Disorder among Patients on Long-Term Opioid Therapy: Impact of Final DSM-5 Diagnostic Criteria on Prevalence and Correlates," *Substance Abuse and Rehabilitation* 6 (2015): 83–91, https://doi.org/10.2147/SAR.S85667.

[287] Matthew J. Bair et al., "Depression and Pain Comorbidity: A Literature Review," *Archives of Internal Medicine* 163, no. 20 (November 10, 2003): 2433–45, https://doi.org/10.1001/archinte.163.20.2433.

[288] Yih-Ing Hser et al., "Chronic Pain among Patients with Opioid Use Disorder: Results from Electronic Health Records Data," *Journal of Substance Abuse Treatment* 77 (June 2017): 26–30, https://doi.org/10.1016/j.jsat.2017.03.006.

[289] Stephen G. Henry et al., "Patients' Experience With Opioid Tapering: A Conceptual Model With Recommendations for Clinicians," *The Journal of Pain* 20, no. 2 (February 1, 2019): 181–91, https://doi.org/10.1016/j.jpain.2018.09.001.

consisting of a psychiatric consultation, 18 weekly meetings with a physician assistant to explore motivation for tapering and learn pain self-management skills, and opioid dose tapering showed promise in reducing opioid dose while not increasing pain severity or interference compared to individuals who remained on the same dose of opioids.[290] Buprenorphine may be a good option for chronic pain patients with opioid dependence who are having difficulty tapering.[291] A meta-analysis has found this medication to have a small but significant effect in lowering pain intensity for patients with comorbid chronic pain and OUD and a moderate to large effect in chronic pain patients without OUD.[292] Chronic pain patients on long-term opioid therapy who, through a shared decision-making process with their providers, undergo opioid tapering should be provided with a range of supportive interventions including assessment and treatment for psychiatric comorbidities, interdisciplinary non-opioid pain management that includes cognitive behavioral therapy and psychological coaching, and buprenorphine treatment if warranted.

16. It is possible that some individuals on long-term opioid therapy in Florida may be captured in the OUD prevalence that I have estimated above (e.g. already have been clinically documented as having an OUD). Using lifetime prevalence of OUD (defined as reporting two or more symptoms of OUD in a person's lifetime) among those on long-term opioid therapy as calculated by Boscarino et al,[293] it is a reasonable assumption that 13.2% are likely to meet criteria for a lifetime moderate to severe OUD (report four or more symptoms), and these individuals on long-term opioid therapy are most likely to be captured in the OUD prevalence estimation. However, the 28.1% of individuals who are likely to experience mild OUD in their lifetime (report 2-3 symptoms) would probably not be captured by my OUD estimation and may be good candidates for buprenorphine treatment as discussed in the paragraph above. The remaining 58.7% of individuals on long-term opioid therapy who are likely to not have a lifetime OUD, should have access to non-opioid pain services to help reduce their opioid use.

17. In addition to the primary prevention intervention of providing counter detailing to all opioid prescribers in the state, academic detailing providing one-on-one, in-person education by appropriately trained healthcare professionals should be targeted to the highest decile prescribers, who are likely to have many patients on long-term opioid therapy who may either feel stuck on opioids or have become addicted. This detailing should include best practices on managing the many patients who are opioid-dependent as

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[290] Mark D. Sullivan et al., "Prescription Opioid Taper Support for Outpatients With Chronic Pain: A Randomized Controlled Trial," *The Journal of Pain* 18, no. 3 (March 2017): 308–18, https://doi.org/10.1016/j.jpain.2016.11.003.

[291] Roger Chou, Jane Ballantyne, and Anna Lembke, "Rethinking Opioid Dose Tapering, Prescription Opioid Dependence, and Indications for Buprenorphine," *Annals of Internal Medicine* 171, no. 6 (September 17, 2019): 427–29, https://doi.org/10.7326/M19-1488.

[292] Asimina Lazaridou et al., "Is Buprenorphine Effective for Chronic Pain? A Systematic Review and Meta-Analysis," *Pain Medicine (Malden, Mass.)* 21, no. 12 (December 25, 2020): 3691–99, https://doi.org/10.1093/pm/pnaa089.

[293] Joseph A. Boscarino, Stuart N. Hoffman, and John J. Han, "Opioid-Use Disorder among Patients on Long-Term Opioid Therapy: Impact of Final DSM-5 Diagnostic Criteria on Prevalence and Correlates," *Substance Abuse and Rehabilitation* 6 (2015): 83–91, https://doi.org/10.2147/SAR.S85667.

well as identifying and treating individuals who have developed OUD as a result of long-term opioid therapy. The top 10% of prescribers, which may include physicians, physician assistants, and nurse practitioners, should be determined annually by the PDMP and receive this type of academic detailing. The impact of this abatement strategy is likely to be most impactful for the first ten years.

(d) TERTIARY PREVENTION

The goal of tertiary prevention is to manage OUD by improving an individual's quality of life, limiting opioid-related harms, and preventing opioid overdoses and overdose deaths.[294] Abatement strategies that fall under tertiary prevention will include interventions that effectively treat cases of OUD, expand access to care, address the treatment gap by linking untreated individuals to evidence-based treatment, and reduce opioid-related harm. These interventions will largely fall into the domains of harm reduction strategies, comprehensive OUD treatment with medications, and recovery support services to provide a full continuum of care for individuals with OUD.

Given the chronic nature of OUD for most affected individuals,[295] access to FDA-approved medications (buprenorphine, methadone, and extended-release naltrexone) should be made available to each individual with OUD, though a variety of factors, such as age, severity, stigma, and patient preference, may not result in 100% uptake of these medications. Each of these medications may be part of an individualized and comprehensive OUD treatment plan, though methadone and buprenorphine are associated with the best outcomes.[296] Each individual who initiates these medications should have access to long-term care, in some instances for a lifetime, primarily because the evidence is clear that treatment retention reduces mortality risk.[297] Other than medication treatment, proposed tertiary prevention interventions are likely to have the most impact within the next 30 years.

Tertiary prevention abatement strategies will consist of individual-level and organizational-level interventions. New infrastructure will need to be built and existing infrastructure will need to be upgraded to expand access to MOUD, thus increasing the supply of evidence-based OUD treatment. In addition, new and innovative programs will need to be implemented and existing programs will need to be enhanced to increase the demand for OUD treatment among those suffering from OUD. The following strategies in this section aim to

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[294] Kolodny et al., "The Prescription Opioid and Heroin Crisis."

[295] Christina Marel et al., "Modelling Long-Term Joint Trajectories of Heroin Use and Treatment Utilisation: Findings from the Australian Treatment Outcome Study," *EClinicalMedicine* 14 (September 2019): 71–79, https://doi.org/10.1016/j.eclinm.2019.07.013; Y. I. Hser et al., "A 33-Year Follow-up of Narcotics Addicts," *Archives of General Psychiatry* 58, no. 5 (May 2001): 503–8, https://doi.org/10.1001/archpsyc.58.5.503.

[296] Wakeman et al., "Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder"; Larochelle et al., "Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association With Mortality."

[297] Santo et al., "Association of Opioid Agonist Treatment With All-Cause Mortality and Specific Causes of Death Among People With Opioid Dependence"; Ma et al., "Effects of Medication-Assisted Treatment on Mortality among Opioids Users"; Sordo et al., "Mortality Risk during and after Opioid Substitution Treatment"; Larochelle et al., "Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association With Mortality."

augment supply and demand along with ensuring that individuals are retained in treatment and that the care delivered is evidence-based and comprehensive.

OUD often follows a course similar to other chronic diseases, where patients in remission remain prone to relapse. And like other chronic diseases, effective treatments are available to manage the condition over the long term. I recommend these treatments, which involve the use of medication, for the large majority of the Florida population that meets criteria for OUD (~90%) given that some individuals will not prefer medication treatment,[298] and others have reported resolving an opioid problem without medication.[299] Although there may never be optimal uptake of medication treatment for OUD, due to a wide range of factors, many of the educational and stigma reduction interventions recommended in this abatement plan aim to address these factors that may allow for attaining this recommended percentage. There are no clear clinical guidelines on matching individuals to one of the three types of MOUD, although opioid agonists (methadone and buprenorphine) are associated with better outcomes. Therefore, it should be assumed that the proportions of each type of MOUD among the 107,044 Floridians that initiated these medications in 2019 will likely be similar in the future, though there may be a slight increase in buprenorphine utilization as this treatment modality offers more flexibility, an attractive feature for stable patients. In general, robust tertiary prevention interventions should be in place for the next 30 years, whereupon they may begin to have a diminished effect as the treatment gap narrows and more individuals with OUD are stable on medications. However, many individuals may need to be on lifetime medication treatment to achieve the best outcomes.

Although some of the more than 107,000 individuals with OUD who have recently initiated MOUD will be in early OUD remission and not need all of the services recommended, most are likely to still need comprehensive and long-term treatment and recovery support services given the chronic nature of OUD and the low treatment retention among those who initiate MOUD. All of the more than 275,000 individuals with OUD who have not recently initiated MOUD are recommended to receive services that link and engage them in treatment services along with access to recovery support and harm reduction services outlined in this section of the abatement plan. Based on my clinical experience treating OUD, not everyone will need ancillary treatment services during a treatment episode (e.g. outpatient treatment). Research supports my clinical observation, as 41% of Medicaid beneficiaries in Pennsylvania who were on buprenorphine treatment also used behavioral health counseling.[300] Therefore, it is a reasonable assumption that half of individuals initiating medication treatment should also receive outpatient treatment, which includes individual and group counseling. Research suggests that it takes at least five serious recovery attempts, on

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[298] Genie L. Bailey, Debra S. Herman, and Michael D. Stein, "Perceived Relapse Risk and Desire for Medication Assisted Treatment among Persons Seeking Inpatient Opiate Detoxification," *Journal of Substance Abuse Treatment* 45, no. 3 (September 2013): 302–5, https://doi.org/10.1016/j.jsat.2013.04.002; Lisa A. Uebelacker et al., "Patients' Beliefs About Medications Are Associated with Stated Preference for Methadone, Buprenorphine, Naltrexone, or No Medication-Assisted Therapy Following Inpatient Opioid Detoxification," *Journal of Substance Abuse Treatment* 66 (July 2016): 48–53, https://doi.org/10.1016/j.jsat.2016.02.009.

[299] Lauren A. Hoffman, Corrie Vilsaint, and John F. Kelly, "Recovery from Opioid Problems in the US Population: Prevalence, Pathways, and Psychological Well-Being," *Journal of Addiction Medicine* 14, no. 3 (2020): 207–16.

[300] Adam J. Gordon et al., "Patterns and Quality of Buprenorphine Opioid Agonist Treatment in a Large Medicaid Program," *Journal of Addiction Medicine* 9, no. 6 (December 2015): 470–77, https://doi.org/10.1097/ADM.0000000000000164.

average, to resolve an opioid problem, suggesting that individuals with OUD will need to undergo several treatment episodes before experiencing OUD remission.[301]

(i) Link individuals with moderate to severe OUD to treatment

The treatment gap refers to the fact that a majority of individuals with OUD do not receive any type of treatment. Among those who meet criteria for OUD according to national surveys, studies have found that only 17-31% get any type of treatment,[302] with still fewer receiving MOUD. Among those with clinically documented OUD, studies using claims data (one using a nationally representative sample of the commercially insured population,[303] and another using a sample of over one million patients across six healthcare systems in five states,[304]) suggest that between 16-21% of patients are receiving MOUD. Specific to Florida, one study used claims data from 2017 and 2018 to show that only 28% of the state's Medicaid beneficiaries with a clinically documented case of OUD were receiving MOUD.[305] This subsection recommends a wide range of interventions to link individuals to OUD treatment that are necessary to address the treatment gap. Many of these interventions are considered innovative and, although evidence-informed and based on a sound scientific rationale, empirical data for these programs is only recently emerging.

1. The strongest risk factor for an opioid-related overdose death is a previous nonfatal overdose,[306] with one study showing that 5.5% of patients who experienced a nonfatal opioid overdose died within one year.[307] The time period right after a nonfatal overdose presents a unique yet frequently missed opportunity to engage individuals with OUD in

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[301] John F. Kelly et al., "How Many Recovery Attempts Does It Take to Successfully Resolve an Alcohol or Drug Problem? Estimates and Correlates From a National Study of Recovering U.S. Adults," *Alcoholism, Clinical and Experimental Research* 43, no. 7 (July 2019): 1533–44, https://doi.org/10.1111/acer.14067.

[302] Namkee G. Choi et al., "Adults Who Misuse Opioids: Substance Abuse Treatment Use and Perceived Treatment Need," *Substance Abuse* 40, no. 2 (April 3, 2019): 247–55, https://doi.org/10.1080/08897077.2019.1573208; Li-Tzy Wu, He Zhu, and Marvin S. Swartz, "Treatment Utilization among Persons with Opioid Use Disorder in the United States," *Drug and Alcohol Dependence* 169 (December 2016): 117–27, https://doi.org/10.1016/j.drugalcdep.2016.10.015; Brendan Saloner and Shankar Karthikeyan, "Changes in Substance Abuse Treatment Use Among Individuals With Opioid Use Disorders in the United States, 2004-2013," *JAMA* 314, no. 14 (October 13, 2015): 1515, https://doi.org/10.1001/jama.2015.10345; Taeho Greg Rhee and Robert A. Rosenheck, "Use of Drug Treatment Services Among Adults With Opioid Use Disorder: Rates, Patterns, and Correlates," *Psychiatric Services (Washington, D.C.)* 70, no. 11 (November 1, 2019): 992–99, https://doi.org/10.1176/appi.ps.201900163.

[303] Jake R. Morgan et al., "Injectable Naltrexone, Oral Naltrexone, and Buprenorphine Utilization and Discontinuation among Individuals Treated for Opioid Use Disorder in a United States Commercially Insured Population," *Journal of Substance Abuse Treatment* 85 (February 2018): 90–96, https://doi.org/10.1016/j.jsat.2017.07.001.

[304] Lapham, "Prevalence and Treatment of Opioid Use Disorders among Primary Care Patients in Six Health Systems."

[305] Johnson et al., "Treatment for Opioid Use Disorder in the Florida Medicaid Population."

[306] Noa Krawczyk et al., "Predictors of Overdose Death Among High-Risk Emergency Department Patients With Substance-Related Encounters: A Data Linkage Cohort Study," *Annals of Emergency Medicine* 75, no. 1 (January 2020): 1–12, https://doi.org/10.1016/j.annemergmed.2019.07.014.

[307] Scott G Weiner et al., "One-Year Mortality of Patients After Emergency Department Treatment for Nonfatal Opioid Overdose" 75, no. 1 (2020): 5.

evidence-based interventions.[308] In Florida, it was reported that 79% of all opioid-related emergency department visits were discharged without a treatment plan from 2016 to 2018 and it is likely that the percentage not offered services is much higher for those that refused medical transport after experiencing a nonfatal overdose.[309] Post-overdose response teams (also known as quick response teams) have emerged to fill this gap, offering an innovative way to mitigate overdose risk and link people to treatment. Although programs vary, the most common model is that a team comprised of a uniformed first responder (e.g. police officer or paramedic) and a public health worker (e.g. social worker or recovery coach) utilize contact information from emergency service calls to visit individuals in the community who have recently experienced a nonfatal overdose and offer harm reduction services and a warm handoff to treatment.[310] The results of these new programs are promising, showing that they reach vulnerable populations and link many individuals to treatment.[311] One pilot study used a randomized design to show that individuals who experienced a nonfatal opioid overdose and were followed up by the post-overdose response team had 20 times higher odds of receiving MOUD compared with the control group.[312] There are several programs in Florida that have begun to offer this service to the community, although expanding these programs is needed to address the treatment gap. Although not a program that does active outreach in the community, Project Saves Lives, operating in five EDs in Jacksonville, employs a recovery coach to provide a warm handoff to treatment and recovery services, and reports a decrease in overdoses among its participants.[313] The Palm Beach County Fire Rescue has collaborated with peers at Rebel Recovery to provide telephone outreach within 72 hours of a person experiencing an opioid overdose, offering a warm handoff to services. The program is associated with a decrease

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[308] Scott W. Formica et al., "Characteristics of Post-Overdose Public Health-Public Safety Outreach in Massachusetts," *Drug and Alcohol Dependence* 219 (February 1, 2021): 108499, https://doi.org/10.1016/j.drugalcdep.2020.108499; Marc R. Larochelle et al., "Touchpoints - Opportunities to Predict and Prevent Opioid Overdose: A Cohort Study," *Drug and Alcohol Dependence* 204 (November 1, 2019): 107537, https://doi.org/10.1016/j.drugalcdep.2019.06.039.

[309] Florida Department of Children and Families, "Patterns and Trends of the Opioid Epidemic in Florida," 2020, https://www.myflfamilies.com/service-programs/samh/publications/docs/Florida%20SEOW%20Annual%20Report%202019.pdf.

[310] Sarah M. Bagley et al., "A Scoping Review of Post Opioid-Overdose Interventions," *Preventive Medicine* 128 (November 2019): 105813, https://doi.org/10.1016/j.ypmed.2019.105813.

[311] James Langabeer et al., "Outreach to People Who Survive Opioid Overdose: Linkage and Retention in Treatment," *Journal of Substance Abuse Treatment* 111 (April 2020): 11–15, https://doi.org/10.1016/j.jsat.2019.12.008; Chin Hwa Gina Dahlem et al., "Recovery Opioid Overdose Team (ROOT) Pilot Program Evaluation: A Community-Wide Post-Overdose Response Strategy," *Substance Abuse*, December 7, 2020, 1–5, https://doi.org/10.1080/08897077.2020.1847239; Katherine M. Waye et al., "Implementing Peer Recovery Services for Overdose Prevention in Rhode Island: An Examination of Two Outreach-Based Approaches," *Addictive Behaviors* 89 (February 2019): 85–91, https://doi.org/10.1016/j.addbeh.2018.09.027.

[312] Christy K. Scott et al., "Findings from the Recovery Initiation and Management after Overdose (RIMO) Pilot Study Experiment," *Journal of Substance Abuse Treatment* 108 (January 2020): 65–74, https://doi.org/10.1016/j.jsat.2019.08.004.

[313] City of Jacksonville, "Project Saves Lives Status Report," 2020, http://myfloridalegal.com/webfiles.nsf/WF/SSWN-BSLN5S/$file/Project+Save+Lives+and+JFRD+Overdose+Status+Report+August+17+2020.pdf.

in opioid-related calls in the county.[314] All of Florida's 67 counties should have a post-overdose response team, with several in counties with several densely populated municipalities. At the very least, this type of program should provide services in all counties in Florida. For comparison, as of 2019, 156 municipalities in Massachusetts, a state with one-third of Florida's population, reported having a post-overdose response team.[315]

2. Using mobile outreach teams is another innovative way to address the treatment gap by delivering treatment and other services to hard-to-reach populations. This intervention typically involves outreach via a mobile van and is well-equipped to overcome the myriad barriers to treatment for vulnerable populations, such as those experiencing homelessness. This intervention is also versatile and can be targeted to overdose hotspots when complemented with a robust surveillance system. These programs are typically found in urban areas, provide buprenorphine treatment on site, and offer a wide range of harm reduction and other services. Mobile outreach has been implemented with success in several scenarios: for individuals with OUD not currently engaged in care and at highest risk for overdose in Boston;[316] across from a Baltimore jail to initiate treatment for those who have been recently incarcerated;[317] and targeting veterans experiencing homelessness in Connecticut (via mobile technology).[318] These programs commonly show increased initiation and engagement in MOUD among high-risk and vulnerable populations. To my knowledge, the mobile component of IDEA Exchange, the first syringe service program in Florida, is an intervention that might be considered a mobile outreach program to address the opioid crisis in the state. Each of Florida's large urban centers (Orlando, Tampa, Jacksonville, Miami, and Fort Lauderdale) should have a mobile outreach unit as a standalone program that provides buprenorphine treatment, harm reduction services, and recovery coaching, similar to the several Community Care in Reach programs throughout Massachusetts.[319]

3. Diversion programs in the criminal justice system can take several forms. Law Enforcement Assisted Diversion (LEAD) was first implemented in Seattle and is typically a pre-arrest intervention that diverts people away from the criminal justice system and

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[314] Valerie Amato, "Bridging the Gap: Curbing Substance Use in Florida," EMS World, 2019, https://www.emsworld.com/article/1223582/bridging-gap-curbing-substance-use-florida.

[315] Formica et al., "Characteristics of Post-Overdose Public Health-Public Safety Outreach in Massachusetts."

[316] Craig Regis et al., "Community Care in Reach: Mobilizing Harm Reduction and Addiction Treatment Services for Vulnerable Populations," *Frontiers in Public Health* 8 (2020): 501, https://doi.org/10.3389/fpubh.2020.00501.

[317] Noa Krawczyk et al., "Expanding Low-Threshold Buprenorphine to Justice-Involved Individuals through Mobile Treatment: Addressing a Critical Care Gap," *Journal of Substance Abuse Treatment* 103 (August 2019): 1–8, https://doi.org/10.1016/j.jsat.2019.05.002.

[318] Theddeus Iheanacho, Kevin Payne, and Jack Tsai, "Mobile, Community-Based Buprenorphine Treatment for Veterans Experiencing Homelessness With Opioid Use Disorder: A Pilot, Feasibility Study," *The American Journal on Addictions* 29, no. 6 (November 2020): 485–91, https://doi.org/10.1111/ajad.13055.

[319] The Kraft Center for Community Health and Massachusetts General Hospital, "Mobile Addiction Services Toolkit," 2019, http://www.kraftcommunityhealth.org/wp-content/uploads/2020/01/Kraft-Center-Mobile-Addiction-Services-Toolkit.pdf.

towards treatment and other community-based programs. The LEAD program in Seattle has been extensively evaluated, showing decreased recidivism and improving employment and housing outcomes among its participants as well as being a cost-effective intervention.[320] Tampa Bay is reportedly exploring a LEAD program[321] and the Civil Citation Network, a similar program, was established in 2013 in Florida's Second Judicial Circuit and has shown promising results.[322] Pre-arrest initiatives like these should be established and expanded in Florida. Given that programs like LEAD are built on collaboration between law enforcement and behavioral health agencies as well as stakeholder buy-in, the state should encourage implementing LEAD in municipalities and provide the funding, although the decision to implement the program should be made at the local level.

4. Another type of diversion program is a drug court. These programs offer individuals with substance use disorders the opportunity to enter treatment and agree to court supervision rather than receiving a jail sentence. They are an important tool in the opioid crisis as 52% of those with prescription drug use disorder and 77% of heroin users have a lifetime history of criminal justice involvement.[323] Drug courts have been shown to be effective. A meta-analysis estimated that recidivism among adult drug court participants was reduced by 38-50% and these effects lasted up to three years.[324] These interventions have also been shown to reduce substance use and be cost-effective.[325] Opioid use is prevalent and increasing among drug court participants. Nationally, in 2015, it was estimated that 22%, 34%, and 31% of adult drug court participants in urban, suburban, and rural areas respectively reported opioids as their primary substance of choice, with 74% of drug court professionals reporting an increase in pharmaceutical medication use by participants.[326] Opioid problems

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[320] Susan E. Collins, Heather S. Lonczak, and Seema L. Clifasefi, "Seattle's Law Enforcement Assisted Diversion (LEAD): Program Effects on Recidivism Outcomes," *Evaluation and Program Planning* 64 (2017): 49–56; Susan E. Collins, Heather S. Lonczak, and Seema L. Clifasefi, "Seattle's Law Enforcement Assisted Diversion (LEAD): Program Effects on Criminal Justice and Legal System Utilization and Costs," *Journal of Experimental Criminology* 15, no. 2 (2019): 201–11; Seema L. Clifasefi, Heather S. Lonczak, and Susan E. Collins, "Seattle's Law Enforcement Assisted Diversion (LEAD) Program: Within-Subjects Changes on Housing, Employment, and Income/Benefits Outcomes and Associations with Recidivism," *Crime & Delinquency* 63, no. 4 (2017): 429–45.

[321] LEAD National Support Bureau, "LEAD Programs in the United States," n.d., https://www.leadbureau.org.

[322] Albert M. Kopak and Gregory A. Frost, "Correlates of Program Success and Recidivism among Participants in an Adult Pre-Arrest Diversion Program," *American Journal of Criminal Justice* 42, no. 4 (2017): 727–45; Albert M. Kopak and Lily Gleicher, "Law Enforcement Deflection and Prearrest Diversion Programs: A Tale of Two Initiatives," *Emerging Best Practices in Law Enforcement Deflection and Community Supervision Programs*, 2020, 37–55.

[323] Tyler N. A. Winkelman, Virginia W. Chang, and Ingrid A. Binswanger, "Health, Polysubstance Use, and Criminal Justice Involvement Among Adults With Varying Levels of Opioid Use," *JAMA Network Open* 1, no. 3 (July 6, 2018): e180558, https://doi.org/10.1001/jamanetworkopen.2018.0558.

[324] Ojmarrh Mitchell et al., "Assessing the Effectiveness of Drug Courts on Recidivism: A Meta-Analytic Review of Traditional and Non-Traditional Drug Courts," *Journal of Criminal Justice* 40, no. 1 (2012): 60–71.

[325] D.B. Marlowe, C.D. Hardin, and C.L. Fox, "Painting the Current Picture: A National Report Card on Drug Courts and Other Problem-Solving Court" (National Drug Court Institute, 2016), https://www.ndci.org/wp-content/uploads/2016/05/Painting-the-Current-Picture-2016.pdf.

[326] Marlowe, Hardin, and Fox.

in drug courts are likely more prevalent in Florida, as prescription drugs were reported as the primary drug of choice by 41% of participants in 2013.[327] Despite these statistics, it is estimated that around half of drug courts in the United States offer any form of MOUD, the first line treatment for OUD, and fewer allow treatment with opioid agonist medications.[328] Florida has made strides to integrate MOUD into drug courts. As part of the Florida Courts Opioid Initiative, circuit champions are selected to receive specialized training and are encouraged to network with other court officials to share their newly acquired knowledge.[329] The Florida Supreme Court disseminates best practices to local drug courts to encourage the use and acceptance of MOUD.[330] Leaders in the state are calling for further expansion of drug courts,[331] as these avenues to treatment have been shown to reduce drug use and recidivism among participants and increase public safety in Florida.[332] As of September 2020, Florida had 89 problem-solving courts (not including DUI courts), including 56 adult drug courts, 20 juvenile drug courts, and 13 dependency drug courts, with the latter designed to treat the entire family affected by substance use.[333] Nineteen of the 20 judicial circuits in Florida have drug courts, as seen in Figure 11 below.

[327] NPC Research, "Florida Adult Felony Drug Courts Evaluation Results" (Supreme Court of the State of Florida, 2013), https://www.flcourts.org/content/download/217045/file/EvaluationReportSummaryPoints.pdf.

[328] Harlan Matusow et al., "Medication Assisted Treatment in US Drug Courts: Results from a Nationwide Survey of Availability, Barriers and Attitudes," *Journal of Substance Abuse Treatment* 44, no. 5 (May 1, 2013): 473–80, https://doi.org/10.1016/j.jsat.2012.10.004.

[329] Florida Courts, "Opioids & Stimulants Initiative," 2021, https://www.flcourts.org/Resources-Services/Court-Improvement/Opioid-Stimulants-Initiative.

[330] Supreme Court of the State of Florida, "Florida Adult Drug Court Best Practice Standards," 2017, https://www.flcourts.org/content/download/216679/file/Florida_Adult_Drug_Court_Standards_Full_Document.pdf.

[331] Florida Statewide Task Force on Opioid Abuse, "Findings and Recommendations of the Statewide Task Force on Opioid Abuse," 2020, https://doseofrealityfl.com/pdfs/opioid-task-force-findings-recommendations-opioid-abuse.pdf.

[332] NPC Research, "Florida Adult Felony Drug Courts Evaluation Results."

[333] Florida Courts, "Problem-Solving Courts," 2021, https://www.flcourts.org/Resources-Services/Court-Improvement/Problem-Solving-Courts.

Figure 11: Problem-Solving Courts in Florida

Source: Florida Courts (2021)

The 3rd judicial circuit, a predominantly rural area in the central part of the state, is the only circuit to not have a drug court. The presence of a drug court is largely dependent on the number of judges willing to participate in this type of program, the ability to provide case management, and the availability of resources within a community. In rural communities, transportation could also pose a significant barrier. An abatement plan should include increasing the capacity of existing drug courts to meet the needs of the population with OUD in Florida, providing all three forms of MOUD to participants and wraparound services to address psychosocial issues. In addition, an adult drug court, juvenile drug court, and dependency drug court should be established in the 4th judicial district, and the number of dependency drug courts in the state should be doubled to ensure that more Floridians with OUD involved in the criminal justice system have access to a promising model that treats the entire family affected by the opioid crisis.[334] An educational intervention should target judges and other court officials in the drug court system to encourage the use and acceptance of MOUD. A new type of drug court, an opioid court, has recently been implemented in ten counties in New York to ensure availability of MOUD and may be a replicable model in Florida.[335]

[334] Stephanie Tabashneck, "Family Drug Courts: Combatting the Opioid Epidemic," *Family Law Quarterly* 52, no. 1 (2018): p183-202.

[335] Katherine S. Elkington et al., "Stepped-Wedge Randomized Controlled Trial of a Novel Opioid Court to Improve Identification of Need and Linkage to Medications for Opioid Use Disorder Treatment for Court-Involved Adults," *Journal of Substance Abuse Treatment*, January 8, 2021, 108277, https://doi.org/10.1016/j.jsat.2021.108277.

5. There are several initiatives where uniformed first responder institutions serve as entry points to treatment. The Angel Program began in 2013 in Gloucester, Massachusetts as a way to increase access to treatment, using a walk-in model that encourages individuals to enter police departments or other designated locations and request assistance without fear of consequences for possessing or using drugs. Research suggests that this program was effective in helping individuals find initial access to treatment.[336] This initiative has evolved into the police-assisted addiction and recovery initiative, with sites across the country. Currently, Florida has five law enforcement departments participating in this initiative.[337] Safe Station is a similar initiative using fire departments as entry points to treatment instead of police departments and has been widely implemented in New Hampshire with promising results.[338] Despite these potential gateways to OUD treatment, funding is frequently cited as a barrier to implementation and sustainability.[339] Increasing access to treatment utilizing first responder institutions has the potential to address the treatment gap, though leadership and collaboration are key to establishing and sustaining these types of programs.[340] Given this recipe for a successful program, Florida should encourage implementing these initiatives in municipalities and provide the funding, although a decision on program adoption should be made at the local level.

6. Although not the primary purpose of harm reduction, these settings can serve as a vital touchpoint for linking individuals with OUD to low-threshold treatment. Most syringe service programs offer referrals to MOUD,[341] and these settings hold promise as a conduit to treatment.[342] IDEA Exchange in Miami is one such SSP that offers linkage to MOUD. Later in this expert report, I make a recommendation for expanding SSPs, in the form of

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[336] Davida M. Schiff et al., "A Police-Led Addiction Treatment Referral Program in Gloucester, MA: Implementation and Participants' Experiences," *Journal of Substance Abuse Treatment* 82 (November 2017): 41–47, https://doi.org/10.1016/j.jsat.2017.09.003.

[337] PAARI, Inc., "The Police Assisted Addiction and Recovery Initiative," 2021, https://paariusa.org/our-partners/#jp-carousel-2626.

[338] Opioid Policy Research Collaborative, "Safe Station | Brandeis Opioid Resource Connector," accessed June 7, 2021, https://opioid-resource-connector.org/program-model/safe-station.

[339] Sarah K. Moore et al., "Implementation of a New Hampshire Community-Initiated Response to the Opioid Crisis: A Mixed-Methods Process Evaluation of Safe Station," *International Journal of Drug Policy* 95 (September 1, 2021): 103259, https://doi.org/10.1016/j.drugpo.2021.103259.

[340] Melissa Davoust et al., "Examining the Implementation of Police-Assisted Referral Programs for Substance Use Disorder Services in Massachusetts," *The International Journal on Drug Policy*, February 2, 2021, 103142, https://doi.org/10.1016/j.drugpo.2021.103142.

[341] Don C. Des Jarlais et al., "Syringe Service Programs for Persons Who Inject Drugs in Urban, Suburban, and Rural Areas - United States, 2013," *MMWR. Morbidity and Mortality Weekly Report* 64, no. 48 (December 11, 2015): 1337–41, https://doi.org/10.15585/mmwr.mm6448a3.

[342] S. A. Strathdee et al., "Needle-Exchange Attendance and Health Care Utilization Promote Entry into Detoxification," *Journal of Urban Health: Bulletin of the New York Academy of Medicine* 76, no. 4 (December 1999): 448–60, https://doi.org/10.1007/BF02351502; R. Heimer, "Can Syringe Exchange Serve as a Conduit to Substance Abuse Treatment?," *Journal of Substance Abuse Treatment* 15, no. 3 (June 1998): 183–91, https://doi.org/10.1016/s0740-5472(97)00220-1; H. Hagan et al., "Reduced Injection Frequency and Increased Entry and Retention in Drug Treatment Associated with Needle-Exchange Participation in Seattle Drug Injectors," *Journal of Substance Abuse Treatment* 19, no. 3 (October 2000): 247–52, https://doi.org/10.1016/s0740-5472(00)00104-5.

comprehensive harm reduction centers that include linkage to treatment. Partnerships with community stakeholders is vital to ensure a warm handoff to evidence-based treatment for an SSP client.

7. Civil commitments may present an opportunity to engage an individual with severe OUD into evidence-based treatment. In Florida, the Marchman Act allows for a civil commitment as long as certain criteria are met as determined by a civil court. Florida uses civil commitments at a rate higher than any other state except for Massachusetts.[343] Despite its frequent use, the evidence on compulsory treatment is mixed.[344] A study using a small sample size of individuals subjected to the Marchman Act did find a rate of treatment completion similar to those who entered treatment voluntarily,[345] which is promising given that it may take several treatment attempts to achieve a successful outcome.[346] In line with the recommendations of the Florida Statewide Task Force on Opioid Abuse,[347] the Marchman Act should be streamlined and modernized. In other words, treatment should occur in an appropriate healthcare facility, should be evidence-based (with use of medications when warranted), and should be immediately available once a court issues a civil commitment. Abatement strategies to expand access to treatment, discussed in the next subsection, should make these scenarios more feasible. In addition, the Marchman Act should be rigorously evaluated to determine its effectiveness to abate the opioid crisis in Florida.

(ii) Expand Access to Evidence-Based Treatment for OUD

Another way to address the OUD treatment gap is to ensure that treatment is accessible, affordable, and of high quality. In the early 1990s, France was experiencing a dramatic increase in opioid overdose deaths. Buprenorphine became widely available in the mid-1990s and its use was associated with a 79% decline in heroin overdose deaths as seen in Figure 12 below.[348] Buprenorphine expansion had a similar effect in Baltimore from 2003-2009 albeit on a smaller

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[343] Paul P. Christopher et al., "Nature and Utilization of Civil Commitment for Substance Abuse in the United States," *The Journal of the American Academy of Psychiatry and the Law* 43, no. 3 (September 2015): 313–20.

[344] Werb et al., "The Effectiveness of Compulsory Drug Treatment."

[345] Timothy J. Sweeney, Michael P. Strolla, and David P. Myers, "Civil Commitment for Substance Use Disorder Patients under the Florida Marchman Act: Demographics and Outcomes in the Private Clinical Setting," *Journal of Addictive Diseases* 32, no. 1 (2013): 108–15, https://doi.org/10.1080/10550887.2012.759873.

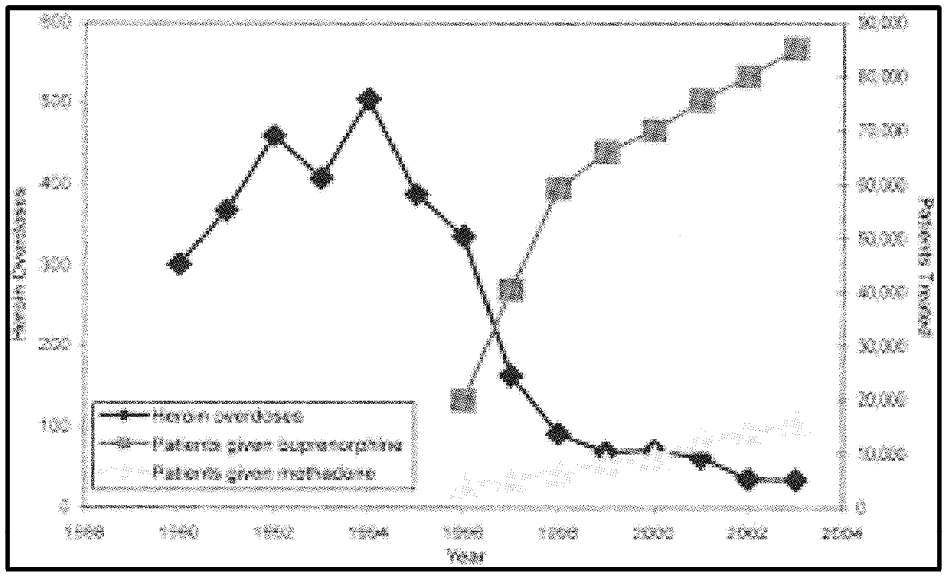
[346] John F. Kelly et al., "How Many Recovery Attempts Does It Take to Successfully Resolve an Alcohol or Drug Problem? Estimates and Correlates From a National Study of Recovering U.S. Adults," *Alcoholism, Clinical and Experimental Research* 43, no. 7 (July 2019): 1533–44, https://doi.org/10.1111/acer.14067.

[347] Florida Statewide Task Force on Opioid Abuse, "Findings and Recommendations of the Statewide Task Force on Opioid Abuse."

[348] Marc Auriacombe et al., "French Field Experience with Buprenorphine," *The American Journal on Addictions* 13 Suppl 1 (2004): S17-28, https://doi.org/10.1080/10550490490440780; Maria Patrizia Carrieri et al., "Buprenorphine Use: The International Experience," *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America* 43 Suppl 4 (December 15, 2006): S197-215, https://doi.org/10.1086/508184.

scale.[349] An essential goal of an abatement plan for the opioid crisis should include strategies to expand access to MOUD. This crucial element has the greatest potential to address the opioid crisis, much like the impact of highly active antiretroviral therapy on the HIV/AIDS Epidemic.

Figure 12: Decrease in Opioid Overdose Deaths in France After Expanding MOUD



Source: Carrieri et al. (2006)

There are still many barriers to MOUD and much potential for expanding its use in the United States and in the state of Florida. One study used data from 2012 to show that Florida would need to nearly double its capacity to deliver buprenorphine treatment based on the number of people with OUD in the state.[350] In addition, the maximum capacity to deliver buprenorphine treatment, as measured in this study, is severely limited by the prescribing patterns of waivered providers (to prescribe buprenorphine, a qualified healthcare professional must become "waivered" by completing additional training and meeting other requirements though this regulation has recently been relaxed). Many waivered providers are either not actively prescribing buprenorphine or treating very few patients.[351] In fact, it is estimated that only 5% of waivered providers are responsible for most of the buprenorphine prescribed.[352] Access to treatment has improved over time, as 36% of substance use facilities offered at least one type of MOUD in 2016

[349] Robert P. Schwartz et al., "Opioid Agonist Treatments and Heroin Overdose Deaths in Baltimore, Maryland, 1995-2009," *American Journal of Public Health* 103, no. 5 (May 2013): 917–22, https://doi.org/10.2105/AJPH.2012.301049.

[350] Jones et al., "National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment."

[351] Cindy Parks Thomas et al., "Prescribing Patterns of Buprenorphine Waivered Physicians," *Drug and Alcohol Dependence* 181 (December 1, 2017): 213–18, https://doi.org/10.1016/j.drugalcdep.2017.10.002; Alexandra Duncan et al., "Monthly Patient Volumes of Buprenorphine-Waivered Clinicians in the US," *JAMA Network Open* 3, no. 8 (August 3, 2020): e2014045, https://doi.org/10.1001/jamanetworkopen.2020.14045.

[352] Bradley D. Stein et al., "Concentration of Patient Care Among Buprenorphine-Prescribing Clinicians in the US," *JAMA* 325, no. 21 (June 1, 2021): 2206–8, https://doi.org/10.1001/jama.2021.4469.

compared with only 20% in 2007; however, only 6% of facilities offered all three types of MOUD in 2016.[353] These lack of options restrict the ability to provide individualized OUD treatment. Florida has already made huge strides in expanding access to MOUD, using most of the State Opioid Response funding to address this issue and reporting that nearly 13,000 individuals received MOUD (55% buprenorphine, 34% methadone, and 11% extended-release naltrexone) in a two-year period from 2017 to 2019.[354] Abatement strategies in this subsection aim to enhance Florida's response to expand access to MOUD by changing the delivery system, increasing the number of treatment programs and providers, and eliminating cost sharing for patients. The ultimate goal is to create an environment in which MOUD is just as easy to obtain for individuals with OUD as it has been to obtain prescription opioids or illicit opioids.

8. Several states have implemented different models that expand access to MOUD. These statewide models include: the hub-and-spoke model that was first implemented in Vermont and has now been replicated in several other states;[355] Medicaid Health Homes that holistically address individuals with OUD, such as the program in Maryland;[356] and Project ECHO, first implemented in New Mexico.[357] Project ECHO is a tele-mentoring program in which specialists train other healthcare professionals, especially primary care providers, to treat medical conditions and offer guidance on specific cases. This program is especially effective in delivering care to underserved populations, such as rural communities, and has been tailored to treat individuals with OUD.[358] Given the state characteristics of Florida and the evidence base for Project ECHO,[359] one strategy to abate the opioid crisis in Florida should include implementing Project ECHO statewide in order to increase the number of healthcare professionals with access to providers trained in addiction medicine and increase the availability of OUD treatment to patients in rural areas of Florida. The program should

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[353] Ramin Mojtabai et al., "Medication Treatment For Opioid Use Disorders In Substance Use Treatment Facilities," *Health Affairs* 38, no. 1 (January 1, 2019): 14–23, https://doi.org/10.1377/hlthaff.2018.05162.

[354] Florida Department of Children and Families, "Outputs and Outcomes from Florida's Opioid State Targeted Response (STR) Grant (5/1/17 through 4/30/19)," n.d., https://www.myflfamilies.com/service-programs/samh/docs/opioid/STR%20Outputs%20and%20Outcomes_FINAL.pdf.

[355] Richard Rawson et al., "Assessment of Medication for Opioid Use Disorder as Delivered within the Vermont Hub and Spoke System," *Journal of Substance Abuse Treatment* 97 (February 2019): 84–90, https://doi.org/10.1016/j.jsat.2018.11.003; Sharon Reif et al., "The Washington State Hub and Spoke Model to Increase Access to Medication Treatment for Opioid Use Disorders," *Journal of Substance Abuse Treatment* 108 (January 2020): 33–39, https://doi.org/10.1016/j.jsat.2019.07.007.

[356] Lisa Clemans-Cope et al., "Experiences of Three States Implementing the Medicaid Health Home Model to Address Opioid Use Disorder-Case Studies in Maryland, Rhode Island, and Vermont," *Journal of Substance Abuse Treatment* 83 (December 2017): 27–35, https://doi.org/10.1016/j.jsat.2017.10.001.

[357] Miriam Komaromy et al., "Project ECHO (Extension for Community Healthcare Outcomes): A New Model for Educating Primary Care Providers about Treatment of Substance Use Disorders," *Substance Abuse* 37, no. 1 (2016): 20–24, https://doi.org/10.1080/08897077.2015.1129388.

[358] James B. Anderson et al., "Project ECHO and Primary Care Buprenorphine Treatment for Opioid Use Disorder: Implementation and Clinical Outcomes," *Substance Abuse*, 2021, 1–9.

[359] Hunter M. Puckett, Jenny S. Bossaller, and Lincoln R. Sheets, "The Impact of Project ECHO on Physician Preparedness to Treat Opioid Use Disorder: A Systematic Review," *Addiction Science & Clinical Practice* 16, no. 1 (January 22, 2021): 6, https://doi.org/10.1186/s13722-021-00215-z.

be able to train all primary care physicians, OBGYNs, nurse practitioners, and physician assistants in Florida to confidently and effectively deliver OUD treatment.

9. The Drug Addiction Treatment Act of 2000 allowed a "waivered" physician to prescribe buprenorphine in an office-based setting, as opposed to receiving treatment at a more structured Opioid Treatment Program. This new modality to deliver OUD treatment, known as office-based opioid treatment (OBOT), was further expanded by laws passed in 2016 and 2018 to allow non-physicians (nurse practitioners and physician assistants) to become waivered and increased the number of patients that physicians could treat. In addition to a shortage in overall providers to prescribe buprenorphine, there are also many barriers to providers' willingness to treat OUD. There have been several models that have been developed to address the provider shortage and overcome these barriers, one being the Massachusetts Collaborative Care Model where nurses working with prescribers play a central role in the evaluation and monitoring of patients. In addition to increasing access to buprenorphine treatment, this model has shown promising results for increasing treatment retention and reducing substance use.[360] Expanding this model to community health centers in Massachusetts increased waivered providers by 375% over three years and also increased the number of OBOT patients.[361] This type of model that utilizes nurse care managers to act as the primary liaison between the patient and the OBOT physician throughout the treatment process should be implemented in the largest community health centers in Florida to increase access to buprenorphine among underserved populations.

10. Utilizing telehealth to expand access to MOUD has been a silver lining of the COVID-19 pandemic. Through relaxing the Ryan Haight Act and mandating parity between in-person and telehealth visits, providers were able to prescribe buprenorphine through a telephone interaction or a video platform to new patients for the first time. Before these policy changes, research has suggested that buprenorphine treatment delivered by telehealth had comparable outcomes to in-person treatment and extended treatment access to rural areas.[362] This is especially relevant as 56% of rural counties lack a provider who can

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[360] Daniel P. Alford et al., "Five Year Experience with Collaborative Care of Opioid Addicted Patients Using Buprenorphine in Primary Care," *Archives of Internal Medicine* 171, no. 5 (March 14, 2011): 425–31, https://doi.org/10.1001/archinternmed.2010.541.

[361] Colleen T. LaBelle et al., "Office-Based Opioid Treatment with Buprenorphine (OBOT-B): Statewide Implementation of the Massachusetts Collaborative Care Model in Community Health Centers," *Journal of Substance Abuse Treatment* 60 (January 2016): 6–13, https://doi.org/10.1016/j.jsat.2015.06.010.

[362] Wanhong Zheng et al., "Treatment Outcome Comparison Between Telepsychiatry and Face-to-Face Buprenorphine Medication-Assisted Treatment for Opioid Use Disorder: A 2-Year Retrospective Data Analysis," *Journal of Addiction Medicine* 11, no. 2 (April 2017): 138–44, https://doi.org/10.1097/ADM.0000000000000287; Eric Weintraub et al., "Outcomes for Patients Receiving Telemedicine-Delivered Medication-Based Treatment for Opioid Use Disorder: A Retrospective Chart Review," *Heroin Addiction and Related Clinical Problems* 23, no. 2 (2021): 5–12; Eric Weintraub et al., "Expanding Access to Buprenorphine Treatment in Rural Areas with the Use of Telemedicine," *The American Journal on Addictions* 27, no. 8 (December 2018): 612–17, https://doi.org/10.1111/ajad.12805; Joseph K. Eibl et al., "The Effectiveness of Telemedicine-Delivered Opioid Agonist Therapy in a Supervised Clinical Setting," *Drug and Alcohol Dependence* 176 (July 1, 2017): 133–38, https://doi.org/10.1016/j.drugalcdep.2017.01.048.

prescribe buprenorphine.[363] Findings from another study among Veterans suggest that telehealth may improve retention for buprenorphine treatment.[364] In addition to provider visits, telehealth and other mobile technology can be leveraged for remote toxicology screens, medication monitoring, and behavioral health counseling. Given the recent pandemic and the changes in policy and delivery of care, the state of Florida should continue to scale telehealth services for MOUD induction and continuation, especially in rural areas.

11. Methadone is one of the three FDA-approved medications to treat OUD and is the only one that is a full opioid agonist. This property of the medication increases the likelihood for overdose to occur when misused. To address these concerns, clinics that administer methadone, called OTPs, must be accredited and certified at the federal level and usually meet certain requirements at the state and local levels. Methadone and the structure provided by the OTP may be better treatment modalities for some individuals. Evidence does suggest that treatment retention is slightly higher in patients on methadone compared to buprenorphine.[365] Therefore, medication treatment with methadone should be an option for all Floridians with OUD. However, the capacity to deliver methadone treatment via the OTP network in Florida may not be able to meet these needs. According to the National Survey of Substance Abuse Treatment Services, in 2019, there were 66 OTPs in Florida. For comparison, there were 70 OTPs in Georgia, a border state with half the population of Florida. The Florida OTPs served 93 clients per 100,000 people in the state, or about 20,000 people, which is 39% lower than the national average.[366] These OTPs are also primarily located in densely populated areas, as seen in Figure 13 below.

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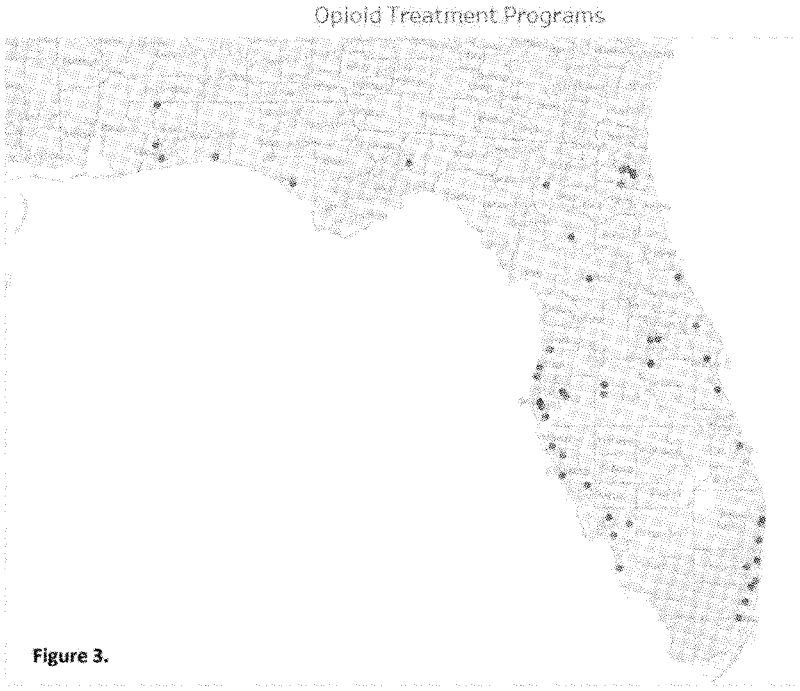
[363] C. Holly A. Andrilla et al., "Geographic Distribution of Providers With a DEA Waiver to Prescribe Buprenorphine for the Treatment of Opioid Use Disorder: A 5-Year Update," *The Journal of Rural Health: Official Journal of the American Rural Health Association and the National Rural Health Care Association* 35, no. 1 (January 2019): 108–12, https://doi.org/10.1111/jrh.12307.

[364] J. Priyanka Vakkalanka et al., "Telehealth Utilization Is Associated with Lower Risk of Discontinuation of Buprenorphine: A Retrospective Cohort Study of US Veterans," *Journal of General Internal Medicine*, June 22, 2021, https://doi.org/10.1007/s11606-021-06969-1.

[365] Richard P. Mattick et al., "Buprenorphine Maintenance versus Placebo or Methadone Maintenance for Opioid Dependence," *The Cochrane Database of Systematic Reviews*, no. 2 (February 6, 2014): CD002207, https://doi.org/10.1002/14651858.CD002207.pub4; Yih-Ing Hser et al., "Long-Term Outcomes after Randomization to Buprenorphine/Naloxone versus Methadone in a Multi-Site Trial," *Addiction (Abingdon, England)* 111, no. 4 (April 2016): 695–705, https://doi.org/10.1111/add.13238.

[366] SAMHSA, "National Survey of Substance Abuse Treatment Services (N-SSATS): 2019. Data on Substance Abuse Treatment Facilities."

Figure 13: Location of Opioid Treatment Programs in Florida



Source: Department of Children and Families (2017)

Florida should enhance its OTP network, contracting with organizations to reach the capacity of the national average at minimum which would require adding at least 42 more OTPs. These facilities should be strategically placed in rural communities as increased distance from an OTP is associated with decreased treatment retention.[367] Additionally, services offered at OTP should be comprehensive. A national study indicated that only one-third of OTPs offered all three FDA-approved medications, 61% provided testing for viral Hepatitis and HIV, 13% provided medication treatment for Hepatitis C, 8% provided medication treatment for HIV, and a minority distributed or prescribed naloxone to their patients. Additionally, most OTPs did not provide housing or employment support, vocational training, or recovery coaching.[368] An OTP offers a unique opportunity to address the wide range of health and social problems that result from OUD. Therefore, each OTP should serve as a comprehensive OUD treatment center that can address these problems.

12. Commonly cited perceived barriers for healthcare professionals in not prescribing buprenorphine include lack of institutional support, inadequate capacity to refer to

[367] Solmaz Amiri et al., "Increased Distance Was Associated with Lower Daily Attendance to an Opioid Treatment Program in Spokane County Washington," *Journal of Substance Abuse Treatment* 93 (October 2018): 26–30, https://doi.org/10.1016/j.jsat.2018.07.006.

[368] Christopher M. Jones et al., "Characteristics and Current Clinical Practices of Opioid Treatment Programs in the United States," *Drug and Alcohol Dependence* 205 (December 1, 2019): 107616, https://doi.org/10.1016/j.drugalcdep.2019.107616.

psychosocial services, and lack of self-efficacy in treating individuals with OUD.[369] All of these barriers can be addressed through initiatives and programs that integrate OUD treatment into the healthcare system. This is a theme of many of the abatement strategies that are proposed in this report, such as Project ECHO, using nurse care managers to facilitate buprenorphine treatment, and integrating MOUD in emergency departments and in prenatal care. A wide range of approaches sustained over many years will be needed to abate the opioid crisis, and various types of integrated models within the healthcare system need to be implemented to identify and link individuals with OUD to treatment, expand access to MOUD, and decrease stigma.[370] Although this report recommends many of these models, large primary care systems in Florida should have the option to integrate social workers, behavioral health specialists, and peers into their OUD treatment model to improve outcomes. This could be done by setting up a discretionary fund that allows these systems to voluntarily apply for these types of ancillary support.

13. EDIB is a promising strategy to identify and treat individuals with OUD.[371] Bridge clinics have emerged as a solution to improving treatment retention for those initiated on buprenorphine in the emergency department.[372] A bridge clinic, also known as an opioid urgent care clinic, is a standalone clinic co-located near a hospital that can serve as a "bridge" from the emergency department to an outpatient setting for continuing buprenorphine treatment while also having the capability to maintain someone on buprenorphine long-term if they do not prefer to be referred to a community outpatient facility. Under this model, after individuals are initiated on buprenorphine in the emergency department and discharged with short-term buprenorphine prescriptions, they are referred to the bridge clinic co-located in the same hospital. These clinics are usually staffed by physicians and mid-level clinicians trained in addiction, social workers, and recovery coaches. Evidence from several of these programs is promising. One bridge clinic reported that more than half of patients initiated on buprenorphine were still adhering to the treatment after two years, along with decreased emergency department utilization

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[369] Margaret Lowenstein et al., "Barriers and Facilitators for Emergency Department Initiation of Buprenorphine: A Physician Survey," *The American Journal of Emergency Medicine* 37, no. 9 (September 2019): 1787–90, https://doi.org/10.1016/j.ajem.2019.02.025; Eliza Hutchinson et al., "Barriers to Primary Care Physicians Prescribing Buprenorphine," *The Annals of Family Medicine* 12, no. 2 (2014): 128–33; Dexter L. Louie, Mehret T. Assefa, and Mark P. McGovern, "Attitudes of Primary Care Physicians toward Prescribing Buprenorphine: A Narrative Review," *BMC Family Practice* 20, no. 1 (2019): 1–8.

[370] P. Todd Korthuis et al., "Primary Care-Based Models for the Treatment of Opioid Use Disorder: A Scoping Review," *Annals of Internal Medicine* 166, no. 4 (February 21, 2017): 268–78, https://doi.org/10.7326/M16-2149; Pooja Lagisetty et al., "Primary Care Models for Treating Opioid Use Disorders: What Actually Works? A Systematic Review," *PloS One* 12, no. 10 (2017): e0186315, https://doi.org/10.1371/journal.pone.0186315.

[371] Gail D'Onofrio et al., "Emergency Department-Initiated Buprenorphine/Naloxone Treatment for Opioid Dependence: A Randomized Clinical Trial," *JAMA* 313, no. 16 (April 28, 2015): 1636–44, https://doi.org/10.1001/jama.2015.3474.

[372] Alister Martin et al., "Beyond Buprenorphine: Models of Follow-up Care for Opioid Use Disorder in the Emergency Department," *The Western Journal of Emergency Medicine* 21, no. 6 (November 2, 2020): 257–63, https://doi.org/10.5811/westjem.2020.7.46079.

among patients after beginning treatment.[373] Another bridge clinic primarily serving an unstably housed population with extended-release buprenorphine found that most patients were still in treatment after six months.[374] A network of bridge clinics has been implemented in California and the overarching organization responsible for this network has put together tools and resources to replicate this model.[375] Implementing hospital bridges has been a goal of Florida's response to the opioid crisis, and a portion of the state's SOR grant has been earmarked to implement these programs. Currently, there are several initiatives that use peers in the emergency department to provide a warm handoff to treatment. Brandon Regional Hospital in the Tampa area has a model program to initiate buprenorphine in the emergency department and provide a warm handoff to treatment.[376] However, the infrastructure is not in place at the largest hospitals in the state to ensure the highest treatment retention, which is a hospital bridge program with a bridge clinic co-located to the hospital. Each large hospital in Florida should also have a co-located bridge clinic.[377] This co-location is important for providing a warm handoff and providing timely continuation of treatment given that coordination between the emergency department and the bridge clinic has been found to be crucial,[378] and decreased wait times are associated with better continuity of care.[379]

14. There are many barriers to expanding access to MOUD in the primary care and emergency department settings. Two of the most important of these barriers are stigma and lack of knowledge. In one survey, only 45% of emergency medicine and 49% of primary care physicians reported that OUD was a treatable disease, and 38% of emergency medicine physicians reported that methadone treatment for OUD was substituting one addiction for another.[380] In two other surveys, only 20% of physicians were interested in treating OUD patients and 75% of these physicians reported high levels of stigma towards individuals

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[373] Ross W. Sullivan, Laura M. Szczesniak, and Susan M. Wojcik, "Bridge Clinic Buprenorphine Program Decreases Emergency Department Visits," *Journal of Substance Abuse Treatment* 130 (April 17, 2021): 108410, https://doi.org/10.1016/j.jsat.2021.108410.

[374] Alyssa M. Peckham et al., "Real-World Outcomes with Extended-Release Buprenorphine (XR-BUP) in a Low Threshold Bridge Clinic: A Retrospective Case Series," *Journal of Substance Abuse Treatment* 126 (July 2021): 108316, https://doi.org/10.1016/j.jsat.2021.108316.

[375] "California Bridge Resources," 2021, https://cabridge.org/tools/resources/.

[376] National Council for Mental Wellbeing, "Addressing Opioid Use Disorder in Emergency Departments: Expert Panel Findings," n.d., https://www.thenationalcouncil.org/wp-content/uploads/2021/02/NCBH_TEP_Opioid_Toolkit_v5_021021.pdf?daf=375ateTbd56.

[377] "Facility/Provider Search Results," FloridaHealthFinder.gov, 2021, https://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx.

[378] Randi Sokol et al., "Linking MATTERS: Barriers and Facilitators to Implementing Emergency Department-Initiated Buprenorphine-Naloxone in Patients with Opioid Use Disorder and Linkage to Long-Term Care," *Substance Use & Misuse* 56, no. 7 (2021): 1045–53, https://doi.org/10.1080/10826084.2021.1906280.

[379] Payel J. Roy et al., "Shorter Outpatient Wait-Times for Buprenorphine Are Associated with Linkage to Care Post-Hospital Discharge," *Drug and Alcohol Dependence* 224 (July 1, 2021): 108703, https://doi.org/10.1016/j.drugalcdep.2021.108703.

[380] Caroline Davidson, Chetna Bansal, and Shannon Hartley, "Opportunities to Increase Screening and Treatment of Opioid Use Disorder among Healthcare Professionals" (Shatterproof, 2019), https://rizema.org/wp-content/uploads/2019/07/GE-Rize-Shatterproof-White-Paper-Final.pdf.

with OUD.[381] Thus, education and stigma reduction among healthcare professionals is essential to expanding access to MOUD. In the context of abating the opioid crisis, OUD treatment may be best delivered at specialty centers tailored to serving this population, at least in the near-term while simultaneously educating healthcare professionals and implementing initiatives to bring OUD treatment into the mainstream healthcare system. These centers should be accessible to all Floridians with OUD and deliver timely and comprehensive medication treatment with buprenorphine or extended-release naltrexone along with ancillary services that address psychosocial needs. They should be staffed by trained professionals delivering compassionate care in an environment conducive to reducing stigma, encouraging treatment-seeking, and improving long-term outcomes. These types of centers would be either standalone facilities or co-located with hospitals that are additional to the OTP network (that would primarily provide methadone) and may serve as bridge clinics from emergency-department initiated buprenorphine. Centers should also be staffed for treating medical comorbidities that are common in OUD, including hepatitis and chronic pain.

15. Opioid use disorder should be treated like other chronic medical diseases and treatment should be tailored to the individual. Although medication treatment is the most critical element of a treatment plan for OUD, ancillary services should be made available to every individual being treated with OUD, although receipt of medication should not be contingent on participation in these services. Ideally, a system of care should be in place where an individual can easily transition from initiation of medication to specialty treatment (e.g. inpatient, partial hospitalization, or intensive outpatient) to recovery housing and other recovery support services. Although some individuals may do well on medication alone, delivering psychosocial interventions in conjunction with medication is important because studies have shown that psychosocial interventions in addition to MOUD are effective for more challenging individuals.[382] There will also be a subset of the population who will refuse medication treatment. For those seeking opioid detoxification treatment, it is estimated that 20-40% of these individuals will not be interested in opioid agonist treatment, though selection bias is present due to the type of treatment that these individuals are seeking.[383] Nonetheless, there are certain to be some that prefer a different treatment modality that does not include medication, which should be made available and include intensive and long-term treatment. Florida will need to expand its infrastructure to

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[381] Emma E. McGinty et al., "Medication for Opioid Use Disorder: A National Survey of Primary Care Physicians," *Annals of Internal Medicine* 173, no. 2 (July 21, 2020): 160–62, https://doi.org/10.7326/M19-3975; Elizabeth M. Stone et al., "The Role of Stigma in U.S. Primary Care Physicians' Treatment of Opioid Use Disorder," *Drug and Alcohol Dependence* 221 (April 1, 2021): 108627, https://doi.org/10.1016/j.drugalcdep.2021.108627.

[382] John Marsden et al., "Efficacy and Cost-Effectiveness of an Adjunctive Personalised Psychosocial Intervention in Treatment-Resistant Maintenance Opioid Agonist Therapy: A Pragmatic, Open-Label, Randomised Controlled Trial," *The Lancet. Psychiatry* 6, no. 5 (May 2019): 391–402, https://doi.org/10.1016/S2215-0366(19)30097-5.

[383] Genie L. Bailey, Debra S. Herman, and Michael D. Stein, "Perceived Relapse Risk and Desire for Medication Assisted Treatment among Persons Seeking Inpatient Opiate Detoxification," *Journal of Substance Abuse Treatment* 45, no. 3 (September 2013): 302–5, https://doi.org/10.1016/j.jsat.2013.04.002; Lisa A. Uebelacker et al., "Patients' Beliefs About Medications Are Associated with Stated Preference for Methadone, Buprenorphine, Naltrexone, or No Medication-Assisted Therapy Following Inpatient Opioid Detoxification," *Journal of Substance Abuse Treatment* 66 (July 2016): 48–53, https://doi.org/10.1016/j.jsat.2016.02.009.

provide individualized, comprehensive, and timely treatment at all levels of care. In Florida, the number having to wait for outpatient services has been increasing over the last five years, with substantial increases among high-risk populations such as those experiencing homelessness and injection drug users.[384] Thus, outpatient care is certainly one area of the treatment system that should be enhanced. A crucial element to abate the opioid crisis in Florida will be providing funding for all levels of care for OUD treatment. This will include medications, the appropriate level of care in the specialty treatment system, adjunctive psychosocial interventions, overdose education and naloxone distribution, and recovery housing and access to other recovery support services.

16. Health insurers may use cost-sharing (e.g. deductibles, copays, coinsurance) and utilization management techniques (e.g. prior authorization) to decrease utilization of different types of medications. Prior authorization has been shown to be detrimental in accessing MOUD.[385] Cost sharing has been shown to negatively impact access and treatment retention.[386] Many OTPs are self-pay and do not take insurance. In Florida, among a survey of individuals receiving methadone treatment at OTPs, out-of-pocket costs to the patient was cited as the most common reason for interfering with treatment compliance, and 3,892 methadone patients were administratively discharged over a ten-year period for inability to pay or loss of insurance.[387] Eliminating costs and barriers to patients is low-hanging fruit in addressing the opioid crisis. Florida has used the SOR grant to fund MOUD for almost 13,000 individuals in a two-year period from 2017 to 2019.[388] However, this funding is short-term and there are limits to how long an individual can receive funding through this

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[384] Florida Department of Children and Families, "Assessment of Behavioral Health Services in Florida: Fiscal Years 2020-2021," 2020, https://www.myflfamilies.com/service-programs/samh/publications/docs/2020-21%20Assessment%20of%20Behavioral%20Health%20Services%20in%20Florida.pdf.

[385] Andrea Kermack et al., "Buprenorphine Prescribing Practice Trends and Attitudes among New York Providers," *Journal of Substance Abuse Treatment* 74 (March 2017): 1–6, https://doi.org/10.1016/j.jsat.2016.10.005; Tami L. Mark, William J. Parish, and Gary A. Zarkin, "Association of Formulary Prior Authorization Policies With Buprenorphine-Naloxone Prescriptions and Hospital and Emergency Department Use Among Medicare Beneficiaries," *JAMA Network Open* 3, no. 4 (April 1, 2020): e203132, https://doi.org/10.1001/jamanetworkopen.2020.3132; Christina M. Andrews et al., "Impact of Medicaid Restrictions on Availability of Buprenorphine in Addiction Treatment Programs," *American Journal of Public Health* 109, no. 3 (2019): 434–36.

[386] Christopher Dunphy et al., "Do Out-of-Pocket Costs Influence Retention and Adherence to Medications for Opioid Use Disorder?," *Drug and Alcohol Dependence* 225 (May 21, 2021): 108784, https://doi.org/10.1016/j.drugalcdep.2021.108784; Chandler McClellan et al., "Price Elasticity of Demand for Buprenorphine/Naloxone Prescriptions," *Journal of Substance Abuse Treatment* 106 (November 2019): 4–11, https://doi.org/10.1016/j.jsat.2019.08.001; Suzanne Kinsky et al., "A Comparison of Adherence, Outcomes, and Costs among Opioid Use Disorder Medicaid Patients Treated with Buprenorphine and Methadone: A View from the Payer Perspective," *Journal of Substance Abuse Treatment* 104 (September 2019): 15–21, https://doi.org/10.1016/j.jsat.2019.05.015.

[387] Florida Department of Children and Families, "Florida's State Targeted Response to the Opioid Crisis Grant: Needs Assessment," 2017, https://www.myflfamilies.com/service-programs/samh/docs/opioid/Needs%20Assessment.pdf.

[388] Florida Department of Children and Families, "Outputs and Outcomes from Florida's Opioid State Targeted Response (STR) Grant (5/1/17 through 4/30/19)."

mechanism. Additional funding that is sustainable should ensure that there is no patient cost for medications for OUD, regardless of payor and whether the patient is uninsured.

17. Although the behavioral health workforce is lagging behind demand in most states, evidence suggests that Florida may have one of the largest supply-demand mismatches.[389] A robust and well-trained workforce can improve access to and quality of OUD treatment as well as improve other areas of the continuum of care such as pain management, youth prevention, and addressing the psychosocial needs of those with OUD. However, the behavioral health workforce has historically been plagued with high turnover partially resulting from low compensation.[390] This is reflected in a survey of the behavioral health workforce in Florida showing that only 66% were "likely" or "very likely" to remain in their position with their current organization within one year, and the lowest level of reported satisfaction related to salary and benefits.[391] Workforce expansion in the treatment system is needed to meet the needs of all Floridians with OUD. An increase in the workforce would include, but not be limited to, recovery support specialists, social workers, healthcare professionals trained in addiction, harm reduction specialists, and mental health counselors. This expansion should be incentivized by a competitive salary, tuition reimbursement, and a generous loan forgiveness program.

(iii) *Increase treatment retention*

The abatement strategies presented in this expert report thus far have addressed the OUD treatment gap through programs that link people to treatment and initiatives that expand access to MOUD. Once an individual begins OUD treatment, retaining them in care is paramount to reduce mortality and improve other outcomes.[392] Despite the benefit of treatment retention, most studies suggest that only around half of those beginning MOUD are still on the treatment regimen after one year.[393] Florida has seen how important treatment retention is among those that initiated MOUD through the SOR Grant. For individuals retained in treatment for one year, 97% were

[389] Department of Health and Human Services, "State-Level Projections of Supply and Demand for Behavioral Health Occupations: 2016-2030," 2018, https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/state-level-estimates-report-2018.pdf.

[390] Laurel A. Brabson et al., "Workforce Turnover in Community Behavioral Health Agencies in the USA: A Systematic Review with Recommendations," *Clinical Child and Family Psychology Review* 23, no. 3 (September 2020): 297–315, https://doi.org/10.1007/s10567-020-00313-5.

[391] Florida Department of Children and Families, "2019 Florida Behavioral Health Workforce Survey," 2019, https://www.myflfamilies.com/service-programs/samh/publications/docs/2019%20Florida%20Behavioral%20Health%20Workforce%20Survey-Final.pdf.

[392] Christine Timko et al., "Retention in Medication-Assisted Treatment for Opiate Dependence: A Systematic Review," *Journal of Addictive Diseases* 35, no. 1 (2016): 22–35, https://doi.org/10.1080/10550887.2016.1100960; Wakeman et al., "Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder."

[393] Hser et al., "Long-Term Outcomes after Randomization to Buprenorphine/Naloxone versus Methadone in a Multi-Site Trial"; Aisling Máire O'Connor et al., "Retention of Patients in Opioid Substitution Treatment: A Systematic Review," *PloS One* 15, no. 5 (2020): e0232086, https://doi.org/10.1371/journal.pone.0232086.

stably housed, an 11.5% increase from the first month of treatment, 61% were employed, an 85% increase, recidivism decreased dramatically, and nonfatal overdoses were rare.[394]

It is recommended that patients have the option to be on MOUD indefinitely. This is because long-term longitudinal studies have shown that OUD is a chronic, relapsing disease for most,[395] and patients that discontinue medication treatment have increased mortality and are highly likely to return to opioid use.[396] Although some individuals treated with MOUD will successfully transition off of medication[397] and others will resolve an opioid problem without the use of medication,[398] the standard of care to produce the best outcomes among the OUD population should be comprehensive treatment that includes long-term use of medication. This section describes abatement strategies to retain individuals in care.

18. Long-acting formulations of MOUD have the potential to increase treatment retention. This may be especially true for certain subpopulations, such as those experiencing homelessness, in criminal justice settings, and residing in rural communities.[399] Long-acting formulations have improved treatment adherence for other disorders. For example, the introduction of long-acting injectables improved treatment adherence and other outcomes for those with schizophrenia, when compared to oral antipsychotics.[400] Studies have shown that long-acting injectable buprenorphine is just as effective as the oral

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[394] Florida Department of Children and Families, "Outputs and Outcomes from Florida's Opioid State Targeted Response (STR) Grant (5/1/17 through 4/30/19)."

[395] Hser et al., "A 33-Year Follow-up of Narcotics Addicts"; Marel et al., "Modelling Long-Term Joint Trajectories of Heroin Use and Treatment Utilisation."

[396] Bohdan Nosyk et al., "Defining Dosing Pattern Characteristics of Successful Tapers Following Methadone Maintenance Treatment: Results from a Population-Based Retrospective Cohort Study," *Addiction (Abingdon, England)* 107, no. 9 (September 2012): 1621–29, https://doi.org/10.1111/j.1360-0443.2012.03870.x; Brandon S. Bentzley et al., "Discontinuation of Buprenorphine Maintenance Therapy: Perspectives and Outcomes," *Journal of Substance Abuse Treatment* 52 (May 2015): 48–57, https://doi.org/10.1016/j.jsat.2014.12.011; Jo Kimber et al., "Survival and Cessation in Injecting Drug Users: Prospective Observational Study of Outcomes and Effect of Opiate Substitution Treatment," *BMJ (Clinical Research Ed.)* 341 (July 1, 2010): c3172, https://doi.org/10.1136/bmj.c3172.

[397] Roger D. Weiss et al., "Long-Term Outcomes from the National Drug Abuse Treatment Clinical Trials Network Prescription Opioid Addiction Treatment Study," *Drug and Alcohol Dependence* 150 (May 1, 2015): 112–19, https://doi.org/10.1016/j.drugalcdep.2015.02.030.

[398] Lauren A. Hoffman, Corrie Vilsaint, and John F. Kelly, "Recovery from Opioid Problems in the US Population: Prevalence, Pathways, and Psychological Well-Being," *Journal of Addiction Medicine* 14, no. 3 (2020): 207–16.

[399] Wilson M. Compton and Nora D. Volkow, "Extended-Release Buprenorphine and Its Evaluation With Patient-Reported Outcomes," *JAMA Network Open* 4, no. 5 (May 3, 2021): e219708, https://doi.org/10.1001/jamanetworkopen.2021.9708.

[400] Taishiro Kishimoto et al., "Long-Acting Injectable versus Oral Antipsychotics in Schizophrenia: A Systematic Review and Meta-Analysis of Mirror-Image Studies," *The Journal of Clinical Psychiatry* 74, no. 10 (October 2013): 957–65, https://doi.org/10.4088/JCP.13r08440.

formulation of the medication,[401] improves patient-centered outcomes,[402] and may be a treatment option for some individuals with OUD.[403] For extended-release naltrexone there is concern that discontinuation of the monthly injection will increase risk of opioid-related mortality.[404] These concerns have been highlighted in large observational studies that have found no effect of extended-release naltrexone on reducing mortality.[405] Therefore, initiation and retention in treatment are especially important for extended-release naltrexone, so highly-motivated individuals with less severe OUD may be the best candidates for this treatment modality. Extended-release formulations of both buprenorphine and naltrexone should be made available to any individual who, through shared decision-making with a healthcare professional, chooses one of these treatment options. Given that diversion is a primary concern when offering MOUD in prisons and jails,[406] utilization of long-acting formulations should be considered in these settings. Due to the difficulty of accessing consistent care, individuals residing in rural areas should have the option of extended-release formulations at no cost. Given the complexities of those experiencing homelessness, extended-release formulations may offer higher treatment retention in this population.

19. Ancillary programs to medication treatment have been shown to increase treatment retention and improve other outcomes for individuals in OUD treatment. Contingency management using voucher-based rewards has been shown to improve treatment retention for both methadone and buprenorphine patients.[407] Given the structure of OTPs, this

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[401] Michelle R. Lofwall et al., "Weekly and Monthly Subcutaneous Buprenorphine Depot Formulations vs Daily Sublingual Buprenorphine With Naloxone for Treatment of Opioid Use Disorder: A Randomized Clinical Trial," *JAMA Internal Medicine* 178, no. 6 (June 1, 2018): 764–73, https://doi.org/10.1001/jamainternmed.2018.1052.

[402] Walter Ling et al., "Effects of Monthly Buprenorphine Extended-Release Injections on Patient-Centered Outcomes: A Long-Term Study," *Journal of Substance Abuse Treatment* 110 (March 2020): 1–8, https://doi.org/10.1016/j.jsat.2019.11.004.

[403] Joanne Neale, Charlotte N. E. Tompkins, and John Strang, "Prolonged-Release Opioid Agonist Therapy: Qualitative Study Exploring Patients' Views of 1-Week, 1-Month, and 6-Month Buprenorphine Formulations," *Harm Reduction Journal* 16, no. 1 (April 3, 2019): 25, https://doi.org/10.1186/s12954-019-0296-4; Benjamin Rolland et al., "Determinants of Interest in Extended-Released Buprenorphine: A Survey among 366 French Patients Treated with Buprenorphine or Methadone," *Drug and Alcohol Dependence* 220 (March 1, 2021): 108492, https://doi.org/10.1016/j.drugalcdep.2020.108492.

[404] Ingrid A Binswanger and Jason M. Glanz, "Potential Risk Windows for Opioid Overdose Related to Treatment with Extended-Release Injectable Naltrexone," *Drug Safety* 41, no. 10 (October 2018): 979–80, https://doi.org/10.1007/s40264-018-0705-8.

[405] Larochelle et al., "Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association With Mortality"; Wakeman et al., "Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder"; Jake R. Morgan et al., "Overdose Following Initiation of Naltrexone and Buprenorphine Medication Treatment for Opioid Use Disorder in a United States Commercially Insured Cohort," *Drug and Alcohol Dependence* 200 (July 1, 2019): 34–39, https://doi.org/10.1016/j.drugalcdep.2019.02.031.

[406] Amy Nunn et al., "Methadone and Buprenorphine Prescribing and Referral Practices in US Prison Systems: Results from a Nationwide Survey," *Drug and Alcohol Dependence* 105, no. 1–2 (November 1, 2009): 83–88, https://doi.org/10.1016/j.drugalcdep.2009.06.015.

[407] Dugosh et al., "A Systematic Review on the Use of Psychosocial Interventions in Conjunction With Medications for the Treatment of Opioid Addiction"; Kathleen M. Carroll and Roger D. Weiss, "The Role of Behavioral

method to increase treatment retention should be piloted in these facilities and expanded as appropriate. Contingency management can be delivered through smartphone apps (also see next paragraph).[408] Enhancement of clinical delivery of treatment through care coordination, which was facilitated through case managers, increased treatment retention for HIV patients[409] and holds promise for MOUD patients. This strategy is currently being used, in the form of retention care coordinators, in the HEALing Communities Study.[410] Retention care coordinators may be especially impactful in office-based settings where there is less structure compared with OTPs. Thus, adjuncts to medication treatment that recognize the chronic nature of OUD will be necessary to increase treatment retention and improve outcomes. Reducing barriers to housing, transportation, and employment for individuals with OUD is also likely to increase treatment retention, which can be done using recovery support sections that are further discussed in the recovery subsection of this report.

20. Digital technologies, such as smartphone apps, have emerged as adjuncts to OUD treatment that can increase treatment retention. One digital technology, a prescription digital therapeutic called reSET-O, delivers neurobehavioral therapy as an adjunct to MOUD and includes contingency management, fluency training, and community reinforcement approach (a type of cognitive behavioral therapy).[411] Preliminary evidence is promising. An initial 12-week randomized controlled clinical trial showed that 82% of OUD patients who received treatment with reSET-O stayed in treatment versus 68% of those who only received treatment as usual.[412] Subsequent real-world studies have supported increased treatment retention by using this digital technology as an adjunct to MOUD.[413] Access to

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Interventions in Buprenorphine Maintenance Treatment: A Review," *The American Journal of Psychiatry* 174, no. 8 (August 1, 2017): 738–47, https://doi.org/10.1176/appi.ajp.2016.16070792.

[408] Anthony DeFulio et al., "A Smartphone-Smartcard Platform for Contingency Management in an Inner-City Substance Use Disorder Outpatient Program," *Journal of Substance Abuse Treatment* 120 (January 2021): 108188, https://doi.org/10.1016/j.jsat.2020.108188.

[409] Mary K. Irvine et al., "Improvements in HIV Care Engagement and Viral Load Suppression Following Enrollment in a Comprehensive HIV Care Coordination Program," *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America* 60, no. 2 (January 15, 2015): 298–310, https://doi.org/10.1093/cid/ciu783; Julia D. López, Enbal Shacham, and Tawnya Brown, "The Impact of the Ryan White HIV/AIDS Medical Case Management Program on HIV Clinical Outcomes: A Longitudinal Study," *AIDS and Behavior* 22, no. 9 (September 2018): 3091–99, https://doi.org/10.1007/s10461-018-2124-3.

[410] Theresa Winhusen et al., "The Opioid-Overdose Reduction Continuum of Care Approach (ORCCA): Evidence-Based Practices in the HEALing Communities Study," *Drug and Alcohol Dependence* 217 (December 1, 2020): 108325, https://doi.org/10.1016/j.drugalcdep.2020.108325.

[411] "ReSET-O/ReSET," Pear Therapeutics, n.d., https://www.resetforrecovery.com/.

[412] Darren R. Christensen et al., "Adding an Internet-Delivered Treatment to an Efficacious Treatment Package for Opioid Dependence," *Journal of Consulting and Clinical Psychology* 82, no. 6 (December 2014): 964–72, https://doi.org/10.1037/a0037496.

[413] Weijia Wang et al., "Economic Modeling of ReSET-O, a Prescription Digital Therapeutic for Patients with Opioid Use Disorder," *Journal of Medical Economics*, 2020, 1–1; Yuri A. Maricich et al., "Real-World Evidence for a Prescription Digital Therapeutic to Treat Opioid Use Disorder," *Current Medical Research and Opinion*, 2020, 1–9.

such a smartphone app as an adjunct to medication should be made available to anyone in Florida as part of comprehensive OUD treatment.

(iv) Ensure the availability of evidence-based OUD treatment for vulnerable populations

Certain populations should be considered high-risk for opioid-related overdoses and other opioid-related harms. Special efforts should be made to identify and engage these populations, which have unique characteristics that might require tailored interventions. In addition, these populations are likely to have distinctive needs and challenges that call for comprehensive treatment models.

21. The opioid crisis has severely impacted pregnant women, new mothers, and infants in Florida. As discussed above, the rate of mothers with OUD at delivery hospitalization increased more than thirteen-fold from 1999-2014 and the rate of neonatal abstinence syndrome increased sixteen-fold from 1999-2013.[414] Pregnancy-related deaths due to drugs increased 88% from 2008 to 2017 in Florida, with these deaths now the leading cause of mortality for mothers during pregnancy or within one year after birth.[415] Other studies suggest that mothers are most at risk for an opioid-related overdose during the postpartum period, especially 7 to 12 months after delivery.[416]

22. ACOG and SAMHSA both recommend opioid agonist treatment with methadone and buprenorphine as first-line treatment in conjunction with behavioral therapy and medical services.[417] Buprenorphine may be a better option for pregnant women as it has shown

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[414] Sarah C. Haight et al., "Opioid Use Disorder Documented at Delivery Hospitalization — United States, 1999–2014," *Morbidity and Mortality Weekly Report* 67, no. 31 (August 10, 2018): 845–49, https://doi.org/10.15585/mmwr.mm6731a1; Jean Y. Ko, "Incidence of Neonatal Abstinence Syndrome — 28 States, 1999–2013," *MMWR. Morbidity and Mortality Weekly Report* 65 (2016), https://doi.org/10.15585/mmwr.mm6531a2.

[415] Florida Alcohol and Drug Abuse Association, "Drug-Related Death Leading Cause of Pregnancy-Associated Death in Florida," 2020, https://cdn.ymaws.com/www.fadaa.org/resource/resmgr/files/resource_center/FADAA_June_2020_TrendAlert6.pdf; Florida Pregnancy-Associated and Mortality Review, "Urgent PAMR Message to Providers and Hospitals," 2020, https://health.usf.edu/-/media/Files/Public-Health/Chiles-Center/FPQC/MOREPAMRMessageMar2020.ashx?la=en&hash=94BD5712F18F4EA21B8F59476A65FA748B43053D&hash=94BD5712F18F4EA21B8F59476A65FA748B43053D.

[416] Davida M. Schiff et al., "Fatal and Nonfatal Overdose Among Pregnant and Postpartum Women in Massachusetts," *Obstetrics and Gynecology* 132, no. 2 (August 2018): 466–74, https://doi.org/10.1097/AOG.0000000000002734; Sidra Goldman-Mellor and Claire E. Margerison, "Maternal Drug-Related Death and Suicide Are Leading Causes of Postpartum Death in California," *American Journal of Obstetrics and Gynecology* 221, no. 5 (November 2019): 489.e1-489.e9, https://doi.org/10.1016/j.ajog.2019.05.045.

[417] SAMHSA, "Clinical Guidance for Treating Pregnant and Parenting Women With Opioid Use Disorder and Their Infants," 2018, https://store.samhsa.gov/product/Clinical-Guidance-for-Treating-Pregnant-and-Parenting-Women-With-Opioid-Use-Disorder-and-Their-Infants/SMA18-5054; The American College of Obstetrics and Gynecology, "Opioid Use and Opioid Use Disorder in Pregnancy," Committee Opinion, 2017, https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/08/opioid-use-and-opioid-use-disorder-in-pregnancy.

similar effectiveness to methadone while decreasing the chance for NAS.[418] The most effective models to treat pregnant women with OUD are comprehensive, women-centered, and family-centered. Given that opioid-related mortality risk is highest up to one year postpartum, programs to address this population should also provide long-term services. These programs, which can be described as "all services under one roof", have been implemented and evaluated to be effective in Oregon,[419] Pennsylvania,[420] North Carolina,[421] and Massachusetts.[422] Figure 13 below shows the geographic differences between absolute counts and rates of NAS in Florida from 2014 to 2018. NAS can serve as a proxy for the prevalence of mothers with OUD to identify areas most in need of interventions.

[418] Marjorie C. Meyer et al., "Methadone and Buprenorphine for Opioid Dependence during Pregnancy: A Retrospective Cohort Study," *Journal of Addiction Medicine* 9, no. 2 (April 2015): 81–86, https://doi.org/10.1097/ADM.0000000000000092.

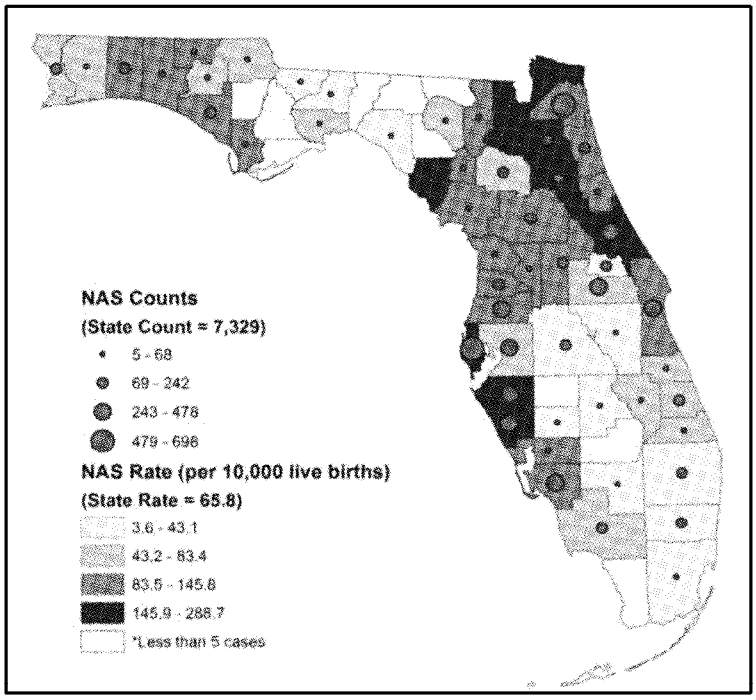
[419] K. John McConnell et al., "Project Nurture Integrates Care And Services To Improve Outcomes For Opioid-Dependent Mothers And Their Children," *Health Affairs (Project Hope)* 39, no. 4 (April 2020): 595–602, https://doi.org/10.1377/hlthaff.2019.01574.

[420] Elizabeth E. Krans et al., "The Pregnancy Recovery Center: A Women-Centered Treatment Program for Pregnant and Postpartum Women with Opioid Use Disorder," *Addictive Behaviors* 86 (November 2018): 124–29, https://doi.org/10.1016/j.addbeh.2018.05.016.

[421] Shelley L. Galvin et al., "A Cohort Comparison of Differences Between Regional and Buncombe County Patients of a Comprehensive Perinatal Substance Use Disorders Program in Western North Carolina," *North Carolina Medical Journal* 81, no. 3 (June 2020): 157–65, https://doi.org/10.18043/ncm.81.3.157.

[422] Mary T. Paterno et al., "Evaluation of a Nurse-Led Program for Rural Pregnant Women With Opioid Use Disorder to Improve Maternal-Neonatal Outcomes," *Journal of Obstetric, Gynecologic, and Neonatal Nursing: JOGNN* 48, no. 5 (September 2019): 495–506, https://doi.org/10.1016/j.jogn.2019.07.002.

Figure 13: Neonatal Abstinence Syndrome Rates and Counts in Florida, 2014-2018



Source: Florida Department of Health

In addition to universal prenatal screening and screening in the hospital, both recommended as secondary prevention interventions, comprehensive treatment programs should be implemented for perinatal OUD in areas disproportionately affected by the opioid crisis. The MORE program, previously discussed, has already shown improvement in hospitals with high NAS rates in Florida for screening, initiating medication, and referring to continuing treatment. However, a treatment model where comprehensive care is delivered to the mother and the infant during the prenatal, perinatal, and postpartum period (up to one year) is needed. This care should be localized to one healthcare system or region to increase coordination. Based on the geographic distribution of NAS counts, counties with counts of more than 243 from 2014 to 2018 (see figure above) should have these programs, for a total of 10 programs statewide. For other counties, the standard of care should be initiating medication after a positive screen for OUD followed by continuation of treatment through a tracking and referral system. The Unite Us collaboration with the Sarasota Memorial Health Care System[423] provides an example of a best practice where mothers are connected to health and social services, including Healthy Start[424] and Early Steps[425] when appropriate. Either having a comprehensive treatment model or care coordination in place is vital for increasing treatment retention, which are associated with improved maternal

[423] Unite Florida, "About Us," n.d., https://florida.uniteus.com/about/.

[424] Florida Department of Health, "Healthy Start," 2021, http://www.floridahealth.gov/programs-and-services/childrens-health/healthy-start/index.html.

[425] Florida Department of Health, "Early Steps," 2019, http://www.floridahealth.gov/programs-and-services/childrens-health/early-steps/index.html.

and perinatal outcomes.[426] Another important component of the continuum of care for pregnant women and mothers with OUD is residential treatment, a setting where these individuals can receive comprehensive and long-term care while also having their children on site. During community visits by the Drug Policy Advisory Council, 15 out of 18 communities cited a shortage of behavioral health and inpatient bed services for pregnant and postpartum women along with a lack of access to medications.[427] Florida should enhance their network of residential treatment programs across the state for this population and ensure that each program has access to providers that can prescribe OUD medications.

23. Peer support specialists (i.e. peer navigators) are used in various settings to help individuals sustain recovery and navigate multiple systems of care. Integrating peer support specialists in the context of perinatal OUD has the potential to improve maternal and child health. Although outcome data is unavailable due to the novelty of this intervention, qualitative evidence suggests that peer support specialists are a positive addition to the mother's treatment team.[428] Peers have also been shown to be effective in the child welfare setting, suggesting that long-term provision of these services may be beneficial to new mothers with OUD.[429] These peers can also help mothers make decisions around contraception as 86% of pregnancies are unintended in women with OUD, twice as common as the general population.[430] Florida has begun placing peers in areas of the state that have been disproportionately affected by NAS, using funding from the Overdose 2 Action[431] grant to employ five peers. The figure in the previous paragraph highlights areas where interventions for perinatal OUD are most needed. Florida should employ peer support specialists as a complement to the ten proposed comprehensive treatment centers for pregnant women with OUD. Additionally, given the high rates of NAS in more rural parts of Florida, there should be a floating peer support specialist as an additional support for women with OUD in three areas: the Panhandle, the central part of the state north of Orlando, and the counties that surround Jacksonville.

24. Pregnant women in the criminal justice system are an especially vulnerable population, as a national study showed that 26% of pregnant women admitted to prisons and 14% admitted to jails met criteria for OUD yet one-third were either taken off of OUD

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[426] Elizabeth E. Krans et al., "Outcomes Associated with the Use of Medications for Opioid Use Disorder during Pregnancy," *Addiction (Abingdon, England)*, May 25, 2021, https://doi.org/10.1111/add.15582.

[427] Drug Policy Advisory Council, "Statewide Drug Policy Advisory Council 2020 Annual Report," 2020, http://www.floridahealth.gov/provider-and-partner-resources/dpac/DPAC_11-30-20.pdf.

[428] Amanda Fallin-Bennett, Alex Elswick, and Kristin Ashford, "Peer Support Specialists and Perinatal Opioid Use Disorder: Someone That's Been There, Lived It, Seen It," *Addictive Behaviors* 102 (March 2020): 106204, https://doi.org/10.1016/j.addbeh.2019.106204.

[429] Joseph P. Ryan et al., "Recovery Coaches and Substance Exposed Births: An Experiment in Child Welfare," *Child Abuse & Neglect* 32, no. 11 (November 2008): 1072–79, https://doi.org/10.1016/j.chiabu.2007.12.011.

[430] Sarah H. Heil et al., "Unintended Pregnancy in Opioid-Abusing Women," *Journal of Substance Abuse Treatment* 40, no. 2 (March 2011): 199–202, https://doi.org/10.1016/j.jsat.2010.08.011.

[431] Florida Department of Health, "Opioid Response Activities FL-OD2A", 2021, http://www.floridahealth.gov/programs-and-services/opioid-response/index.html

medications or not offered them, thus experiencing withdrawal.[432] Given the very high prevalence of OUD in prisons and jails among this population, this setting provides an opportunity to initiate evidence-based treatment and provide a warm handoff to continuing care upon release. Prisons and jails should have the capacity to continue MOUD for pregnant women with OUD who are incarcerated and currently on these medications, and these settings should have the option to begin extended-release formulations of buprenorphine or naltrexone, depending on shared decision-making with a trained provider, with a warm handoff to continuing care upon release along with appropriate psychosocial services. In addition to providing these services, several pilots that deliver these services within one program model should be implemented, similar to other programs implemented in other parts of the country.[433]

25. As discussed above, there is considerable intersection of the opioid crisis and the criminal justice system, as around 18% of those in jails and prisons report regularly using opioids before incarceration,[434] which likely serves as a good proxy for the percentage that will need OUD treatment. It is estimated that 52% of those with prescription drug use disorder and 77% of heroin users have a lifetime history of criminal justice involvement,[435] and between 24-36% of those with heroin use disorder pass through the corrections system annually.[436] These statistics show that individuals with OUD are overrepresented in the criminal justice system, highlighting an important touchpoint to identify OUD and link to evidence-based treatment. Despite this opportunity, only 20% of those in prisons and jails receive formal treatment.[437] Many times, this treatment is not adequate or evidence based. Very few prisons and jails offer opioid agonist therapy with either buprenorphine or methadone as a treatment option,[438] despite evidence that such treatment increases

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[432] Carolyn Sufrin et al., "Opioid Use Disorder Incidence and Treatment among Incarcerated Pregnant Women in the United States: Results from a National Surveillance Study," *Addiction (Abingdon, England)* 115, no. 11 (November 2020): 2057–65, https://doi.org/10.1111/add.15030.

[433] Elizabeth Needham Waddell et al., "Reducing Overdose after Release from Incarceration (ROAR): Study Protocol for an Intervention to Reduce Risk of Fatal and Non-Fatal Opioid Overdose among Women after Release from Prison," *Health & Justice* 8, no. 1 (July 10, 2020): 18, https://doi.org/10.1186/s40352-020-00113-7; Tracy Brawley, "Reducing the Risk of Post-Incarceration Opioid Overdose in Women" (Oregon Health & Science University, 2019), https://news.ohsu.edu/2019/09/11/reducing-the-risk-of-post-incarceration-opioid-overdose-in-women.

[434] Jennifer Bronson et al., "Drug Use, Dependence, and Abuse among State Prisoners and Jail Inmates, 2007–2009," *Washington, DC: United States Department of Justice, Office of Juvenile Justice and Delinquency Prevention*, 2017, https://bjs.ojp.gov/content/pub/pdf/dudaspji0709.pdf.

[435] Winkelman, Chang, and Binswanger, "Health, Polysubstance Use, and Criminal Justice Involvement Among Adults With Varying Levels of Opioid Use."

[436] Amy E. Boutwell et al., "Arrested on Heroin: A National Opportunity," *Journal of Opioid Management* 3, no. 6 (December 2007): 328–32, https://doi.org/10.5055/jom.2007.0021.

[437] Redonna K. Chandler, Bennett W. Fletcher, and Nora D. Volkow, "Treating Drug Abuse and Addiction in the Criminal Justice System: Improving Public Health and Safety," *JAMA : The Journal of the American Medical Association* 301, no. 2 (January 14, 2009): 183–90, https://doi.org/10.1001/jama.2008.976.

[438] Sachini Bandara et al., "Methadone and Buprenorphine Treatment in United States Jails and Prisons: Lessons from Early Adopters," *Addiction (Abingdon, England)*, May 17, 2021, https://doi.org/10.1111/add.15565.

community treatment engagement and decreases illicit opioid use after release.[439] For example, one study found that beginning or continuing opioid agonist therapy in incarcerated settings was associated with a 75% reduction in all-cause mortality and an 85% reduction in overdose-related mortality after release.[440]

26. Ideally, initiatives would be in place to divert individuals with OUD away from prisons and jails and towards treatment. However, treatment programs have been successful in these settings.[441] In a statewide initiative, the Rhode Island Department of Correction maintained individuals entering the prison system on their respective OUD medication and provided linkage to continuing care upon release. The new initiative was associated with a 61% reduction in overdose-related mortality among recently incarcerated individuals compared with the same time period in the previous year.[442] In Florida, the Accepting Change Through Treatment program in Seminole County Jail is a model program that begins OUD medication and other treatment services before an individual is released into the community and provides support for continuation of care after incarceration.[443] According to the findings from the Florida Statewide Task Force on Opioid Abuse, which recommends expanding access to MOUD in the criminal justice system, less than one-third of county jails make OUD medications available, mostly extended-release naltrexone before release.[444] The Department of Children and Families is leading an educational initiative to make this treatment option more available in the prison setting. All 67 county jails and 57 prisons in Florida should have programs in place to screen individuals entering these facilities for the presence of OUD. All prisons in Florida should have the capacity to begin extended-release formulations of buprenorphine or naltrexone, depending on shared decision-making with a trained clinician, prior to release and provide a warm-handoff for continuation of care. All jails in Florida should have programs in place to maintain or begin all three types of MOUD, with a preference for extended-release formulations. Extended-release formulations may be a better fit from the perspective of the patient as one study showed that incarcerated individuals on oral opioid agonist treatment were more interested

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[439] Kelly E. Moore et al., "Effectiveness of Medication Assisted Treatment for Opioid Use in Prison and Jail Settings: A Meta-Analysis and Systematic Review," *Journal of Substance Abuse Treatment* 99 (April 2019): 32–43, https://doi.org/10.1016/j.jsat.2018.12.003.

[440] John Marsden et al., "Does Exposure to Opioid Substitution Treatment in Prison Reduce the Risk of Death after Release? A National Prospective Observational Study in England," *Addiction (Abingdon, England)* 112, no. 8 (August 2017): 1408–18, https://doi.org/10.1111/add.13779.

[441] SAMHSA, "Use of Medication-Assisted Treatment for Opioid Use Disorder in Criminal Justice Settings," 2019, https://store.samhsa.gov/sites/default/files/d7/priv/pep19-matusecjs.pdf; Pew Charitable Trusts, "Opioid Use Disorder Treatment in Jails and Prisons," 2020, https://www.pewtrusts.org/-/media/assets/2020/04/caseformedicationassistedtreatmentjailsprisons.pdf.

[442] Traci C. Green et al., "Postincarceration Fatal Overdoses After Implementing Medications for Addiction Treatment in a Statewide Correctional System," *JAMA Psychiatry* 75, no. 4 (April 1, 2018): 405–7, https://doi.org/10.1001/jamapsychiatry.2017.4614.

[443] Grace Toohey, "Seminole Jail's Innovative Addiction Treatment Program Aims to Combat Opioid Epidemic," *Orlando Sentinel*, January 2, 2020, https://www.orlandosentinel.com/news/seminole-county/os-ne-seminole-jail-drug-treatment-program-20200102-6wu2d6lsiveh7oyeuy5mg3wvze-story.html.

[444] Florida Statewide Task Force on Opioid Abuse, "Findings and Recommendations of the Statewide Task Force on Opioid Abuse."

in switching to extended-release buprenorphine compared with non-incarcerated individuals, stating discreetness of treatment as a reason to switch.[445] The recommendations for jails and prisons are different based on both the shorter time period spent in jails and the reported opioid overdose deaths in correctional facilities that disproportionately occur in jails.[446]

27. Reentry programs are essential for previously incarcerated individuals with OUD. Studies have shown that the risk of opioid-related overdose death is 40-129 times higher in the two weeks after release compared to the general population.[447] Another study found that only 5% of justice-involved individuals who are referred to specialty treatment for OUD receive methadone or buprenorphine compared with 41% from other referral sources. Taken together, these studies suggest reentry programs that link to evidence-based treatment will substantially improve outcomes for individuals with OUD who are recently released from prisons and jails. In Florida, implementation of Jail Bridge programs has been encouraged as part of the SOR 2 grant to provide treatment transition and coverage for individuals reentering communities from criminal justice settings.[448] The SCORE Initiative in Seminole County, along with being a post-overdose response program, also provides access to a peer support specialist upon reentry. A replicable statewide model that provides comprehensive support to individuals with OUD transitioning into the community is Recovery Kentucky, which is a network of 18 recovery centers that provides a peer-led supportive housing program primarily serving those reentering the community from incarceration for up to one year. Also providing life skills and vocational training, this program has shown positive individual and societal outcomes.[449] All prisons and jails in Florida should have an OUD-specific reentry program in place to provide comprehensive services and link to evidence-based treatment. These services might best be served in a network of recovery centers like the Recovery Kentucky model. A component of all reentry

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[445] Mathieu Chappuy et al., "Factors of Interest in Extended-Release Buprenorphine: Comparisons Between Incarcerated and Non-Incarcerated Patients with Opioid Use Disorder," *Patient Preference and Adherence* 15 (2021): 1259–67, https://doi.org/10.2147/PPA.S311674.

[446] Eliana Kaplowitz et al., "Fentanyl-Related Overdose during Incarceration: A Comprehensive Review," *Health & Justice* 9, no. 1 (May 19, 2021): 13, https://doi.org/10.1186/s40352-021-00138-6.

[447] Ingrid A. Binswanger et al., "Release from Prison — A High Risk of Death for Former Inmates," *The New England Journal of Medicine* 356, no. 2 (January 11, 2007): 157–65, https://doi.org/10.1056/NEJMsa064115; Shabbar I. Ranapurwala et al., "Opioid Overdose Mortality Among Former North Carolina Inmates: 2000–2015," *American Journal of Public Health* 108, no. 9 (September 2018): 1207–13, https://doi.org/10.2105/AJPH.2018.304514.

[448] Florida Department of Children and Families, "Florida's State Opioid Response (SOR) 2 Grant Project," 2021, https://www.lsfhealthsystems.org/wp-content/uploads/2021/01/Florida-SOR-Guidance-1.7.21.pdf.

[449] University of Kentucky Center on Drug & and Alcohol Research, "Findings from the Recovery Center Outcome Study," 2019, https://cdar.uky.edu/rcos/RCOS_2019_Report.pdf; T. K. Logan, Jennifer Cole, and Robert Walker, "Examining Recovery Program Participants by Gender: Program Completion, Relapse, and Multidimensional Status 12 Months After Program Entry," *Journal of Drug Issues* 50, no. 4 (2020): 436–54.

programs should be overdose education and naloxone distribution (OEND) given the high risk for opioid overdose among this population.[450]

(v) Expand harm reduction services across Florida

Harm reduction services are an essential component of the continuum of care for OUD. Rather than abstinence-only and zero-tolerance approaches that criminalize opioid use, create barriers to treatment, and propagate stigma, a harm reduction approach meets individuals with OUD where they are at and recognizes the daunting barriers that they face. Some people with OUD may not perceive a need for treatment or will not be ready to stop using opioids,[451] so these types of services are vital in reducing individual and societal harms from the opioid crisis and providing critical linkages to treatment. A comprehensive abatement plan should include scaling up these services, namely naloxone distribution, syringe service programs, and drug checking, to address those still actively using opioids.

28. Naloxone is an opioid antagonist that reverses an opioid overdose when given in enough time and at the appropriate dose. Expanding the access and availability of naloxone in communities is likely one of the most impactful interventions in decreasing opioid-related overdose deaths.[452] Increasing naloxone capacity is vital, as it is estimated that 40% of fatal opioid overdoses involve witnesses, but only a few attempted to use naloxone.[453] In fact, it is estimated that one death is prevented for every 227 naloxone kits distributed.[454] Naloxone is made available to the community through three main mechanisms: dispensing from a pharmacy, distribution by community-based organizations through OEND programs, and administration by uniformed first responders to an overdose, sometimes followed by naloxone distribution through a leave behind program.[455] Recommendations

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[450] Lynn D. Wenger et al., "Overdose Education and Naloxone Distribution in the San Francisco County Jail," *Journal of Correctional Health Care: The Official Journal of the National Commission on Correctional Health Care* 25, no. 4 (October 2019): 394–404, https://doi.org/10.1177/1078345819882771.

[451] SAMHSA, "Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health."

[452] Jeromie Ballreich et al., "Modeling Mitigation Strategies to Reduce Opioid-Related Morbidity and Mortality in the US," *JAMA Network Open* 3, no. 11 (November 2, 2020): e2023677, https://doi.org/10.1001/jamanetworkopen.2020.23677; Irvine et al., "Modelling the Combined Impact of Interventions in Averting Deaths during a Synthetic-Opioid Overdose Epidemic"; Pitt, Humphreys, and Brandeau, "Modeling Health Benefits and Harms of Public Policy Responses to the US Opioid Epidemic."

[453] Christine L. Mattson et al., "Opportunities to Prevent Overdose Deaths Involving Prescription and Illicit Opioids, 11 States, July 2016-June 2017," *MMWR. Morbidity and Mortality Weekly Report* 67, no. 34 (August 31, 2018): 945–51, https://doi.org/10.15585/mmwr.mm6734a2.

[454] Phillip O. Coffin and Sean D. Sullivan, "Cost-Effectiveness of Distributing Naloxone to Heroin Users for Lay Overdose Reversal," *Annals of Internal Medicine* 158, no. 1 (January 1, 2013): 1–9, https://doi.org/10.7326/0003-4819-158-1-201301010-00003.

[455] Becca M. Scharf et al., "Best Practices for a Novel EMS-Based Naloxone Leave behind Program," *Prehospital Emergency Care: Official Journal of the National Association of EMS Physicians and the National Association of State EMS Directors* 25, no. 3 (June 2021): 418–26, https://doi.org/10.1080/10903127.2020.1771490; Janet Weiner, Sean M Murphy, and Czarina Behrends, "Expanding Access to Naloxone: A Review of Distribution Strategies" (Penn LDI/CHERISH Issue Brief, 2019), https://ldi.upenn.edu/sites/default/files/pdf/LDI%20CHERISH%20Brief_May2019.pdf.

to increase distribution most effectively and efficiently through each of these three channels is discussed below.

29. Dispensing naloxone through pharmacies is guided by the state's naloxone access law. Florida has a statewide standing order for first responders to access naloxone without a prescription, but a layperson must still obtain a prescription from a prescriber. A special population to target for naloxone distribution through pharmacies are individuals maintained on high doses of opioids for chronic pain. These individuals are at increased risk for overdose, though only an estimated 2% of these individuals nationally are co-prescribed naloxone.[456] Florida requires prescribers to provide a naloxone prescription when writing an opioid prescription for certain indications.[457] However, cost can be a barrier at the point of sale. Therefore, naloxone should be made available at pharmacies for free, and all those who are on very high doses of opioids (90 MME per day or more) and one member of their household should also have access to naloxone, as individuals cannot administer naloxone themselves and family members are likely to witness an opioid overdose.[458] Analysis of Florida PDMP data shows that 285,061 individuals were on 90 MME or more per day at some point during 2019.[459] Due to the ease of administration compared to injectable naloxone, all naloxone distributed through this channel should be in the nasal spray formulation. Given that naloxone has a shelf life of 12 to 24 months, kits should be renewed every year.[460]

30. Naloxone distribution has been shown to be most effective for mortality reduction when targeted towards people who use drugs,[461] and this form of community access to naloxone is typically provided through OEND programs. These programs are an evidence-based intervention to reduce opioid-related morbidity and mortality, distributing naloxone kits to individuals most likely to witness an opioid overdose and training laypersons to respond

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[456] Bradley D. Stein et al., "Individual and Community Factors Associated with Naloxone Co-Prescribing Among Long-Term Opioid Patients: A Retrospective Analysis," *Journal of General Internal Medicine*, 2021, 1–6.

[457] Traci C. Green et al., "Laws Mandating Coprescription of Naloxone and Their Impact on Naloxone Prescription in Five US States, 2014–2018," *American Journal of Public Health* 110, no. 6 (April 16, 2020): 881–87, https://doi.org/10.2105/AJPH.2020.305620.

[458] Sarah M. Bagley et al., "Expanding Access to Naloxone for Family Members: The Massachusetts Experience," *Drug and Alcohol Review* 37, no. 4 (May 2018): 480–86, https://doi.org/10.1111/dar.12551.

[459] Florida PDMP analysis by Securities Litigation and Consulting Group, Inc. The queries used to arrive at this number are contained in the backup materials provided with the report of Dr. McCann.

[460] Schuyler Pruyn et al., "Quality Assessment of Expired Naloxone Products from First-Responders' Supplies," *Prehospital Emergency Care: Official Journal of the National Association of EMS Physicians and the National Association of State EMS Directors* 23, no. 5 (October 2019): 647–53, https://doi.org/10.1080/10903127.2018.1563257.

[461] Alex S. Bennett et al., "From Peers to Lay Bystanders: Findings from a Decade of Naloxone Distribution in Pittsburgh, PA," *Journal of Psychoactive Drugs* 50, no. 3 (August 2018): 240–46, https://doi.org/10.1080/02791072.2018.1430409; A. Y. Walley et al., "Opioid Overdose Rates and Implementation of Overdose Education and Nasal Naloxone Distribution in Massachusetts: Interrupted Time Series Analysis," *BMJ* 346, no. jan30 5 (January 30, 2013): f174–f174, https://doi.org/10.1136/bmj.f174; Eliza Wheeler et al., "Opioid Overdose Prevention Programs Providing Naloxone to Laypersons — United States, 2014," *MMWR. Morbidity and Mortality Weekly Report* 64, no. 23 (June 19, 2015): 631–35.

during overdose events. A systematic review on the effectiveness of distributing naloxone kits suggests that administering naloxone by a layperson is successful in reversing an opioid overdose 96-98% of the time.[462] OEND programs are crucial in targeting high-risk populations who may be reluctant to go to pharmacies and clinical sites to obtain naloxone. This may also be the most important channel for overall naloxone distribution in communities, as it is reported that OEND programs distributed twice as much naloxone in 2019 compared to the amount of naloxone that retail pharmacies dispensed in 2018.[463] This may be even more important for Florida, where there is no standing order at pharmacies to obtain naloxone. Sometimes, a statewide initiative is in place to coordinate naloxone distribution and build a network of OEND programs that can train first responders and laypersons. In Florida, the Florida Department of Children and Families oversees a statewide overdose prevention program and reports distributing over 90,000 naloxone kits from 2016 to 2020.[464] Outreach efforts and programs should ensure that every person with OUD along with their family members and friends should be trained on overdose education and have naloxone readily available.[465] While the size of the family and social network of individuals in need of naloxone access is not available, data from the General Social Survey indicate that the average individual in the United States reports four individuals as being their close social network members (including family and friends).[466] Therefore, every Floridian with OUD and their close social networks having access to naloxone would amount to 1,911,500 kits needed to be distributed. This will require enhancing the statewide initiative, distributing naloxone through newly developed harm reduction centers, and OEND programs targeting those transitioning from incarceration to society and those in treatment centers. In addition, public access to naloxone in non-traditional settings, through Naloboxes (which make naloxone available in public areas), should be available in places such as public libraries, public restrooms, malls, airports, and movie theaters.[467] A recent survey of public librarians in Florida revealed that 17% had witnessed an overdose in the past year, the highest rate among the five states surveyed.[468] Due to the ease of administration compared to injectable naloxone, all naloxone distributed through

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[462] Rebecca McDonald and John Strang, "Are Take-Home Naloxone Programmes Effective? Systematic Review Utilizing Application of the Bradford Hill Criteria," *Addiction (Abingdon, England)* 111, no. 7 (July 2016): 1177–87, https://doi.org/10.1111/add.13326.

[463] Gery P. Guy et al., "Vital Signs: Pharmacy-Based Naloxone Dispensing - United States, 2012-2018," *MMWR. Morbidity and Mortality Weekly Report* 68, no. 31 (August 9, 2019): 679–86, https://doi.org/10.15585/mmwr.mm6831e1; Eliza Wheeler and Maya Doe-Simkins, "Harm Reduction Programs Distribute One Million Doses of Naloxone in 2019," *Medium*, 2020, https://medium.com/@ejwharmreduction.

[464] Amanda Muller, "Statewide Harm Reduction Initiatives," Florida Department of Children and Families, 2020, https://www.myflfamilies.com/service-programs/samh/publications/ROSC/202006/7.shtml.

[465] Bagley et al., "Expanding Access to Naloxone for Family Members."

[466] Peter V. Marsden, "Core Discussion Networks of Americans," *American Sociological Review*, 1987, 122–31.

[467] Geoffrey A. Capraro and Claudia B. Rebola, "The NaloxBox Program in Rhode Island: A Model for Community-Access Naloxone," *American Journal of Public Health* 108, no. 12 (December 2018): 1649–51, https://doi.org/10.2105/AJPH.2018.304735.

[468] Rachel Feuerstein-Simon et al., "Opioid Overdose in Public Libraries: Results from a Five State Survey," *MedRxiv*, June 7, 2020, 2020.06.05.20123422, https://doi.org/10.1101/2020.06.05.20123422.

this channel should be in the nasal spray formulation. Given that naloxone has a shelf life of 12 to 24 months, kits should be renewed every year.[469]

31. Uniformed first responders, such as law enforcement, fire department, EMTs, and paramedics, extend the workforce of non-physicians that can administer naloxone in community settings. A study in an Ohio community found that an increase in the number of law enforcement officers trained in overdose education and carrying naloxone was associated with a reduction in opioid overdose deaths and increased survival among opioid overdose victims.[470] The Florida Department of Health has implemented the Helping Emergency Responders Obtain Support program to distribute naloxone to first responders. However, first responders must go through a competitive application process due to limited funding. All first responders should have access to overdose education training through the OEND network and have available a sufficient and continuous supply of naloxone without onerous barriers to obtaining the opioid overdose antidote. In addition to administering naloxone in the community, first responders should also have the capability to leave behind naloxone to individuals experiencing an overdose and their family members or friends at the scene when medical transport is refused, which appears to get naloxone into social networks likely to witness an opioid overdose.[471]

32. According to the CDC, acute cases of Hepatitis C Virus (HCV) have increased more than three-fold nationally from 2010-2016, reflecting rising rates of injection drug use from an increasing cohort of opioid-addicted individuals, and injection drug use contributed to around 20% of recorded HIV cases in 2016.[472] New cases of HCV in Florida have been rapidly increasing and are higher than the national average.[473] In a study done in Miami at the IDEA Exchange, Florida's first SSP, the prevalence of HCV and HIV was 44.4% and 10.2% respectively among 837 participants accessing the SSP for the first time.[474] Despite this high prevalence, it is estimated that half or more of those with HCV and 45% of young adults with HIV are unaware that they have these infectious diseases.[475] This is significant

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[469] Pruyn et al., "Quality Assessment of Expired Naloxone Products from First-Responders' Supplies."

[470] Jessica Rando et al., "Intranasal Naloxone Administration by Police First Responders Is Associated with Decreased Opioid Overdose Deaths," *The American Journal of Emergency Medicine* 33, no. 9 (September 2015): 1201–4, https://doi.org/10.1016/j.ajem.2015.05.022.

[471] Scharf et al., "Best Practices for a Novel EMS-Based Naloxone Leave behind Program."

[472] Centers for Disease Control and Prevention, "2016 Surveillance Data for Viral Hepatitis in U.S.," 2018, https://www.cdc.gov/hepatitis/statistics/2016surveillance/commentary.htm; National Institute on Drug Abuse, "Drug Use and Viral Infections (HIV, Hepatitis) DrugFacts," 2020, https://www.drugabuse.gov/publications/drugfacts/drug-use-viral-infections-hiv-hepatitis.

[473] Florida Alcohol and Drug Abuse Association and Florida Department of Children and Families, "Parallel Hepatitis C & Opioid Epidemics: A Change in Recommendations," 2020, https://cdn.ymaws.com/www.fadaa.org/resource/resmgr/files/resource_center/FADAA_TrendAlert_2020-04.pdf.

[474] Tyler S. Bartholomew et al., "Baseline Prevalence and Correlates of HIV and HCV Infection among People Who Inject Drugs Accessing a Syringe Services Program; Miami, FL," *Harm Reduction Journal* 17, no. 1 (June 10, 2020): 40, https://doi.org/10.1186/s12954-020-00385-0.

[475] Health and Human Services, "U.S. Statistics: People with HIV," 2019, https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics; John W. Ward, "The Hidden Epidemic of Hepatitis C Virus Infection

given that there are effective treatments for HIV and curative treatments for HCV. Screening for HIV and HCV among injection drug users has been found to be effective and cost-effective.[476] In addition to screening in comprehensive harm reduction centers, HIV and HCV screening in state and local health departments, with linkage to infectious disease treatment as well as OUD treatment, would create an expansion of these needed services. All those with OUD should be screened for HIV and HCV and appropriately treated, whether this screening takes place at a health department, OUD treatment center, or harm reduction center.

33. Good Samaritan laws (GSL) can include a provision that provides protection to witnesses who seek medical assistance for someone or for themselves who are experiencing a drug-related overdose and are intended to reduce overdose mortality by removing barriers to calling for medical assistance. A GSL that includes protection from arrest is associated with reduced opioid-related mortality.[477] However, the most frequently cited reason for not calling for medical assistance is fear of law enforcement, even in the context of GSLs.[478] In other states, even though GSLs were in place, the majority of people who used drugs had no knowledge of these laws,[479] though knowledge of these laws is associated with three times greater odds of calling 911 when witnessing an overdose.[480] In Florida, the GSL was amended in 2019 to provide more protections for witnesses to an overdose and the individual experiencing the overdose. Given this recent change, the fear of police among people who use drugs, and the general lack of knowledge about these laws, Florida needs to disseminate information and increase awareness of the newly amended GSL. This would be best operationalized through a mass media campaign, using a variety of platforms that

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in the United States: Occult Transmission and Burden of Disease," *Topics in Antiviral Medicine* 21, no. 1 (November 28, 2016): 15–19.

[476] Lauren E. Cipriano et al., "Cost Effectiveness of Screening Strategies for Early Identification of HIV and HCV Infection in Injection Drug Users," *PloS One* 7, no. 9 (2012): e45176, https://doi.org/10.1371/journal.pone.0045176.

[477] Leah Hamilton et al., "Good Samaritan Laws and Overdose Mortality in the United States in the Fentanyl Era," *The International Journal on Drug Policy* 97 (June 3, 2021): 103294, https://doi.org/10.1016/j.drugpo.2021.103294.

[478] Stephen Koester et al., "Why Are Some People Who Have Received Overdose Education and Naloxone Reticent to Call Emergency Medical Services in the Event of Overdose?," *The International Journal on Drug Policy* 48 (October 2017): 115–24, https://doi.org/10.1016/j.drugpo.2017.06.008; Dennis P. Watson et al., "Lay Responder Naloxone Access and Good Samaritan Law Compliance: Postcard Survey Results from 20 Indiana Counties," *Harm Reduction Journal* 15, no. 1 (April 6, 2018): 18, https://doi.org/10.1186/s12954-018-0226-x.

[479] Tristan I. Evans et al., "Factors Associated with Knowledge of a Good Samaritan Law among Young Adults Who Use Prescription Opioids Non-Medically," *Harm Reduction Journal* 13, no. 1 (July 26, 2016): 24, https://doi.org/10.1186/s12954-016-0113-2; Kristin E. Schneider et al., "Knowledge of Good Samaritan Laws and Beliefs About Arrests Among Persons Who Inject Drugs a Year After Policy Change in Baltimore, Maryland," *Public Health Reports* 135, no. 3 (May 1, 2020): 393–400, https://doi.org/10.1177/0033354920915439.

[480] Andrea Jakubowski et al., "Knowledge of the 911 Good Samaritan Law and 911-Calling Behavior of Overdose Witnesses," *Substance Abuse* 39, no. 2 (2018): 233–38, https://doi.org/10.1080/08897077.2017.1387213.

could reach those most likely to witness a drug overdose. A similar approach has been used in New York and Delaware.[481]

34. Pharmacists have the potential to play an important role in the opioid crisis, including screening and monitoring opioid prescribing, collaboratively managing OUD medications with prescribers, and providing access to harm reduction supplies, such as naloxone and syringes, along with overdose education. However, pharmacists consistently report lack of training as a barrier.[482] In addition, findings from one study suggest that pharmacists and pharmacy technicians are the most frequent perpetrators of stigma as reported by individuals in OUD remission.[483] An educational outreach initiative, such as academic detailing, could increase the role of pharmacists in the opioid crisis,[484] which has been done in a statewide initiative in North Dakota[485] and in several communities in Oregon.[486] Even though Florida dispenses naloxone from a pharmacy at a higher rate than the national average,[487] academic detailing to pharmacists could improve naloxone distribution while also educating pharmacists on the E-FORCSE, dispensing OUD medications, and the role of safe storage and disposal for patients' dispensed opioids. Similar to how the E-FORCSE can be used to tailor academic detailing to the highest tier opioid prescribers, the same approach can be used to target academic detailing to pharmacies that are in the lowest tier (10%) for dispensing naloxone. Academic detailing should also include an anti-stigma training program.

35. Syringe service programs (SSP) are community-based programs that can provide a variety of services, such as needle exchange, testing for infectious diseases, naloxone distribution,

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[481] Delaware Health and Social Services, "Two Laws, One Goal: Saving Lives," n.d., https://www.helpisherede.com/Content/Documents/Help_Is_Here_Delaware_Good_Samaritan_Fact_Sheet.pdf; New York City Police Department, "NYPD Launches Public Service Announcement to Increase 'Good Samaritan Law' Awareness," 2017, https://www1.nyc.gov/site/nypd/news/pr0623/nypd-launches-public-service-announcement-increase-good-samaritan-law-awareness.

[482] Tanvee Thakur, Meredith Frey, and Betty Chewning, "Pharmacist Roles, Training, and Perceived Barriers in Naloxone Dispensing: A Systematic Review," *Journal of the American Pharmacists Association* 60, no. 1 (January 1, 2020): 178–94, https://doi.org/10.1016/j.japh.2019.06.016.

[483] Amanda Burgess et al., "Experiences of Stigma among Individuals in Recovery from Opioid Use Disorder in a Rural Setting: A Qualitative Analysis," *Journal of Substance Abuse Treatment* 130 (May 21, 2021): 108488, https://doi.org/10.1016/j.jsat.2021.108488.

[484] Shannon E. Rudolph et al., "Identifying Barriers to Dispensing Naloxone: A Survey of Community Pharmacists in North Carolina," *Journal of the American Pharmacists Association*, JAPhA Residency Issue, 58, no. 4, Supplement (July 1, 2018): S55-S58.e3, https://doi.org/10.1016/j.japh.2018.04.025.

[485] Elizabeth Skoy et al., "Implementation of a Statewide Program within Community Pharmacies to Prevent Opioid Misuse and Accidental Overdose," *Journal of the American Pharmacists Association: JAPhA* 60, no. 1 (February 2020): 117–21, https://doi.org/10.1016/j.japh.2019.09.003; Mark A. Strand et al., "Program Evaluation of the Opioid and Naloxone Education (ONE Rx) Program Using the RE-AIM Model," *Research in Social & Administrative Pharmacy: RSAP* 16, no. 9 (September 2020): 1248–54, https://doi.org/10.1016/j.sapharm.2019.11.016.

[486] Adriane N. Irwin et al., "Impact of the RESPOND Toolkit on Community Pharmacists' Opioid Safety Attitudes, Self-Efficacy, and Knowledge," *Journal of the American Pharmacists Association: JAPhA* 60, no. 3 (June 2020): 450-455.e3, https://doi.org/10.1016/j.japh.2019.11.030.

[487] Guy et al., "Vital Signs."

and linkage to treatment. There is a strong evidence base for this intervention. Systematic reviews and meta-analyses support the role of SSPs in reducing the incidence of HIV.[488] Meanwhile, reviews of the evidence suggest that there are no deleterious effects of SSPs, such as increasing drug use, crime, or the circulation of unused needles.[489] On the contrary, SSPs have been associated with increased treatment seeking among participants.[490] Specific to Florida, the implementation of IDEA Exchange in Miami, the first SSP in the state as a pilot program, was associated with reductions in both overdose-related hospitalizations and injection-related risk behaviors.[491] Florida recently passed state legislation to legalize SSPs beyond the initial pilot program if a county commissioner passes an ordinance. The state now has several SSPs that are either newly established or are in the process of being implemented. However, this network of SSPs should be expanded to address the needs of Floridians. This need can be extrapolated from the national prevalence of past-year injection drug use (0.3%).[492] Further, these SSPs should be enhanced to be comprehensive harm reduction centers, which are equipped to provide needle exchange, fentanyl test strips, mobile outreach, testing for HCV and HIV and linkage to treatment, wound care, and referral to social services and OUD treatment, similar to the IDEA Exchange. In addition, these centers would serve as vital distribution points for naloxone, getting this lifesaving antidote into the hands of those at highest risk and most likely to witness an opioid overdose.

36. Lastly, programs should be in place to link people to treatment after utilizing harm reduction services, such as in SSPs or after successful naloxone administration. There should be a warm handoff in place and the availability of treatment-on-demand. Although harm reduction strategies are warranted on their own merit, in a recovery-oriented systems

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[488] Abu S. Abdul-Quader et al., "Effectiveness of Structural-Level Needle/Syringe Programs to Reduce HCV and HIV Infection among People Who Inject Drugs: A Systematic Review," *AIDS and Behavior* 17, no. 9 (2013): 2878–92; Esther J. Aspinall et al., "Are Needle and Syringe Programmes Associated with a Reduction in HIV Transmission among People Who Inject Drugs: A Systematic Review and Meta-Analysis," *International Journal of Epidemiology* 43, no. 1 (2014): 235–48; Lucy Platt et al., "Needle Syringe Programmes and Opioid Substitution Therapy for Preventing Hepatitis C Transmission in People Who Inject Drugs," *The Cochrane Database of Systematic Reviews* 9 (September 18, 2017): CD012021, https://doi.org/10.1002/14651858.CD012021.pub2; Alex Wodak and Annie Cooney, "Do Needle Syringe Programs Reduce HIV Infection among Injecting Drug Users: A Comprehensive Review of the International Evidence," *Substance Use & Misuse* 41, no. 6–7 (2006): 777–813, https://doi.org/10.1080/10826080600669579.

[489] G. Alan Marlatt and Katie Witkiewitz, "Update on Harm-Reduction Policy and Intervention Research," *Annual Review of Clinical Psychology* 6 (2010): 591–606, https://doi.org/10.1146/annurev.clinpsy.121208.131438; Steffanie A. Strathdee and David Vlahov, "The Effectiveness of Needle Exchange Programs: A Review of the Science and Policy," *AIDScience* 1, no. 16 (2001): 1–33.

[490] Hagan et al., "Reduced Injection Frequency and Increased Entry and Retention in Drug Treatment Associated with Needle-Exchange Participation in Seattle Drug Injectors."

[491] Tyler S. Bartholomew et al., "Reduction in Injection Risk Behaviors after Implementation of a Syringe Services Program, Miami, Florida," *Journal of Substance Abuse Treatment* 127 (2021): 108344; K. J. Bornstein et al., "Hospital Admissions among People Who Inject Opioids Following Syringe Services Program Implementation," *Harm Reduction Journal* 17 (2020): 1–5.

[492] Amy Lansky et al., "Estimating the Number of Persons Who Inject Drugs in the United States by Meta-Analysis to Calculate National Rates of HIV and Hepatitis C Virus Infections," *PloS One* 9, no. 5 (2014): e97596, https://doi.org/10.1371/journal.pone.0097596.

of care (ROSC), all interventions should be designed to move people through the continuum of care and into sustained OUD remission. These types of interventions have already been discussed above and include post-overdose response teams, emergency department-initiated buprenorphine, mobile outreach, and linkages to OUD treatment at comprehensive harm reduction centers.

(vi) *Expand recovery support services that can address psychosocial needs of Floridians in early remission of OUD*

To sustain the gains made during the initial treatment phase, wraparound services outside of professional treatment are needed for most individuals being treated for OUD. Known as recovery support services (RSS), these services are an integral part of a ROSC, are often delivered by peers, and typically represent continuing care after an initial treatment episode (i.e. recovery management). In parallel with Florida's goal of building and maintaining a robust ROSC across the state, a wide array of RSS should be offered to support those in remission from OUD.

37. Recovery community organizations (RCO) have emerged as a hub for delivering RSS, which may include recovery coaching, employment and job training linkages, and providing space for mutual help meetings. These organizations may also serve as an access point for treatment and recovery services or provide assertive outreach to hard-to-reach populations. Oftentimes, employees of an RCO have lived experience themselves and represent a large portion of the peer workforce in a state.[493] In addition to delivering services, RCOs may provide policy advocacy and public education. RCOs are commonly used by individuals with OUD as a study of 31 RCOs in New England showed that the primary substance of choice for those who engaged in these organizations was opioids.[494] Engagement in RCOs has been shown to increase an individual's recovery capital,[495] which is a measure of an individual's assets to sustain recovery, as well as improve quality of life and reduce substance use problems.[496] Currently, the state of Florida has 12 RCO's in existence with two more in the process of being established, which are partially funded by the SOR grant, according to information received from the Florida Department of Children and Families. To provide an adequate network of RCOs that could serve all Floridians, I estimate that a minimum of 50 RCOs are needed. For comparison, Georgia currently has a robust network of 32 RCOs that serve 10.6 million people.[497] According from information

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[493] John F. Kelly et al., "New Kid on the Block: An Investigation of the Physical, Operational, Personnel, and Service Characteristics of Recovery Community Centers in the United States," *Journal of Substance Abuse Treatment* 111 (April 2020): 1–10, https://doi.org/10.1016/j.jsat.2019.12.009.

[494] John F. Kelly et al., "One-Stop Shopping for Recovery: An Investigation of Participant Characteristics and Benefits Derived From U.S. Recovery Community Centers," *Alcoholism, Clinical and Experimental Research* 44, no. 3 (March 2020): 711–21, https://doi.org/10.1111/acer.14281.

[495] Robert D. Ashford et al., "Peer-Based Recovery Support Services Delivered at Recovery Community Organizations: Predictors of Improvements in Individual Recovery Capital," *Addictive Behaviors* 119 (August 2021): 106945, https://doi.org/10.1016/j.addbeh.2021.106945; Kelly et al., "One-Stop Shopping for Recovery."

[496] John F. Kelly et al., "Recovery Community Centers: Characteristics of New Attendees and Longitudinal Investigation of the Predictors and Effects of Participation," *Journal of Substance Abuse Treatment* 124 (May 2021): 108287, https://doi.org/10.1016/j.jsat.2021.108287.

[497] Georgia Council on Substance Abuse, "Find a RCO," n.d., https://gasubstanceabuse.org/find-a-rco/.

received from the Florida Department of Children and Families, the state is currently following a blueprint laid out by the Georgia Council on Substance Abuse to develop these grassroot organizations, which consists of community listening forums and recovery symposiums to garner the required buy-in from the community before an RCO is established. In addition to establishing a network of RCOs, these organizations would also need to be sustained through an annual budget. A statewide RCO, similar to the Massachusetts Organization for Addiction and Recovery or the Georgia Council on Substance Abuse, would need to be in place as a coordinating center. Presently, Floridians in Recovery is a statewide RCO in Florida, though its capacity would need to be enhanced to support this network of RCOs.

38. Peer-based recovery support services (PRSS) can be employed in a variety of settings, such as emergency departments, hospitals, the criminal justice system, re-entry programs, harm reduction organizations, the child welfare system, neonatal intensive care units, opioid treatment programs, RCOs, and manning helplines. Given the versality of peers, having a strong and flexible workforce across the state is important. PRSS leverage the lived experience of peers to deliver non-clinical support, such as recovery coaching, and are typically implemented at vital touchpoints that present opportunities to engage individuals with OUD. Even though the evidence is emerging for PRSS, two systematic reviews show promising results.[498] One study found that integrating recovery coaches into medical settings was associated with a 44% decrease in hospitalizations, a 9% decrease in emergency department visits, and a higher likelihood of buprenorphine treatment engagement and opioid abstinence over a six-month period.[499] Currently, Florida has a workforce of 650 trained recovery support specialists that primarily work out of the 12 RCOs across the state. The South Florida Wellness Network in Broward County employs around 50 of these specialists and serves as a good model for other RCOs, representing an organization that can send peers into a variety of settings across the county to deliver services. Following this model, at least 2,500 recovery support specialists working in the needed 50 RCOs would represent the minimum peer workforce to meet the needs of Floridians. In addition, hospitals with high rates of NAS and urban emergency departments that see a high rate of nonfatal overdoses should also employ recovery coaches and peer support specialists as part of the model to initiate buprenorphine in these settings.[500]

39. Addressing the psychosocial needs of those in early remission from OUD is paramount given the high risk for returning to opioid use during this time period. These needs may

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[498] Ellen L. Bassuk et al., "Peer-Delivered Recovery Support Services for Addictions in the United States: A Systematic Review," *Journal of Substance Abuse Treatment* 63 (April 2016): 1–9, https://doi.org/10.1016/j.jsat.2016.01.003; David Eddie et al., "Lived Experience in New Models of Care for Substance Use Disorder: A Systematic Review of Peer Recovery Support Services and Recovery Coaching," *Frontiers in Psychology* 10 (2019): 1052, https://doi.org/10.3389/fpsyg.2019.01052.

[499] Jessica F. Magidson et al., "Peer Recovery Coaches in General Medical Settings: Changes in Utilization, Treatment Engagement, and Opioid Use," *Journal of Substance Abuse Treatment* 122 (March 2021): 108248, https://doi.org/10.1016/j.jsat.2020.108248.

[500] Carolyn Bogan et al., "Implementation of Emergency Department-Initiated Buprenorphine for Opioid Use Disorder in a Rural Southern State," *Journal of Substance Abuse Treatment* 112S (March 2020): 73–78, https://doi.org/10.1016/j.jsat.2020.02.007.

include basic essentials, such as food security, transportation, utility bills, obtaining a driver's license, or paying rent for sober housing, and these necessities are likely to vary from person to person. Some of these social determinants have been associated with sustaining OUD remission and decreasing the risk of overdose death.[501] In addition to helping individuals develop a recovery plan and access recovery support services, Access to Recovery is a statewide program in Massachusetts that provides those in early recovery from a substance use disorder with vouchers to meet basic needs for six months. Only costing an average of $2,000 per participant, the program reports some impressive outcomes, such as high rates of both employment and housing and low rates of recidivism.[502] Florida should have a similar program in place for those who have just initiated OUD treatment. This six-month program would address important psychosocial needs of those in early remission from OUD, such as basic essentials.

40. Many individuals in remission from OUD will be either adolescents (aged 12-17) or emerging adults (aged 18-25). These age groups may find it especially difficult to sustain recovery in the environments they are in, where substance use is often seen as normative. Important services for these individuals are education-related RSS, such as recovery high schools and collegiate recovery programs (CRP). These RSS increase the likelihood of sustained recovery and citizenship. Education is a gateway to employment opportunities and has been shown to be a protective factor in overdose deaths.[503] Although more outcome studies are needed, recovery high schools appear to function as continuing care for adolescents in remission from a substance use disorder.[504] Collegiate recovery programs have been associated with higher GPA and low rates of relapse.[505] Nearly a quarter of students in CRPs reported being in recovery from opioid addiction.[506] Currently, Florida has one recovery high school, River Oaks Center in Jacksonville, that is recognized by the

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[501] Ju Nyeong Park et al., "Situating the Continuum of Overdose Risk in the Social Determinants of Health: A New Conceptual Framework," *The Milbank Quarterly* 98, no. 3 (September 2020): 700–746, https://doi.org/10.1111/1468-0009.12470.

[502] Massachusetts Access to Recovery, "Outcomes and Impact," 2021, https://www.ma-atr.org/about-atr/outcomes-and-impacts/.

[503] Jessica Y. Ho, "The Contribution of Drug Overdose to Educational Gradients in Life Expectancy in the United States, 1992-2011," *Demography* 54, no. 3 (June 2017): 1175–1202, https://doi.org/10.1007/s13524-017-0565-3.

[504] Andrew J. Finch, D. Paul Moberg, and Amanda Lawton Krupp, "Continuing Care in High Schools: A Descriptive Study of Recovery High School Programs," *Journal of Child & Adolescent Substance Abuse* 23, no. 2 (2014): 116–29, https://doi.org/10.1080/1067828X.2012.751269; Emily E. Tanner-Smith et al., "Who Attends Recovery High Schools after Substance Use Treatment? A Descriptive Analysis of School Aged Youth," *Journal of Substance Abuse Treatment* 89 (June 2018): 20–27, https://doi.org/10.1016/j.jsat.2018.03.003.

[505] Robert D. Ashford et al., "What We Know about Students in Recovery: Meta-Synthesis of Collegiate Recovery Programs, 2000-2017," *Addiction Research & Theory* 26, no. 5 (2018): 405–13; Emily A. Hennessy et al., "A Multi-Site Study of Emerging Adults in Collegiate Recovery Programs at Public Institutions," *Social Science & Medicine (1982)* 278 (June 2021): 113955, https://doi.org/10.1016/j.socscimed.2021.113955; Alexandre B. Laudet et al., "Characteristics of Students Participating in Collegiate Recovery Programs: A National Survey," *Journal of Substance Abuse Treatment* 51 (April 2015): 38–46, https://doi.org/10.1016/j.jsat.2014.11.004.

[506] Austin M. Brown et al., "Alumni Characteristics of Collegiate Recovery Programs: A National Survey," *Alcoholism Treatment Quarterly* 37, no. 2 (2019): 149–62; Laudet et al., "Characteristics of Students Participating in Collegiate Recovery Programs."

Association of Recovery Schools,[507] and has two CRPs, Florida State University and the University of Tampa, that are recognized by the Association for Recovery in Higher Education.[508] At a minimum, there should be a fully-funded public recovery high school in every metropolitan area in Florida with a population of more than one million with an additional one in each of the two most populated metropolitan areas, for a total of six programs. It is estimated that there are 1.6 million emerging adults who have resolved a substance use problem,[509] or about 6% representing this age group in the United States. Therefore, at a minimum, there should be sufficient demand for a fully funded CRPs in each college or university with an enrollment of 20,000 or more, for a total of 16 programs.

41. Employment is a strong predictor of sustained remission from substance use disorders, such as OUD.[510] For instance, employment was found to be predictive of treatment completion among those in addiction treatment, and the best predictor of post-treatment recovery at six months was an increase in months employed.[511] Employment is especially important for those with OUD. In a 33-year longitudinal study of those with heroin use disorder, employment was strongly associated with sustained remission: 56% of the group that had five or more years of abstinence from opioids were employed compared with 15% of the group that had less than five years of opioid abstinence.[512] Among 110 clients in a methadone program, those that were employed did better on a wide range of outcomes compared with those that were not employed even though opioid use was similar across these two groups.[513] Despite the protective effect of employment, an individual in OUD remission is likely to face significant barriers to finding a job, such as a criminal record, lack of transportation, discrimination, or stigma.[514] Presently, Florida does not have a statewide initiative to address these barriers and increase employment among those in OUD remission. Other states, such as New Hampshire, have implemented a statewide recovery-friendly workplace initiative that supports current employees with OUD, encourages hiring employees in OUD remission, and provides trainings to reduce stigma. Florida should

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[507] Association of Recovery Schools, "Find a School," 2021, https://recoveryschools.org/find-a-school/.

[508] Association of Recovery in Higher Education, "Collegiate Recovery Program Members," 2020, https://collegiaterecovery.org/crps-crcs/.

[509] John F. Kelly et al., "Prevalence and Pathways of Recovery from Drug and Alcohol Problems in the United States Population: Implications for Practice, Research, and Policy," *Drug and Alcohol Dependence* 181 (December 1, 2017): 162–69, https://doi.org/10.1016/j.drugalcdep.2017.09.028.

[510] Stephen Magura and Tina Marshall, "The Effectiveness of Interventions Intended to Improve Employment Outcomes for Persons with Substance Use Disorder: An Updated Systematic Review," *Substance Use & Misuse* 55, no. 13 (2020): 2230–36, https://doi.org/10.1080/10826084.2020.1797810.

[511] Ethan Sahker, Saba Rasheed Ali, and Stephan Arndt, "Employment Recovery Capital in the Treatment of Substance Use Disorders: Six-Month Follow-up Observations," *Drug and Alcohol Dependence* 205 (December 1, 2019): 107624, https://doi.org/10.1016/j.drugalcdep.2019.107624.

[512] Hser et al., "A 33-Year Follow-up of Narcotics Addicts."

[513] Elizabeth Lowe et al., "The Impact of Employment on Perceived Recovery from Opiate Dependence," *Drugs and Alcohol Today* 18, no. 4 (January 1, 2018): 206–16, https://doi.org/10.1108/DAT-12-2017-0062.

[514] Bronwyn A. Hunter and Leonard A. Jason, "Correlates of Employment among Men in Substance Use Recovery: The Influence of Discrimination and Social Support," *Journal of Prevention & Intervention in the Community*, June 24, 2021, 1–15, https://doi.org/10.1080/10852352.2021.1940756.

launch a statewide recovery-friendly workplace initiative as a starting point to supporting better employment outcomes among those in OUD remission.

42. Housing insecurity is a risk factor for overdose death, and evidence suggests that this insecurity has been increasing over time among those seeking treatment for OUD.[515] Finding housing conducive to recovery from OUD presents a particular challenge for those returning to the community from incarceration or inpatient treatment, highlighting the need for interventions targeting these transition periods.[516] Recovery housing, also known as transitional housing, is a service that fills this gap, providing short-term housing for those in early remission from OUD while also providing peer support and continuing care. A review of the evidence for recovery housing suggests that they are associated with higher rates of employment, high income, reduced substance use, and reduced recidivism.[517] Oxford homes in particular have been shown to be effective.[518] Investments should be made to increase the availability and quality of recovery housing in Florida. All those who initiate OUD treatment should be offered recovery housing as part of the continuum of care to build positive social networks, a foundation in recovery, and reduce the risk of relapse.

(vii) *Increase knowledge and decrease stigma among healthcare professionals and in the community*

Two of the most important barriers in integrating OUD treatment into the mainstream healthcare system are stigma and lack of knowledge. A survey previously highlighted in this report revealed that only 45% of emergency medicine and 49% of primary care physicians reported that OUD was a treatable disease, and 38% of emergency medicine physicians reported that methadone treatment for OUD was substituting one addiction for another.[519] Two peer-reviewed studies using surveys showed that one-third of primary care physicians believed OUD treatment without medication was just as effective as using medication, only 20% of primary physicians were interested in treating patients with OUD, and 75% of these physicians reported high levels of

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[515] Saanie Sulley and Memory Ndanga, "Inpatient Opioid Use Disorder and Social Determinants of Health: A Nationwide Analysis of the National Inpatient Sample (2012-2014 and 2016-2017)," *Cureus* 12, no. 11 (November 3, 2020): e11311, https://doi.org/10.7759/cureus.11311; Massachusetts Department of Public Health, "An Assessment of Fatal and Nonfatal Opioid Overdoses in Massachusetts (2011 – 2015)," 2017, https://www.mass.gov/files/documents/2017/08/31/legislative-report-chapter-55-aug-2017.pdf.

[516] Olivia K. Sugarman et al., "Interventions for Incarcerated Adults with Opioid Use Disorder in the United States: A Systematic Review with a Focus on Social Determinants of Health," *PLOS ONE* 15, no. 1 (January 21, 2020): e0227968, https://doi.org/10.1371/journal.pone.0227968.

[517] Sharon Reif et al., "Recovery Housing: Assessing the Evidence," *Psychiatric Services (Washington, D.C.)* 65, no. 3 (March 1, 2014): 295–300, https://doi.org/10.1176/appi.ps.201300243.

[518] Leonard A. Jason and Joseph R. Ferrari, "Oxford House Recovery Homes: Characteristics and Effectiveness," *Psychological Services* 7, no. 2 (May 2010): 92–102, https://doi.org/10.1037/a0017932; Anthony T. Lo Sasso et al., "Benefits and Costs Associated with Mutual-Help Community-Based Recovery Homes: The Oxford House Model," *Evaluation and Program Planning* 35, no. 1 (February 2012): 47–53, https://doi.org/10.1016/j.evalprogplan.2011.06.006.

[519] Davidson, Bansal, and Hartley, "Opportunities to Increase Screening and Treatment of Opioid Use Disorder among Healthcare Professionals."

stigma towards individuals with OUD, on par with the general population.[520] Therefore, increasing knowledge and reducing stigma among healthcare professionals is critical in addressing the opioid crisis. This can be done through different types of interventions and trainings that increase a healthcare professional's willingness and confidence to deliver care to patients with OUD. In addition to healthcare professionals, increasing knowledge and reducing stigma among the general population is important for garnering public support for shifting from punitive to public health-oriented approaches to address the opioid crisis and creating an environment conducive to decreasing stigma-related barriers to obtaining treatment and sustaining OUD remission. In summary, interventions increasing knowledge and reducing stigma among healthcare professionals and the general population have the potential to increase the capacity of the healthcare system to deliver OUD treatment and encourage treatment-seeking among those with OUD.

43. Stigma is frequently cited as a reason for not seeking addiction treatment among those who recognize a need for this type of care.[521] Empirical evidence shows that individuals with alcohol use disorders are less likely to utilize treatment if they perceive high stigma in the community.[522] The impact of social stigma on treatment utilization may be even more pronounced for those with OUD, as drug use disorders are one of the most stigmatized conditions across the globe and are more stigmatized than alcohol use disorders.[523] This delay in seeking treatment for individuals with OUD will increase opioid-related morbidity and mortality, exacerbating the opioid crisis. Therefore, interventions are needed to mitigate social stigma among the general population. One of these interventions is a mass media campaign. This type of campaign has been implemented in four states as part of the HEALing Communities Study.[524] In addition, Colorado[525] and Pennsylvania[526] have initiated statewide stigma campaigns. In Florida, the Marion County Sheriff's Office launched a community-based stigma reduction campaign at the county-level, which correlated with a decrease in opioid-related mortality.[527] Florida has a website operated by the Department of Children and Families entitled "I Save FL" that provides treatment and

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[520] McGinty et al., "Medication for Opioid Use Disorder"; Stone et al., "The Role of Stigma in U.S. Primary Care Physicians' Treatment of Opioid Use Disorder."

[521] SAMHSA, "Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health."

[522] K. M. Keyes et al., "Stigma and Treatment for Alcohol Disorders in the United States," *American Journal of Epidemiology* 172, no. 12 (December 15, 2010): 1364–72, https://doi.org/10.1093/aje/kwq304.

[523] Robin Room, "Stigma, Social Inequality and Alcohol and Drug Use," *Drug and Alcohol Review* 24, no. 2 (March 2005): 143–55, https://doi.org/10.1080/09595230500102434; Robin Room et al., "Cross-Cultural Views on Stigma, Valuation, Parity, and Societal Values towards Disability," in *Disability and Culture: Universalism and Diversity* (Seattle: Hogrefe & Huber Publishers, 2001), 247–97.

[524] R. Craig Lefebvre et al., "Health Communication Campaigns to Drive Demand for Evidence-Based Practices and Reduce Stigma in the HEALing Communities Study," *Drug and Alcohol Dependence* 217 (December 1, 2020): 108338, https://doi.org/10.1016/j.drugalcdep.2020.108338.

[525] Colorado Office of Behavioral Health, "Life the Label," n.d., https://liftthelabel.org/.

[526] The Public Goods Project, "Life Unites Us," n.d., https://lifeunitesus.com/.

[527] Florida Statewide Task Force on Opioid Abuse, "Findings and Recommendations of the Statewide Task Force on Opioid Abuse."

harm reduction resources.[528] This resource should be enhanced to also support stigma reduction. The state should implement a mass media campaign targeting all Floridians with three main aims: increasing awareness that OUD is a disease that can be treated; educating the public on the effectiveness of MOUD; and disseminating knowledge about the I Save FL website. According to CDC guidelines, a one-year communication campaign should reach 75-85% of the target audience (all Floridians aged 12 and over) quarterly.[529] These interventions can be effective in changing health behavior if designed with a thoughtful approach.[530] Therefore, the campaign needs to have a simple yet effective message that has been developed by communication and content experts and that has been piloted and pretested using methods such as focus groups. It should include narratives of real people who have had success with MOUD to complement statistics and should incorporate the importance of language in reducing stigma.[531] This abatement strategy parallels both the recommendations of the Drug Policy Advisory Council and the Florida Statewide Task Force on Opioid Abuse.[532] Notably, although this intervention is directly aimed at reducing stigma, many of the abatement strategies in this report are also likely to reduce stigma indirectly.

44. Increasing knowledge and reducing stigma is essential to bringing OUD treatment into the mainstream healthcare system. Provider stigma could be toward individuals with OUD or towards OUD treatment medications, as highlighted in the introduction of this subsection. Further evidence also shows the prevalent negative attitudes toward OUD and MOUD. A systematic review indicates that negative attitudes of healthcare professionals toward individuals with substance use disorder is common and contribute to suboptimal healthcare.[533] Another study revealed that one-third of primary care physicians believed that OUD treatment without medication is just as effective as with medication despite strong evidence to the contrary, and only 20% of physicians surveyed were interested in treating OUD.[534] These start numbers reveal the formidable barriers that must be overcome to bring OUD treatment into the mainstream healthcare system. A systematic review of stigma interventions for providers shows that educational interventions can be helpful in attitudinal change, though direct contact with individuals in recovery is most likely to

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[528] Florida Department of Children and Families, "I Save FL," 2020, https://www.isavefl.com/.

[529] Centers for Disease Control and Prevention, "Best Practices for Comprehensive Tobacco Control Programs—2014," 2021, https://www.cdc.gov/tobacco/stateandcommunity/best_practices/index.htm.

[530] Melanie A. Wakefield, Barbara Loken, and Robert C. Hornik, "Use of Mass Media Campaigns to Change Health Behaviour," *Lancet (London, England)* 376, no. 9748 (October 9, 2010): 1261–71, https://doi.org/10.1016/S0140-6736(10)60809-4.

[531] Shatterproof, "Addiction Language Guide," n.d., https://www.shatterproof.org/sites/default/files/2021-02/Stigma-AddictionLanguageGuide-v3.pdf.

[532] Drug Policy Advisory Council, "Statewide Drug Policy Advisory Council 2020 Annual Report"; Florida Statewide Task Force on Opioid Abuse, "Findings and Recommendations of the Statewide Task Force on Opioid Abuse."

[533] Leonieke C. van Boekel et al., "Stigma among Health Professionals towards Patients with Substance Use Disorders and Its Consequences for Healthcare Delivery: Systematic Review," *Drug and Alcohol Dependence* 131, no. 1–2 (July 1, 2013): 23–35, https://doi.org/10.1016/j.drugalcdep.2013.02.018.

[534] McGinty et al., "Medication for Opioid Use Disorder."

produce a sustained change.[535] Research has also shown that language plays an important role in stigma reduction.[536] Therefore, a contact-based intervention using narratives from individuals in recovery and incorporating best practices on language should be delivered through academic detailing, continuing medical education, and communication campaigns. These educational and outreach initiatives can serve the two-fold purpose of increasing knowledge and reducing stigma among healthcare professionals, ultimately increasing the uptake of MOUD and the capacity to deliver this type of care.

45. A frequently cited barrier to providing OUD treatment in primary care is lack of access to addiction specialist co-management for the patient.[537] Healthcare professionals may feel ill-equipped to treat OUD without the help of a specialist because other frequently cited barriers are lack of knowledge in treating OUD and lack of psychosocial supports for patients.[538] One way to overcome these barriers is through a statewide consultation service that allows providers to consult experts in OUD treatment and also obtain guidance for opioid prescribing and pain management. This type of program has been implemented in Maryland and Massachusetts, and it has been shown to increase access to specialty consultation and training.[539] This statewide program would complement Project ECHO, discussed in detail above, as an ongoing service for prescribers to increase their willingness and ability to deliver OUD treatment to their patients.

46. The President's Commission on Combating Drug Addiction and the Opioid Crisis calls for an expansion of residency fellowships specific to addiction training as less than one-third of medical schools in the United States have these types of fellowships and addiction medicine has only recently been recognized as a medical subspecialty.[540] Federal policies

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[535] Jennifer Bielenberg et al., "A Systematic Review of Stigma Interventions for Providers Who Treat Patients with Substance Use Disorders," *Journal of Substance Abuse Treatment*, 2021, 108486, https://doi.org/10.1016/j.jsat.2021.108486.

[536] Robert D. Ashford, Austin M. Brown, and Brenda Curtis, "Substance Use, Recovery, and Linguistics: The Impact of Word Choice on Explicit and Implicit Bias," *Drug and Alcohol Dependence* 189 (August 1, 2018): 131–38, https://doi.org/10.1016/j.drugalcdep.2018.05.005; John F. Kelly and Cassandra M. Westerhoff, "Does It Matter How We Refer to Individuals with Substance-Related Conditions? A Randomized Study of Two Commonly Used Terms," *The International Journal on Drug Policy* 21, no. 3 (May 2010): 202–7, https://doi.org/10.1016/j.drugpo.2009.10.010.

[537] Kathryn Foti et al., "Primary Care Physicians' Preparedness to Treat Opioid Use Disorder in the United States: A Cross-Sectional Survey," *Drug and Alcohol Dependence* 225 (August 1, 2021): 108811, https://doi.org/10.1016/j.drugalcdep.2021.108811.

[538] Hutchinson et al., "Barriers to Primary Care Physicians Prescribing Buprenorphine"; Sarah M. Oros et al., "Facilitators and Barriers to Utilization of Medications for Opioid Use Disorder in Primary Care in South Carolina," *International Journal of Psychiatry in Medicine* 56, no. 1 (January 2021): 14–39, https://doi.org/10.1177/0091217420946240.

[539] Massachusetts Consultation Service for Treatment of Addiction and Pain, "About MCSTAP," 2019, https://mcstap.com/About/About.aspx; Sarah Sweeney et al., "Program Development and Implementation Outcomes of a Statewide Addiction Consultation Service: Maryland Addiction Consultation Service (MACS)," *Substance Abuse*, August 19, 2020, 1–8, https://doi.org/10.1080/08897077.2020.1803179.

[540] Chris Christie et al., "The President's Commission on Combating Drug Addiction and the Opioid Crisis," *Washington, DC: US Government Printing Office*, 2017,

have targeted this workforce shortage. The 21st Century Cures Act provided funding to expand addiction medicine fellowships and a bill being considered in Congress, the Opioid Workforce Act, would add 1,000 additional residency positions in addiction medicine, addiction psychiatry, and pain management.[541] In Florida, there are 135 addiction medicine specialists representing 0.26% of the physician workforce.[542] In line with recommendations from Florida's Drug Policy Advisory Council, residency programs in addiction medicine and addiction psychiatry, which are one-year fellowships, should be expanded.

47. There is great promise in the early training of future healthcare professionals as a sustainable measure in addressing the opioid crisis and preventing a similar crisis in the future. In addition to initiating counter detailing on opioid prescribing to prevent new cases of OUD, medical school education and training can equip future physicians to identify and treat OUD as well as prevent overdose deaths through prescribing naloxone. These trainings can also incorporate interventions that reduce stigma. Florida has made great strides to begin the process of integrating these trainings into medical school curricula statewide. The University of Central Florida College of Medicine expanded its opioid and pain-management curriculum to be used during all four years of medical school and graduate medical education.[543] The Council of Florida Medical School Deans created a multidisciplinary pain-management education workgroup and disseminated the document *Pain Management and Opioid Stewardship Education for Florida's Medical Schools: Framework for Developing Core Competencies and Instructional Guide for Curriculum Development* to encourage better education on opioid prescribing and alternatives for pain management.[544] Florida is currently using SOR grant funding to develop and implement medical education curricula on screening, diagnosis, and treatment of OUD in all 10 allopathic and osteopathic medical schools in the state.[545] Given the fact that nearly all of medical students will treat individuals with OUD in some capacity, integration of adequate education on OUD into medical school curricula is warranted, in line with the

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https://www.alsde.edu/sec/pss/Suicide%20Prevention/President's%20Commission%20on%20Combatting%20Drugs%20Abuse%20Addiction%20and%20Opioid%20Crisis.pdf.

[541] Joseph H. Wu, Josiah D. Rich, and Eli Y. Adashi, "Addiction Medicine After COVID-19: The Imperative of a Trained Workforce," *American Journal of Preventive Medicine* 60, no. 5 (2021): 729–31.

[542] Drug Policy Advisory Council, "Statewide Drug Policy Advisory Council 2020 Annual Report."

[543] Association of American Medical Colleges, "How Academic Medicine Is Addressing the Opioid Epidemic," 2019, https://www.aamc.org/system/files/d/1/63-opioids_-_how_academic_medicine_is_addressing_the_opioid_epidemic_-_20190222.pdf.

[544] Council of Florida Medical School Deans, "Pain Management and Opioid Stewardship Education for Florida Medical Schools," 2018, https://com-jax-emergency-pami.sites.medinfo.ufl.edu/wordpress/files/2019/01/Medical-School-Pain-and-Opioid-Curriculum-Framework-8-31-18.pdf.

[545] Florida Department of Children and Families, "Florida's State Opioid Response Project: Annual Report 2019," 2020, https://www.myflfamilies.com/service-programs/samh/docs/opioid/FL%20SOR%20Annual%20Report%20Year%201%202019_UPDATED%20January%202020.pdf.

recommendations from the Florida Statewide Task Force on Opioid Abuse.[546] Topics should include four domains: cautious opioid prescribing and alternative options for pain management, screening and diagnosis of OUD, best practices in treatment of OUD and overdose prevention, and the impact of stigma toward individuals with OUD in the healthcare system.[547] The program should be expanded to enhance the curriculum currently under development and ensure its sustainability.

(e) ADDITIONAL INTERVENTIONS

(i) Comprehensive and long-term support to the children of the opioid crisis

As discussed above, the opioid crisis has had a disastrous and intergenerational impact on children and families in Florida. This has led to an increased burden on the foster care system, rising numbers of opioid-addicted parents involved in the criminal justice system, grandparents raising grandchildren, trauma at the individual and community level, and a generation of babies born dependent on opioids. It is estimated that 138,000 children in Florida were affected by the opioid crisis in 2017, with a rate that is 11% higher than the national average.[548] Interventions targeting the family unit and the children of the opioid crisis are needed to mitigate the long-term impact of these exposures.

48. As previously discussed, parental drug abuse is the primary reason for child removals in Florida and this rate has been increasing steadily since 2003.[549] The opioid crisis has contributed to this rise.[550] This has put a burden on the state's foster care system. In addition to the increase of children in the system, stay periods in foster care are longer when children are removed for parental drug use,[551] and the removal is less likely to result in reunification compared with removal for other reasons.[552] Abatement interventions to support the foster care system should include the use of evidence-based interventions that help stabilize and

[546] Florida Statewide Task Force on Opioid Abuse, "Findings and Recommendations of the Statewide Task Force on Opioid Abuse."

[547] Madison C. Ratycz, Thomas J. Papadimos, and Allison A. Vanderbilt, "Addressing the Growing Opioid and Heroin Abuse Epidemic: A Call for Medical School Curricula," *Medical Education Online* 23, no. 1 (December 2018): 1466574, https://doi.org/10.1080/10872981.2018.1466574.

[548] Suzanne C. Brundage, Adam Fifield, and Lee Partridge, "The Ripple Effect: National and State Estimates of the US Opioid Epidemic's Impact on Children" (United Hospital Fund, 2020), https://uhfnyc.org/media/filer_public/6e/80/6e80760f-d579-46a3-998d-1aa816ab06f6/uhf_ripple_effect_national_and_state_estimates_chartbook.pdf.

[549] Florida Department of Children and Families, "Florida's Child Welfare Statistics," 2021, https://www.myflfamilies.com/programs/childwelfare/dashboard/index.shtml.

[550] Jeremy Kohomban et al., "The Foster Care System Was Unprepared for the Last Drug Epidemic–Let's Not Repeat History" (The Brookings Institute, 2018), https://www.brookings.edu/blog/up-front/2018/01/31/the-foster-care-system-was-unprepared-for-the-last-drug-epidemic-lets-not-repeat-history/.

[551] Jody Brook et al., "Parental Substance Abuse and Family Reunification," *Journal of Social Work Practice in the Addictions* 10, no. 4 (2010): 393–412.

[552] Tyrone C. Cheng, "Factors Associated with Reunification: A Longitudinal Analysis of Long-Term Foster Care," *Children and Youth Services Review* 32, no. 10 (2010): 1311–16; Mónica López et al., "Factors Associated with Family Reunification for Children in Foster Care," *Child & Family Social Work* 18, no. 2 (2013): 226–36.

strengthen families that have a parent with OUD whenever possible, in the hopes of avoiding out-of-home placements. Evidence suggests that, when possible, children have better outcomes when remaining in the home.[553] This would directly relieve the burden on the foster care system. Expanding access to evidence-based treatment and closing the treatment gap for OUD, as discussed in the tertiary prevention section below, will help greatly with this. The problem court system in Florida can also be leveraged, specifically dependency (i.e. "family") courts. One study showed that parents involved in family court entered treatment more quickly, stayed in treatment longer, and completed more treatment episodes compared with parents not involved in family court, and children entered permanent placements more quickly and were more likely to be reunified with their parents.[554] Florida currently has 27 early childhood courts (ECCs), a type of dependency court that can provide comprehensive supports to families affected by OUD. This network of ECCs should be expanded to include seven more of these types of courts. This would include six of the seven judicial circuits that do not have ECCs and have had more than 5 cases of NAS from 2014-2018.[555] An additional ECC in the 4th judicial circuit (Jacksonville area), which has been particularly hard hit by high NAS rates, should have an additional ECC to make a total of two in the area. An expansion of dependency courts is discussed below. Foster parents and kinship caregivers (e.g. grandparents) should also be supported. Ensuring that these caregivers have the critical support they need to deliver high quality childcare can be enhanced by Florida's involvement in the CHildren Need AMazing ParentS initiative.[556]

49. Rates of NAS in Florida increased nearly sixteen-fold from 1999 to 2013.[557] Not every fetus that is opioid-exposed will develop NAS after birth. For example, a large study found that 59% of opioid-exposed infants were diagnosed with NAS.[558] In addition, some mothers on buprenorphine or methadone will give birth to infants with NAS. The current evidence suggests that there may be long-term consequences of NAS to affected infants, though more research is needed.[559] Interventions in the abatement plan should decrease

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[553] Joseph J. Doyle Jr, "Child Protection and Child Outcomes: Measuring the Effects of Foster Care," *American Economic Review* 97, no. 5 (2007): 1583–1610.

[554] Beth L. Green et al., "How Effective Are Family Treatment Drug Courts? Outcomes from a Four-Site National Study," *Child Maltreatment* 12, no. 1 (February 2007): 43–59, https://doi.org/10.1177/1077559506296317.

[555] Melissa Jordan, "Florida Overdose Data to Action: Improving Surveillance to Drive Local Prevention Strategies" (Florida Department of Health, 2020), https://www.nahdo.org/sites/default/files/2020-08/Day%20Two%20Slides/202-36%20Melissa%20Jordan%20OD2A%20-%20NAHDO%20-%20MJordan%20-%208-18-20%20FINAL.pdf; Florida Courts, "Problem-Solving Courts," 2021, https://www.flcourts.org/Resources-Services/Court-Improvement/Problem-Solving-Courts.

[556] Kohomban et al., "The Foster Care System Was Unprepared for the Last Drug Epidemic–Let's Not Repeat History."

[557] Jean Y. Ko, "Incidence of Neonatal Abstinence Syndrome — 28 States, 1999–2013," *MMWR. Morbidity and Mortality Weekly Report* 65 (2016), https://doi.org/10.15585/mmwr.mm6531a2.

[558] JoAnna K. Leyenaar et al., "Infant Mortality Associated With Prenatal Opioid Exposure," *JAMA Pediatrics* 175, no. 7 (July 1, 2021): 706–14, https://doi.org/10.1001/jamapediatrics.2020.6364.

[559] Sara J. Arter et al., "Longitudinal Outcomes of Children Exposed to Opioids In-Utero: A Systematic Review," *Journal of Nursing Scholarship: An Official Publication of Sigma Theta Tau International Honor Society of Nursing* 53, no. 1 (January 2021): 55–64, https://doi.org/10.1111/jnu.12609; Kathryn Dee Lizcano MacMillan,

NAS rates over time. In addition, secondary and tertiary prevention interventions should identify and comprehensively treat pregnant women with OUD. Also, interventions to expand family courts, support the foster care system, and mitigate the impact of adverse childhood experiences should improve outcomes for children that experience NAS. Currently, Florida is providing support, such as enrollment in Early Steps, for babies who are diagnosed with NAS, but not babies who are opioid-exposed. A recent study in *JAMA* found that opioid-exposed infants who did not develop NAS appeared to be at increased risk of mortality but infants who did develop NAS did not have increased mortality compared to controls, suggesting that the treatments and supports provided to those diagnosed with NAS may be protective.[560] Therefore, interventions to support opioid-exposed maternal-infant dyads are warranted, regardless of the perceived severity of neonatal opioid withdrawal. Florida should provide early intervention services, known as Early Steps, to all opioid-exposed infants in the state.

50. Childhood trauma experienced as a result of the opioid crisis can create an intergenerational impact of OUD and its accompanying health and social problems if measures are not in place for the early identification and treatment of these vulnerable individuals. Childhood trauma is sometimes measured as adverse childhood experiences, which have been found to be associated with earlier age of opioid initiation and both increased prescription opioid misuse and history of an overdose.[561] Adverse childhood experiences have also been found to be a risk factor in a wide range of health behaviors and medical conditions including smoking, cancer, heart disease, and respiratory disease.[562] To mitigate the risks that come with being exposed to adverse childhood experiences, such as a child witnessing the overdose of a parent, a statewide program should be in place where first responders can communicate with educational institutions to identify and deliver appropriate services to children. The Handle with Care initiative in West Virginia is a statewide collaboration between law enforcement and school officials that provides a trauma-informed approach to ensure that all children exposed to trauma receive appropriate interventions so that their ability to succeed in school is not jeopardized.[563] Increasing the number of counselors appropriately trained in mental health in public and private schools to the recommended ratio of 250:1 should help identify children at risk for ACE-related negative outcomes and provide early intervention. Finally, each public and private school in Florida should have the opportunity to go through training to become a trauma-informed school. Organizations

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"Neonatal Abstinence Syndrome: Review of Epidemiology, Care Models, and Current Understanding of Outcomes," *Clinics in Perinatology* 46, no. 4 (December 2019): 817–32, https://doi.org/10.1016/j.clp.2019.08.012.

[560] Leyenaar et al., "Infant Mortality Associated With Prenatal Opioid Exposure."

[561] Melissa T. Merrick et al., "Adverse Childhood Experiences Increase Risk for Prescription Opioid Misuse," *The Journal of Primary Prevention* 41, no. 2 (April 2020): 139–52, https://doi.org/10.1007/s10935-020-00578-0; Michael D. Stein et al., "Adverse Childhood Experience Effects on Opioid Use Initiation, Injection Drug Use, and Overdose among Persons with Opioid Use Disorder," *Drug and Alcohol Dependence* 179 (October 1, 2017): 325–29, https://doi.org/10.1016/j.drugalcdep.2017.07.007.

[562] Karen Hughes et al., "The Effect of Multiple Adverse Childhood Experiences on Health: A Systematic Review and Meta-Analysis," *The Lancet Public Health* 2, no. 8 (August 1, 2017): e356–66, https://doi.org/10.1016/S2468-2667(17)30118-4.

[563] West Virginia Center for Children's Justice, "Handle with Care," n.d., http://handlewithcarewv.org/index.php.

such as the Trauma and Learning Policy Initiative in Massachusetts are available to help schools and communities with this transition.

51. Education can be a pathway to economic and social mobility, especially for children from disadvantaged backgrounds. The collateral consequences associated with the opioid crisis – living with a family member that has OUD, witnessing an opioid overdose or overdose death, and trauma at the community-level – have the potential to negatively impact the school performance of children. One study provides suggestive evidence that exposure to the opioid crisis negatively impacts educational outcomes of children.[564] Although the evidence for this association is only preliminary, it is worth mentioning that other abatement interventions should close this disparity. As previously recommended, increasing the number of counselors in public and private schools to the recommended ratio of 250:1 should help provide early intervention to children at risk for low educational outcomes. Over time, tertiary preventions discussed below should increase the number of parents with OUD that are in evidence-based treatment. Community-level interventions discussed above may also provide support mechanisms for these children.

(ii) *System-level factors, sustainability, and evaluation*

52. Although many of the abatement interventions have a strong evidence base to support their effectiveness, some are innovative programs that are evidence-informed and based on a sound scientific rationale. Many of these have preliminary evidence supporting them as part of pilot programs. Rigorous evaluation of these more novel programs is critical to establish an evidence base, inform program improvement, and identify effective programs that should be replicated. An evaluation team solely devoted to systematically evaluating abatement interventions, especially ones where evidence is preliminary and emerging, is recommended. This type of team would not only improve Florida's response to the opioid crisis but would also inform the national response. Given the scope of the response needed to abate the opioid crisis in Florida, a large evaluation team is needed. There should be an executive director, operations director, four senior program managers that oversee departments that align with the four main sections of this report (primary prevention, secondary prevention, tertiary prevention, and additional interventions), four program officers to support the program managers in each department, four financial officers that would support the budgets of the abatement programs, two evaluators in each department (eight total), and two administrative assistants in each department (eight total). This team would also need to be located in a brick and mortar building and supported with technology, ideally in one of the major urban areas of Florida. The evaluation team should be sustained for ten years, a sufficient time period to learn about what is working to address the opioid crisis.

[564] Rajeev Darolia and John Tyler, "The Opioid Crisis and Community-Level Spillovers onto Children's Education" (Brookings Institute, 2020), https://www.brookings.edu/research/the-opioid-crisis-and-community-level-spillovers-onto-childrens-education/.

53. A study of SOR grants found variable commitment to sustainability across response plans with less than half the states adequately describing sustainability plans.[565] Sustainability is essential for the continued delivery of essential services for individuals with OUD, many who will need lifelong services and have recurrences of OUD symptoms. Most of the interventions in this abatement plan are recommended to be financially supported for ten, twenty, or thirty years. However, these services are likely to be needed after these time periods. Each program established by this abatement plan should be trained on sustainability and put together a sustainability plan.

54. As this abatement plan shows, many systems are involved in addressing the opioid crisis. Therefore, collaboration and coordination are vital in delivering effective and efficient services across the different levels of prevention. This can be done by enhancing and interlinking data and surveillance systems. Florida has built and maintained a surveillance system for controlled substance prescribing, nonfatal and fatal overdoses, child welfare statistics, and neonatal abstinence syndrome. Much of this data is presented in publicly available dashboards. Since individuals with OUD experience many health and social problems, interlinking these systems is especially important. For example, Massachusetts has a Public Health Data Warehouse where all claims for health services and most of the social services are interlinked into one database. This allowed the state to calculate an accurate OUD prevalence of 4.6% for 2015.[566] Florida should implement an all-payer claims database to better understand and monitor the opioid crisis in the state. Another state-level measure to address the opioid crisis has been overdose fatality review teams, such as the programs implemented in Maryland[567] and Rhode Island.[568] As Florida is a large state, local review teams in each of the six regions of the state would likely be most effective to provide actionable information on recent opioid-related overdose deaths and support near real-time surveillance of the opioid crisis in each region. I recommend that these teams be supported by a lead epidemiologist, two supporting epidemiologists, and two administrative staff. It is assumed that this team would operate out of one of the county health departments in each region. These overdose teams should be sustained for ten years, after which the opioid-related overdose death rate should have plummeted and stabilized at a low rate as a result of abatement interventions.

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[565] Carlos Gallo et al., "Sustainability Planning in the US Response to the Opioid Crisis: An Examination Using Expert and Text Mining Approaches," *PloS One* 16, no. 1 (2021): e0245920, https://doi.org/10.1371/journal.pone.0245920.

[566] Joshua A. Barocas et al., "Estimated Prevalence of Opioid Use Disorder in Massachusetts, 2011-2015: A Capture-Recapture Analysis," *American Journal of Public Health* 108, no. 12 (December 2018): 1675–81, https://doi.org/10.2105/AJPH.2018.304673.

[567] Erin Haas et al., "Local Overdose Fatality Review Team Recommendations for Overdose Death Prevention," *Health Promotion Practice* 20, no. 4 (2019): 553–64.

[568] H. Holly Hackman et al., "Multidisciplinary Team Reviews of Drug Overdose Deaths and the Use of Minigrants to Advance Recommendations: A Statewide Pilot in Rhode Island," *Journal of Public Health Management and Practice* 26, no. 3 (2020): 236–42.

VII. CONCLUSION

Over the past 25 years, hundreds of thousands of Florida residents developed OUD, as a result of the over-supply of opioids described above. Tackling this man-made epidemic to effectively reduce opioid-related morbidity and mortality and the complex array of health and social problems caused by the increased prevalence of OUD will require patience and persistence. For this effort to be successful it must be carefully organized and well-funded. However, OUD and its harms can be prevented and treated, and the opioid crisis abated, using the interventions I recommend.

[redacted]

July 30, 2021
Date

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EDUCATION AND TRAINING

Columbia University College of Physicians and Surgeons, New York, NY
Fellowship in Public Psychiatry (2003-2004)

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Mount Sinai School of Medicine, New York, NY
Internship & Residency in Psychiatry (1999-2003)

Temple University School of Medicine, Philadelphia, PA
M.D. (1995-1999)

Queens College, Flushing, NY
B.A., Sociology (1989-1994)

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PRESENT POSITIONS

Brandeis University, Heller School for Social Policy and Management, Waltham, MA.
Medical Director, Opioid Policy Research Collaborative (2016 – present)

Columbia University, Mailman School of Public Health, New York, NY.
Course Director, Addressing the Opioid Crisis (2018– present)

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PAST POSITIONS

Phoenix House, New York, NY
Chief Medical Officer & Senior Vice President (2013-2016)

Maimonides Medical Center, Brooklyn, NY
Chair, Department of Psychiatry (2008 – 2013)
Vice Chair, Department of Psychiatry (2006 – 2008)

New York City Department of Health and Mental Hygiene, New York, NY
Office of the Executive Deputy Commissioner
Medical Director for Special Projects (2003-2005)

ACADEMIC APPOINTMENTS

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CONSULTING AND ADVISING

World Health Organization
National Judicial Opioid Task Force
Pennsylvania Department of Aging
The National Governors Association
The National Association of Attorneys General
New York State Interagency Task Force

AWARDS

Partnership for Drug Free New Jersey 2019 Angel of Hope Award
University of Chicago 2018 Leon I. Goldberg Award
Dynamite Youth Center Foundation Annual Award
Brooklyn Housing & Family Services Annual Award
American Association of Psychiatric Administrators Annual Award
NYC Department of Health and Mental Hygiene Outstanding Service Award
Mount Sinai School of Medicine Mildred Hope Witkin Award
American Psychiatric Foundation Daniel X. Freedman Congressional Fellowship
Mount Sinai School of Medicine Teacher of the Year
City University of New York Jonas Salk Award
Ford Foundation Diversity Initiative Award

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Co-Investigator, Risk Management and Compensation in the Era of Naloxone. Funded by the National Institutes of Health.

Principal Investigator, Impact of the New Jersey State Opioid Prescribing Law. Funded by Partnership for Drug Free New Jersey

Principal Investigator, Utilization of the New York State Prescription Drug Monitoring Program to Reduce Risky Prescribing. Funded by the United States Food and Drug Administration

Principal Investigator, Treatment of Opioid Addicted Chronic Pain Patients with Buprenorphine. Funded by Maimonides Medical Center Research Foundation.

Co-investigator, Pilot Study of Buprenorphine Maintenance for Opioid Addicted Jail Inmates. Funded by National Institute on Drug Abuse.

Co-investigator, Substance Abuse, HIV, & Hepatitis Prevention for Minority Populations and Minority Reentry Populations in Communities of Color, funded by the Substance Abuse and Mental Health Services Administration.

JOURNAL PEER REVIEWS

New England Journal of Medicine
JAMA
JAMA Internal Medicine
JAMA Psychiatry
Health Affairs
Journal of Public Health
Drug and Alcohol Dependence
American Journal of Public Health
The American Journal on Addictions
American Journal of Preventive Medicine
Substance Abuse: Research and Treatment

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Academic Journals & Books

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4. Kolodny A. How FDA Failures Contributed to the Opioid Crisis. AMA J Ethics. 2020;22(8):E743-750. doi: 10.1001/amajethics.2020.743.

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2. Kolodny, A. "Trump is not off to a good start with opioid addiction." The Hill. April 25, 2017.

3. Kolodny, A. "Crooked Doctors Are Not Fueling the Opioid Epidemic." New York Times. Feb 17, 2016.

4. Kolodny, A. "Crush-Resistant Opioids: Not All They're Cracked Up to Be." Media Planet. Nov 8, 2015.

5. Kolodny A. "Naloxone: Necessary but Not Nearly Enough." HuffPost. June 11, 2014.

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SELECTED KEYNOTE PRESENTATIONS

The Prescription Opioid and Heroin Crisis: Responding to an Epidemic of Addiction
The American Association of Oral and Maxillofacial Surgeons Annual Conference
San Francisco, CA, October 12, 2017.

The Prescription Opioid Addiction Crisis
California Healthcare Foundation
Oakland, CA, September 22, 2016.

The North American Opioid Addiction Epidemic
International Medicine in Addiction Conference
Melbourne, Australia, March 21, 2015.

The North American Opioid Addiction Epidemic
World Health Organization
Geneva, Switzerland, Nov 6, 2014.

Overview of the Opioid Analgesic Epidemic.
National Governors' Association Meeting
Frankfort, Kentucky, January 15, 2013.

An Iatrogenic Epidemic—Lessons from the Opioid Experiment
Seventh Annual Conference of The Addiction Institute of New York
New York NY March 2, 2012.

The History of Heroin Treatment: from Methadone to Buprenorphine
Bicentennial Celebration, New York City Department of Health and Mental Hygiene
New York, NY, August 24, 2005.

The History of Heroin Treatment: from Methadone to Buprenorphine
Bicentennial Celebration, New York City Department of Health and Mental Hygiene
New York, NY, August 24, 2005.

SELECTED TESTIMONY

U.S. Senate, Caucus on International Narcotics Control, "America's Addiction to Opioids: Heroin and Prescription Drug Abuse," 113th Congress, May 14, 2014.

U.S. Senate, Committee on Homeland Security and Governmental Affairs, "Unintended Consequences: Medicaid and the Opioid Epidemic," January 17, 2018.

U.S. House of Representatives, Committee on Energy & Commerce, Subcommittee on Health. "Combatting the Opioid Crisis," February 28, 2018.

U.S. District Court for the Northern District of Ohio. "Multi-District Litigation Against Opioid Manufacturers and Distributers," January 31, 2018. Invited by counsel for county governments to testify about causes of the U.S. opioid crisis.

District Court, Cleveland County, State of Oklahoma. "Oklahoma Attorney General vs Purdue Pharma et al." July 2019. Testified as an expert witness for the State of Oklahoma.

SELECTED MEDIA APPEARANCES

The Wall Street Journal, November 27, 2019. "Major League Baseball Close to a New Opioids Policy."

The New York Times, April 24, 2019. "Trump Declares Commitment to Ending Opioid Crisis 'Once and for All'."

The Financial Times, June 20, 2018. "Rehab USA: how should America treat its opioid victims?"

New York Times, February 14, 2018. How a Police Chief, a Governor and a Sociologist Would Spend $100 Billion to Solve the Opioid Crisis.

The New Yorker, October 30, 2017. "The Family that Built an Empire of Pain."

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New York Times, October 22, 2015. "Obama Strikes Personal Note as He Urges Help for Addiction."

New York Times, October 8, 2015. "F.D.A. Approval of OxyContin Use for Children Continues to Draw Scrutiny."

NPR On Point with Tom Ashbrook, October 6, 2015. "American Opioid Addiction Keeps Growing."

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Wall Street Journal, October 1, 2014. "Maker of Painkiller Tries to Curb Abuse."

Washington Post, September 28, 2014. "Overdose deaths spur families to march on Mall over opioid epidemic."

New York Times, August 28, 2014. Heroin's Death Toll Rising in New York, Amid a Shift in Who Uses It

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Wall Street Journal, January 25, 2013. FDA Panel Calls for New Curbs on Common Painkiller

Washington Post, December 30, 2012. "Rising Painkiller Addiction Shows Damage from Drugmakers' Role in Shaping Medical Opinion."

SCHEDULE 1

Publications Last 10 years

1. Foti K, Heyward J, Tajanlangit M, Meek K, Jones C, Kolodny A, Alexander GC. Primary care physicians' preparedness to treat opioid use disorder in the United States: A cross-sectional survey. Drug Alcohol Depend. 2021 Aug 1;225:108811. doi: 10.1016/j.drugalcdcp.2021.108811. Epub 2021 Jun 18. PMID: 34175786.

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SCHEDULE 2

Testimony

Trial Testimony:
State of Oklahoma, et al. v. Purdue Phamra L.P., et al., District Court of Cleveland County, State of Oklahoma Case No. CJ-2017-816

Deposition Testimony:

The State of Rhode Island v. Purdue Pharma, et al.

The State of Alabama v. Endo Health Solutions, et al.,

The State of New Hampshire v. Johnson & Johnson, et al. Case No. Docket No. 217-2018-CV-00678

The City of Huntington v. AmerisourceBergen Drug Corporation; Case No. 3:17-01362; and *Cabell County Commission*, Case No. 3:17-01665 (S.D.W. Va.)

In Re.: National Prescription Opiate Litigation, Northern District of Ohio Case No. 2017-md-2804

State of Oklahoma, et al. v. Purdue Phamra L.P., et al., District Court of Cleveland County, State of Oklahoma Case No. CJ-2017-816

CORRECTED SCHEDULE 3

LIST OF MATERIALS, FACTS, AND DATA CONSIDERED

PUBLICATION AND REPORTS

Abdul-Quader, A. et al., Effectiveness of Structural-Level Needle/Syringe Programs to Reduce HCV and HIV Infection among People Who Inject Drugs: A Systematic Review, AIDS and Behavior 17, no. 9 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6509353/.

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JAN-OK-00149992, Frank Mashett January 20, 2019 Deposition Exhibit 5

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OTHER

Burt Rosen [Purdue] Deposition (Jan. 16, 2019)

SUBCOMMITTEE ON HEALTH, COMMITTEE ON VETERANS' AFFAIRS U.S. HOUSE OF REPRESENTATIVES, 113th Congress. BETWEEN PERIL AND PROMISE: FACING THE DANGERS OF VA'S SKYROCKETING USE OF PRESCRIPTION PAINKILLERS TO TREAT VETERANS, OCTOBER 10, 2013

Testimony of Raymond J. Stratmeyer Vice President, Johnson & Johnson International Before House Subcommittee on Crime February 27, 1990.

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Securities Litigation and Consulting Group, Inc., *Florida PDMP analysis* (2021), the queries used to arrive at this number are contained in the backup materials provided with the report of Dr. McCann.

Exhibit 3

CVS caremark™

Opioid Prescriber Toolkit

CVS caremark™

Preface

Treating patients with chronic noncancer pain involves a thoughtful balance of providing adequate pain relief and avoiding adverse effects, while monitoring for opioid use disorder, fraud and drug diversion. Opioids can be safe and effective to treat pain when appropriately prescribed and monitored. However, the United States is experiencing a public health epidemic of prescription drug misuse and death by overdose, largely driven by nonmedical use of prescription pain relievers.

Data reported by the Centers for Disease Control and Prevention show that sales of prescription opioids in the United States have nearly quadrupled from 1999 to 2014 but with no overall change in the amount of pain Americans report. In 2014, approximately 10.3 million people over the age of 12 reported nonmedical use of prescription opioids in the past year and about 1.9 million people either abused or were dependent on prescription opioids. That year, more Americans misused opioids than heroin and cocaine combined. Death by prescription opioid overdose also increased to almost 19,000 people in 2014. That is why, as a leading provider of pharmacy services, CVS Caremark® is a strong advocate of appropriate prescribing, monitoring for safety, potential prescription drug misuse, and fraud, and responding appropriately to questionable behavior.

In 2011, the White House Administration released its Prescription Drug Abuse Prevention Plan which outlined goals for addressing prescription drug misuse and overdose. Since then, the Administration has expanded efforts in other major areas of the opioid crisis, including health care provider and patient education, prescription drug monitoring programs, community prevention and overdose response, medication-assisted treatment for opioid use disorder, and law enforcement and supply reduction.

This Opioid Prescriber Toolkit is designed to assist you in providing appropriate therapy to patients with chronic noncancer pain. Enclosed are materials related to pain management guidance, clinical tools for managing chronic noncancer pain, information on clinical and public health topics, and material for distribution to your patients.

Sincerely,

Clinical Services

Please take a moment to let us know if you have found these materials useful in your practice. We welcome your suggestions. Please use the enclosed Physician Response Form at the end of the toolkit to provide us with your feedback.

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1 Executive Summary of the Guiding Principles of Pain Management

Chronic pain is a common public health problem in the United States. Major professional organizations publish policies, treatment guidelines, and position statements to guide practitioners and regulators in effective pain management and judicious use of opioid therapy. The table below summarizes the aims of these publications. Highlights of the Centers for Disease Control and Prevention (CDC) *Guideline for Prescribing Opioids for Chronic Pain*, American Pain Society/American Academy of Pain Medicine (APS/AAPM) *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, and the Pharmacy Quality Alliance (PQA) Performance Measures *Use of Opioids from Multiple Providers or at High Dosage in Persons Without Cancer* follow the table.

Guiding Policy	Executive Summary
Centers for Disease Control and Prevention (CDC) *Guideline for Prescribing Opioids for Chronic Pain*	Provides guidance about opioid prescribing for primary care clinicians treating adult patients with chronic pain outside of active cancer treatment, palliative care, and end-of-life care. Guidelines aim to: • Raise awareness of the benefits and risks of opioids for chronic pain • Improve safety and effectiveness of pain treatment • Reduce risks associated with long-term opioid therapy
American Pain Society/ American Academy of Pain Medicine Treatment Guidelines (APS/AAPM) *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*	Serves as an evidence-based guide for practitioners and regulators to help foster a medical practice environment where the judicious use of opioids may be used to reduce suffering from chronic pain. Guidelines cover: • Patient selection and risk stratification • Informed consent and opioid management plans • Initiation and titration of chronic opioid therapy • Monitoring patients for treatment progress and aberrant drug-related behaviors • Opioid-related adverse effects • Dose escalations and high-dose therapy • Indications for discontinuation of therapy
Pharmacy Quality Alliance (PQA) *Use of Opioids from Multiple Providers or at High Dosage in Persons Without Cancer*	PQA develops medication-use quality measures in areas such as medication safety, medication adherence and appropriateness. PQA identifies the high-priority areas for health care and gaps in existing performance measure sets. The measures may be used to compare medication-use quality rates across organizations.

1 Highlights of the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain

The CDC's Guideline for Prescribing Opioids for Chronic Pain was published in 2016 to improve communication between providers and patients about the risks and benefits of opioid therapy for patients with chronic pain outside of active cancer treatment, palliative care and end-of-life care. This guideline is part of an effort by the United States government to fight the prescription opioid overdose epidemic the country has been experiencing for over a decade. Some of the primary goals of the guideline are to improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder and overdose. This guideline is intended for primary care clinicians (eg, family physicians, internists, nurse practitioners, and physician assistants) who are treating patients with chronic pain in outpatient settings.

There are 12 recommendations offered by the CDC, broken down by three guiding principles.

1 Determining When to Initiate or Continue Opioids for Chronic Pain	Nonpharmacologic therapy and non-opioid therapy are preferred for chronic pain
	Consider opioid therapy only if expected benefits for both pain and function outweigh risks to the patient
	Opioid therapy should be combined with nonpharmacologic and nonopioid therapy
	Before starting opioid therapy, establish realistic treatment goals for pain and function
	Consider how opioid therapy will be discontinued if benefits do not outweigh risks
	Continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety
	Continuously discuss with patients known risks and realistic benefits of opioid therapy as well as patient and clinician responsibilities for managing therapy

2 Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation	When starting opioid therapy, prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids
	When initiating opioid treatment, prescribe the lowest effective dosage. Start low and go slow
	Assess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day

1 Highlights of the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain Continued

2 Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

- When opioids are used for acute pain, prescribe the lowest effective dose of immediate-release opioids at a quantity no greater than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed
- Evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy or of dose escalation
- Evaluate benefits and harms of continued therapy with patients every 3 months or more frequently
- If benefits do not outweigh harms of continued opioid therapy, optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids

3 Assessing Risk and Addressing Harms of Opioid Use

- Before starting and periodically during opioid therapy, evaluate risk factors for opioid-related harms
- Considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present
- Review patient history of controlled substance prescriptions via state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving high opioid dosages or dangerous combinations that put him or her at high risk for overdose
- Review PDMP data when starting opioid therapy and during therapy every prescription to every 3 months
- Utilize urine drug testing before starting opioid therapy and consider urine drug testing at least annually to identify prescribed medications, other controlled prescription drugs and illicit drugs
- Avoid prescribing opioids and benzodiazepines concurrently
- Arrange medication assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for opioid use disorder

Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65 (No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.

1 Highlights of the American Pain Society (APS)–American Academy of Pain Medicine (AAPM) Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain

The APS and AAPM have issued evidence-based guidelines on chronic opioid therapy in adults with chronic noncancer pain. The principles outlined should serve as a guide for both practitioners and regulators regarding the judicious use of opioids in the course of medical practice. In 2009, the APS and the AAPM commissioned a multidisciplinary panel to develop evidence-based guidelines on chronic opioid therapy in adults with chronic noncancer pain.

Selected Highlights of the APS–AAPM Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain	
Patient selection and risk stratification	• Pain history, drug history, physical exam • Assessment of psychosocial factors and family history • Assessment of likelihood of substance misuse or addiction • Diagnostic tests to evaluate the underlying pain condition • Evaluation on whether the pain condition may be treated more effectively with nonopioid therapy
Informed consent and opioid management plans	• When starting therapy, informed consent should be obtained • Discussion with the patient about therapeutic goals, expectations, potential risks, and alternatives to opioid therapy • Written pain management plan to document patient and clinician responsibilities and expectations; patient education
Initiation and titration of chronic opioid therapy	• Regard initial treatment as a therapeutic trial, not a definitive course of treatment • Opioid selection, initial dosing, and titration should be individualized according to the patient's health status, previous exposure to opioids, attainment of therapeutic goals, and predicted or observed harms
Monitoring patients	• Periodic reassessment should include documentation of - Pain intensity and level of functioning - Progress toward therapeutic goals - Presence of adverse events - Adherence to therapy - Urine drug screens for patients who are high risk or display aberrant behaviors
Aberrant drug-related behaviors	• Evaluate whether patients engaging in aberrant drug-related behaviors should - Continue to receive opioids or switch to alternative therapy - Receive consultation or co-management with addiction/mental health specialist

1 Highlights of the American Pain Society (APS)–American Academy of Pain Medicine (AAPM) Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain Continued

Selected Highlights of the APS–AAPM Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain	
Opioid-related adverse effects	• Anticipate, identify, and treat common opioid-associated adverse effects
Dose escalations and high-dose therapy	• When repeated dose escalations occur, evaluate potential causes, and reassess benefits relative to harms • In patients who require relatively high doses of chronic opioid therapy, evaluate for unique opioid-related adverse effects, changes in health status, and adherence to therapy on an ongoing basis, and consider more frequent follow-up visits
Indications for discontinuation of therapy	• Taper or wean patients off of therapy who engage in repeated aberrant drug-related behaviors or drug misuse/diversion, experience no progress toward meeting therapeutic goals, or experience intolerable adverse effects

Adapted from: Chou R, et al.

References
1. Chou R, Fanciullo GJ, Fine PG, et al; American Pain Society–American Academy of Pain Medicine Opioids Guidelines Panel. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *J Pain*. 2009;10(2):113-130. http://www.jpain.org/article/PIIS1526590008008316/fulltext. Accessed July 15, 2016.

2. *Use of Opioids for the Treatment of Chronic Pain*: A statement from the *American Academy of Pain Medicine*. Chicago, IL: Academy of Pain Medicine; March 2013. http://www.painmed.org/files/use-of-opioids-for-the-treatment-of-chronic-pain.pdf. Accessed July 14, 2016.

1 Pharmacy Quality Alliance (PQA) Performance Measures on the Use of Opioids from Multiple Providers or at High Dosage in Persons Without Cancer

The PQA develops medication-use quality measures in areas such as medication safety, medication adherence and appropriateness. The group identifies the high-priority areas for health care and gaps in existing performance measure sets. Ideally, the measures are used to compare and benchmark medication-use rates across organizations, provide feedback to plans and pharmacies on their performance and track quality improvement initiatives as they are implemented. The goal is to drive enhancements in our healthcare system that foster improved patient outcomes with evidence-based patient care.

Three new performance measures that focus on opioid misuse and abuse were introduced in 2015. These measures evaluate use of high doses of opioids, multiple providers of opioids and the combination of the two in patients without cancer.

The PQA opioid performance measures were shaped by analyzing commercially insured patients' claims data, clinical literature and state PDMP. Results from the analyses showed that efforts to prevent opioid overdose deaths should focus on strategies that target:

1. High-dose opioid users; and/or
2. Persons who seek care from multiple doctors and pharmacies.

The approach the PQA suggests will help assist health plans in managing the number of patients who meet the measure criteria and allow them to plan respective interventions.

Measure 1: Use of Opioids at High Dosage in Persons Without Cancer	This measure identifies the proportion of individuals that are receiving prescriptions for opioids at a high dose (with a daily dosage greater than 120 mg morphine equivalent dose (MED) for 90 consecutive days or longer) that could be inappropriate or could contribute to an adverse event.
Measure 2: Use of Opioids from Multiple Providers in Persons Without Cancer	This measure identifies the proportion of individuals that are receiving opioid prescriptions from 4 or more prescribers AND 4 or more pharmacies, which may indicate uncoordinated care and/or doctor/pharmacy shopping.
Measure 3: Use of Opioids at High Dosage and from Multiple Providers in Persons Without Cancer	This measure identifies the proportion of individuals that are receiving opioid prescriptions from 4 or more prescribers AND 4 or more pharmacies where the daily dose is greater than 120 mg MED for 90 consecutive days or longer. The measure may indicate misuse, abuse, or inappropriate and/or fragmented care.

In 2016, the PQA announced that the specific measure *Use of Opioids at High Dosage in Persons Without Cancer*, will be included in the Medicaid Adult Core Set of Measures. The Centers for Medicare & Medicaid Services Medicaid Adult Core Set of Measures standardizes the measurement of healthcare quality across state Medicaid programs.

References

1. Pharmacy Quality Alliance (PQA). Newly Endorsed PQA Performance Measures Use of Opioids from Multiple Providers or at High Dosage in Persons Without Cancer. Springfield (VA): Pharmacy Quality Alliance (PQA); 2015.

2. Pharmacy Quality Alliance (PQA). (2016) PQA Measure of Use of Opioids at High Dosage in Persons Without Cancer Included in Medicaid Adult Core Set of Measures for 2016. [Press release]. Retrieved from http://pqaalliance.org/images/uploads/files/2016%20July%2012_Press%20Release_PQA%20Opioids%20in%20Adult%20Core%20Set.pdf.

1 Current Guidelines for the Treatment of Selected Types of Pain

The following is a list of treatment guidelines for selected types of chronic pain. Many of these publications can be found online via the internet link provided or using PubMed, a free searchable database of life sciences journals. To retrieve a guideline, visit the PubMed website at **http://www.ncbi.nlm.nih.gov/pubmed/** and enter the PubMed ID number provided.

Chronic Noncancer Pain

CDC Guideline for Prescribing Opioids for Chronic Pain–United States, 2016

Dowell D, Haegerich TM, Chou R. *MMWR Recomm Rep*. 2016 Mar 18. 65(1):1-49. doi: 10.3109/15360288.2016.1173761. (PubMed ID: 27301691)

Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain

Chou R, Fanciullo GJ, Fine PG, et al for the American Pain Society–American Academy of Pain Medicine Opioids Guidelines Panel. *J Pain*. 2009;10(2):113-130. (PubMed ID: 19187889)

Principles of Analgesic Use. 7th ed.

American Pain Society. Chicago, IL: American Pain Society; 2016:118.

Methadone for Pain Management: Improving Clinical Decision Making. American Academy of Pain Medicine

The American Academy of Pain Medicine. Chicago IL. July, 2016. http://www.painmed.org/files/methadone-for-pain-management-improving-clinical-decision-making.pdf

American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain: Part 1–Evidence assessment

Manchikanti L, Abdi S, Atluri S, et al. *Pain Physician*. 2012;15(suppl 3):S1-S65. (PubMed ID: 22786448)

American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic non-cancer pain: Part 2–Guidance

Manchikanti L, Abdi S, Atluri S, et al. *Pain Physician*. 2012;15(suppl 3):S67-S116. (PubMed ID: 22786449)

Low Back Pain

Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society

Chou R, Qaseem A, Snow V, et al; Clinical Efficacy Assessment Subcommittee of the American College of Physicians and the American College of Physicians/American Pain Society Low Back Pain Guidelines Panel [erratum, *Ann Intern Med*. 2008;148(3):247-248]. *Ann Intern Med*. 2007;147(7):478-491. (PubMed ID: 17909209)

Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society

Chou R, Loeser JD, Owens DK, et al; American Pain Society Low Back Pain Guideline Panel. *Spine* (Phila Pa 1976). 2009;34(10):1066-1077. (PubMed ID: 19363457)

1 Current Guidelines for the Treatment of Selected Types of Pain Continued

Neuropathic Pain

Pharmacotherapy for neuropathic pain in adults: a systematic review and meta-analysis
Finnerup NB, Attal N, Haroutounian S, et al. *Lancet Neurol*. 2015 Feb;14(2):162-73. doi: 10.1016/S1474-4422(14)70251-0. (PubMed ID: 25575710)

Evidence-based guideline: treatment of painful diabetic neuropathy: report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation
Bril V, England J, Franklin GM, et al. *Neurology*. 2011;76(20):1758-1765. (PubMed ID: 21482920)

Fibromyalgia

EULAR revised recommendations for the management of fibromyalgia
Macfarlane GJ, Kronisch C, Dean LE, et al. *Ann Rheum Dis*. 2016 Jul 4. DOI: 10.1136/annrheumdis-2016-209724. (PubMed ID: 27377815)

Cancer Pain

NCCN Clinical Practice Guidelines in Oncology. Adult Cancer Pain
National Comprehensive Cancer Network. https://www.nccn.org

Management of Chronic Pain in Survivors of Adult Cancers: American Society of Clinical Oncology Clinical Practice Guideline
Paice JA, Portenoy R, Lacchetti C, et al. *J Clin Oncol*. 2016 Jul 25. (PubMed ID: 27458286)

Persistent Pain in Older Persons

Pharmacological management of persistent pain in older persons
American Geriatric Society Panel on the Pharmacologic Management of Persistent Pain in Older Persons. *J Am Geriatr Soc*. 2009;57(8):1331-1346. (PubMed ID: 19573219)

Opioids and the management of chronic severe pain in the elderly: consensus statement of an international expert panel with focus on the six clinically most often used World Health Organization step III opioids (buprenorphine, fentanyl, hydromorphone, methadone, morphine, oxycodone)
Pergolizzi J, Boger RH, Budd K, et al. *Pain Practice*. 2008;8(4):287–313. (PubMed ID: 18503626)

Migraine Headache

Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Report of the Guideline Development Subcommittee of the American Academy of Neurology
Simpson DM, Hallett M, Ashman EJ, et al. *Neurology*. 2016 May 10;86(19):1818-26. (PubMed ID: 27164716)

1 Current Guidelines for the Treatment of Selected Types of Pain Continued

Migraine Headache

Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society

Silberstein SD, Holland S, Freitag F, et al [erratum, *Neurology*. 2013 Feb 26;80(9):871]. U.S. *Neurology*. 2012;78(17):1337-1345. (PubMed ID: 22529202)

*Current as of July 2016.

Physician Tools for the Day-to-Day Management of Patients with Chronic Pain

Section Two

Section 2 Topics

A 10-Step Pain Assessment and Treatment Algorithm from the American Society of Interventional Pain Physicians Guidelines for Responsible Opioid Prescribing in Chronic Noncancer Pain

Sample Opioid Pain Care Agreements

- Department of Veterans Affairs & Department of Defense
- American Academy of Pain Medicine

Predicting Addiction

Urine Drug Screening for Opioids

Evaluations for Chronic Noncancer Pain

- Initial Evaluation for Chronic Noncancer Pain Flowsheet
- Interim Evaluation for Chronic Noncancer Pain Flowsheet—Follow-up

2 A 10-Step Pain Assessment and Treatment Algorithm from the American Society of Interventional Pain Physicians

Step 1: Initial Assessments

- Comprehensive assessment of patient
- Assessment of risk of misuse
- Utilize PDMP data
- Urine drug screening

Step 2: Establish Diagnosis

- Neurophysiologic studies, MRI, X-rays, CT
- Psychological evaluation
- Pain specialist consultations as needed

Key Point: Only relevant and appropriate diagnostic findings should be provided to patients by their treating physician to avoid increased fear, activity avoidance, and requests for increased opioids.

Step 3: Establish Medical Necessity Step

- Physical diagnosis
- Therapy with noncontrolled substances, behavioral interventions, physical modalities, or other alternatives

Key Point: Continued medical necessity depends on the 4 "A's":

- Analgesia
- Activity
- Aberrant behavior
- Adverse effects

Step 4: Establish Treatment Goals

- Decrease pain by 30% and/or increase function by 30%
- Minimal adverse effects
- Realistic patient expectations

Key Point: Assess outcomes by a numeric rating pain scale, functional assessment using the Oswestry Disability Index, Neck Disability Index, employment status, and/or improvement in activity.

Step 5: Assess Effectiveness of Opioid Therapy

- Understand the effectiveness and limitations of long-term opioid therapy
- Recognize the specific circumstances for which long-verses short-acting opioids should be prescribed
- Evaluate contraindications to opioid therapy

Step 6: Provide for Informed Decision-Making

- Use a controlled substance agreement
- Educate patient on the potential benefits, adverse effects, complications, and risks of opioid therapy as well as signs of overdose
- Discuss safe storage

Step 7: Begin Initial Treatment (8-12 Weeks)

- Stratification of risk
- Understanding opioids and morphine-equivalent dosing
- Start with low-dose short-acting opioids and titrate gradually to higher amounts if necessary

Step 8: Monitor Adherence

- Utilize PDMPs
- Urine drug screening
- Pill counts
- Behavioral assessment during each visit

Step 9: Monitor Side Effects

- Breathing
- Constipation
- Sedation
- Driving

Step 10: Determine Outcomes

Taper and Discontinue if Patient Experiences:	Continue if Patient Experiences:
• Persistent or new pain and/or lack of analgesia	• Analgesia of 30% and/or activity increase by 30%
• Abuse, misuse	• No abuse or misuse and adverse effects are manageable
• Lack of activity	
• Adverse effects or aberrant behavior	

CT=computed tomography; MRI=magnetic resonance imaging; PDMP=Prescription Drug Monitoring Program

Adapted from: Manchikanti L, Abdi S, Atluri S, et al. American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2-Guidance. *Pain Physician*. 2012;15(suppl 3):S67-S116.

2 Sample Opioid Pain Care Agreements Department of Veterans Affairs

An opioid pain care agreement outlines patient goals and prescriber expectations for patients who consent to chronic controlled substance therapy. This agreement may also be used to describe potential adverse effects, certain patient rights, and the consequences of failing to adhere to the terms of the agreement. The signed agreement may serve as documentation of an informed consent discussion. Here are two examples of patient agreements that you may adapt for your practice.

Department of Veterans Affairs and Department of Defense (VA/DoD)

APPENDIX C: Sample Opioid Pain Care Agreement

1. I understand that my provider and I will work together to find the most appropriate treatment for my chronic pain. I understand the goals of treatment are not to eliminate pain, but to partially relieve my pain in order to improve my ability to function. Chronic opioid therapy is only **one** part of my overall pain management plan.
2. I understand that my provider and I will continually evaluate the effect of opioids on achieving the treatment goals and make changes as needed. I agree to take the medication at **the dose and frequency prescribed** by my provider. I agree not to increase the dose of opioids on my own and understand that doing so may lead to the treatment with opioids being stopped.
3. I understand that the common adverse effects of opioid therapy include constipation, nausea, sweating and itchiness of the skin. Drowsiness may occur when starting opioid therapy or when increasing the dosage. I agree to refrain from driving a motor vehicle or operating dangerous machinery until such drowsiness disappears.
4. I will not seek opioid medications from another physician for the treatment of my chronic pain. Regular follow-up care is required and only my provider will prescribe these medications for my chronic pain for me at scheduled appointments.
5. I will attend all appointments, treatments and consultations as requested by my providers. I will attend all pain appointments and follow pain management recommendations.
6. I will not give or sell my medication to anyone else, including family members; nor will I accept any opioid medication from anyone else. I agree to be responsible for the secure storage of my medication at all times. If these medications are stolen, I will report this to police and my provider and will produce a police report of this event if requested to do so.
7. I understand that if my prescription runs out early for any reason (for example, if I lose the medication or take more than prescribed), my provider may not prescribe extra medication for me. I may have to wait until the next prescription is due.
8. I understand that the use of other medications can cause adverse effects or interfere with opioid therapy. Therefore, I agree to notify my provider of the use of all substances, including marijuana, alcohol, medications not prescribed for me (tranquilizers), and all illicit drugs.
9. I agree to periodic unscheduled drug screens.
10. I understand that I may become physically dependent on opioid medications, which in a small number of patients may lead to addiction. I agree that if necessary, I will permit referral to addiction specialists as a condition of my treatment plan.

2 Sample Opioid Pain Care Agreements Department of Veterans Affairs Continued

APPENDIX C: Sample Opioid Pain Care Agreement Continued

11. I understand that my failure to meet these requirements may result in my provider choosing to stop writing opioid prescriptions for me. Withdrawal from the medications will be coordinated by the provider and may require specialist referrals.
12. I hereby agree that my provider has the authority to discuss my pain management with other health care professionals and my family members when it is deemed medically necessary in the provider's judgment.
13. My providers may obtain information from State controlled substances databases and other prescription monitoring programs.

Patient Signature .....

Date .....

Patient Name Printed .....

Physician Name .....

Reference

The Management of Opioid Therapy for Chronic Pain Working Group. Department of Veterans Affairs and Department of Defense Clinical practice guideline for management of opioid therapy for chronic pain. Department of Veterans Affairs and Department of Defense, Version 2.0. May 2010. http://www.healthquality.va.gov/Chronic_Opioid_Therapy_COT.asp. Accessed July 20, 2016.

2 Sample Opioid Pain Care Agreements American Acadamy of Pain Medicine

Agreement on Controlled Substances Therapy for Chronic Pain Treatment

The purpose of this agreement is to create an understanding regarding controlled substances (a type of medication that is regulated by states and the Federal government) that may benefit your chronic pain symptoms. My goal is to treat you safely with these potent medications and also to prevent abuse of or addiction to these medications. Medications such as opioids (narcotic analgesics), benzodiazepine tranquilizers, barbiturate sedatives, and muscle relaxants such as Soma (carisoprodol), that may be useful in managing pain, can be problematic in several ways. These medications have "street value" and potential for abuse. Although these medications may be prescribed with the goal of improving your comfort and functionality, their medical use is also associated with the risk of serious adverse effects such as development of an addiction disorder or a relapse in a person with a prior addiction history. The extent of this risk is uncertain, but it is known to be higher in certain vulnerable patients. My goal is to have you take the lowest possible dose of medication that is reasonably effective in managing your pain and improving your function, and when possible, have it tapered and eventually discontinued, while at the same time monitoring and managing these potential risks.

Because these medications have the potential for abuse or diversion (i.e. sharing, trading or selling to **anyone** other than whose name is on the prescription), strict accountability is necessary for both medical safety and legal reasons. Therefore, the following policies are agreed to by you, the patient, to help me keep you safe and to provide you with good care.

1. You must get a prescription for all controlled substances from the physician whose name appears below or, during his or her absence, by the covering physician, unless specific written authorization is obtained for an exception. (Multiple sources can lead to untoward medication interactions or poor coordination of treatment.)
2. You must obtain all controlled substances from the same pharmacy. Should the need arise to change pharmacies, our office must be informed. The pharmacy that you have selected is:

   ..... Phone .....
3. You must inform our office of any new medications or medical conditions and of any adverse effects you experience from any of the medications that you take.
4. You must give the prescribing physician permission to discuss all diagnostic and treatment details with dispensing pharmacists or other professionals who provide your health care for purposes of maintaining accountability and coordinating your care.
5. You may not share, sell or otherwise permit others to have access to these medications. You must take all medications exactly as prescribed, unless you develop side effects. If you develop side effects, you must consult with your doctor or local emergency providers.
6. You must not stop these medications abruptly or without consulting the prescribing physician, as an abstinence/withdrawal syndrome may develop.
7. You must agree that your urine may be tested for controlled substances before initiation of therapy and that random urine follow up testing may be done. You must cooperate in such testing, and you must agree that the presence of unauthorized substances, illicit substances or absence of prescribed medications may prompt referral for assessment for addictive disorder and possible tapering and discontinuation of the controlled substances immediately or in the future.
8. You will not give your prescriptions or bottles of these medications to anyone else. These substances may be sought by other individuals with chemical dependency and should be closely safeguarded. You will take the highest degree of care with your medications and prescriptions. You will not leave them where others might see or otherwise have access to them.
9. You must bring original containers of medication to each office visit.

2 Sample Opioid Pain Care Agreements American Acadamy of Pain Medicine Continued

10. You must keep all controlled substances in a secure area. Since the medications may be hazardous or lethal to a person who is not tolerant to their effects, especially a child, you must keep them out of reach of such people.
11. You must exercise extreme caution when taking these medications and driving or operating heavy machinery. The use of these medications may induce drowsiness or change your mental abilities, thereby making it unsafe to drive or operate heavy machinery. The effects of these medications are particularly problematic during any dose changes. If you are the slightest bit impaired, you must refrain from these activities.
12. You must discuss the long-term use of controlled substances with your physician. Prolonged opioid use can be associated with serious health risks. You need to understand these risks.
13. You must agree that medications will not be replaced if they are lost, flushed down the toilet, destroyed, left on an airplane, etc. If your medication has been stolen and you complete a police report regarding the theft and present that report to the prescribing physician, an exception may be made at the discretion of your treating physician.
14. You must agree that early refills will not be given.
15. You understand that prescriptions may be issued early only if the physician or patient will be out of town when a refill is due. These prescriptions will contain instructions to the pharmacist that they not be filled prior to the appropriate date.
16. You agree that, if the responsible legal authorities have questions concerning your treatment, as might occur, for example, if you were obtaining medications at several pharmacies, all confidentiality is waived and these authorities may be given full access to our records of controlled substances administration.
17. You agree that failure to adhere to these policies may result in tapering and cessation of therapy with controlled substance prescribing by this physician or referral for further specialty assessment.
18. You agree that prescription renewals are contingent on keeping scheduled appointments. Do not phone for prescriptions after hours or on weekends. If you receive any controlled substances in an ER, you must report that incident to your prescriber, in writing, within 48 hours.
19. You recognize that any medical treatment is a trial, and that continued prescription is contingent on evidence of benefit and improved functionality.
20. You acknowledge that the risks and potential benefits of therapy with controlled substances have been explained to you and that you have had the opportunity to ask any questions that you may have.

You understand and agree that failure to adhere to these policies will be considered noncompliance and may result in cessation of opioid prescribing by your physician and possible dismissal from this clinic.

You affirm that you have full right and power to sign and be bound by this agreement. You further affirm that you have been given the opportunity to ask any questions you may have and that you have read, understand, and accept all of its terms.

Patient Signature .....

Date .....

Patient Name Printed .....

Physician Name .....

Reference
Agreement on Controlled Substances Therapy for Chronic Pain Treatment. Chicago, IL: American Academy of Pain Medicine; 2013. http://www.painmed.org/files/agreement-on-controlled-substances-therapy.pdf. Accessed July 14, 2016.

2 Predicting Addiction

Identifying patients who misuse opioids in the course of chronic opioid therapy for pain is complex.[1,2] Disentangling opioid abuse or dependence from legitimate pain management complexities like tolerance, withdrawal, or potential overdose is often difficult.[2] There are no absolute factors that place individuals at risk for the development of prescription drug use disorders.[2] Some conventionally studied components that may contribute to a patient's risk for opioid addiction include genetic predisposition, comorbid psychiatric conditions, prior substance use disorder, cultural factors, and substance availability.[1] A recent investigation utilizing mathematical modeling of data claims from commercially-insured individuals uncovered several other correlates of opioid use disorders (OUD). Results showed that those likely to have OUD were[2]:

- male and younger
- less likely to be the primary insured individual, and are more likely to be a dependent or spouse/partner of the primary insured
- receiving a larger supply of opioids and had a prescription history of more opioids
- receiving more short-acting opioids
- filling prescriptions at more pharmacies
- utilizing more medical and psychiatric services (physician and outpatient mental health visits, general inpatient and inpatient mental health admissions, and emergency department encounters)
- prescribed more concomitant medications such as selective serotonin reuptake inhibitors and benzodiazepines

If patient data is readily available to physicians and health plans, evaluating these predictors may be of clinical utility in identifying patients who may be potentially at risk for OUDs and implementing prevention efforts.[2] Additionally, proper patient history, examination, and ongoing monitoring should be employed. Various screening tools may also be helpful to predict risk of addiction.[3] Below you will find a list of screening tools that may assist you in assessing risks and benefits of opioid therapy.

Assessing Risk-Benefit: Screening Tests and Questionnaires

Screening tools to monitor opioid adherence and possible misuse should be considered at initial evaluation and as necessary thereafter. The sample screening tools listed below have certain relevance and limitations depending on the clinical situation and cannot be applied universally to all patients.[3]

- Cut-down, annoyed, guilt, eye-opener (CAGE) Adapted to Include Drugs (CAGE-AID) Questionnaire
- Current Opioid Misuse Measure (COMM)
- Opioid Risk Tool (ORT)
- Pain Assessment and Document Tool (PADT)
- Pain Medication Questionnaire (PMQ)
- Screener and Opioid Assessment for Patients in Pain—Revised (SOAPP-R)
- Screening Tool for Addiction Risk (STAR)

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2 Urine Drug Screening for Opioids

Urine drug screening (UDS) can be used as part of a universal precautions approach aimed to help prevent misuse, abuse, and diversion of opioids.[1] UDS is considered an objective indicator to monitor adherence and/or misuse during opioid therapy and as a balance to patient self report, physician assessment, and behavioral monitoring. UDS is most commonly used for the following purposes[2,3]:

- To detect the presence or absence of prescribed medications to ensure appropriate use and compliance with treatment
- To identify unprescribed and illicit substances that are not expected to be present in the urine
- To assist in confirming or invalidating suspicions of drug diversion

Positive and negative UDS results assist the physician in making appropriate dose or drug changes to ensure effective pain management. UDS helps identify unreported drugs patient may be taking that increase the risk of overdose when combined with an opioid (e.g. other nonprescribed opioids, benzodiazepines, and heroin). And finally, negative UDS results can help identify the patient that may be diverting (sharing or selling) opioids and not taking them.[3]

Physicians may face multiple issues with UDS, one of which is the suggestion that the physician does not trust the patients or that patients are not trustworthy.[4] That is why it is imperative that practitioners explain to patients that UDS is a routine procedure for all patients on opioid therapy and is used as a means to safeguard their health, optimize therapy, and realize missed opportunities to facilitate treatment for any potential substance use disorder.[3] One constructive result of an imminent UDS is that it can provide the physician an opportunity to have a candid conversation with the patient about unreported substances they may be using or illicit activity that may be reflected in the UDS results.[3]

Suggested frequency of UDS includes a baseline screen before initiating therapy, compliance testing within 1 to 3 months of initiating therapy, and then random monitoring every 6 to 12 months.[2] After that, if a patient continues opioid therapy, UDS will be required once a year. Patients with abnormal results at any time will require more frequent screening as determined by the prescribing physician.[2]

Limitations related to the reliability of the urine drug screens and drug metabolism exist and must be recognized.[2] There are 2 types of urine drug screens, immunoassay and gas chromatography/mass spectrometry (GC-MS).[2,3] Initial UDS with immunoassay is appropriate and cost effective in an office setting.[3,5] The test is sensitive but not specific.[2] It can identify the presence of a class of drugs but cannot always differentiate between drugs of the same class.[2] To identify individual drugs and metabolites, the immunoassay may require follow-up lab confirmation with GC-MS, which can be costly but increases accuracy by up to 9%.[2,3,5]

Limitations of Opioid Urine Drug Screening[2,6]

Immunoassay tests show a low sensitivity for semisynthetic or synthetic opioids such as oxycodone, fentanyl, methadone, and buprenorphine. A negative response does not exclude the use of opioids.[6]

Immunoassays can produce false-positive results from cross-reactivity with other substances. For example, several quinolone antibiotics can potentially cause false-positive results for opiates. Quinolones are not misinterpreted as opiates by gas chromatography/mass spectroscopy.[2,6]

2 Urine Drug Screening for Opioids Continued

Interpreting Unexpected Results of Urine Drug Screens[4]

Unexpected Results	Possible Explanation	Suggested Actions for Physician
UDS negative for prescribed opioid	• False negative • Non-compliance • Diversion	• Repeat test using chromatography • Obtain history of the patient's use of medications for preceding week • Ask if patient has given the drug to others • Monitor compliance with pill count
UDS positive for non-prescribed opioid or benzodiazepine	• False positive • Patient obtaining opioids from other sources	• Repeat UDS regularly • Ask patient if they accessed opioids from other sources • Assess for opioid misuse or addiction • Review or revise treatment agreement
UDS positive for illicit drugs	• False positive • Patient is occasional user or addicted to illicit drug	• Repeat UDS regularly • Assess for abuse or addiction and refer to addiction treatment as needed
Urine creatinine is <2–3 mmol/liter	• Patient added water to sample	• Repeat UDS • Consider supervised collection or temperature testing • Obtain history of the patient's use of medications for preceding week • Review or revise treatment agreement
Urine sample is cold	• Delay in handling sample • Patient added water to sample	• Repeat UDS and consider supervised collection or temperature testing • Obtain history of the patient's use of medications for preceding week • Review or revise treatment agreement

UDS=urine drug screen
Adapted from: Manchikanti L, et al.4

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2 Evaluations for Chronic Noncancer Pain

Evaluation and documentation is essential for a successful pain management plan. The following templates contain sample criteria for initial and interim assessments of patients requiring chronic opioid therapy. These templates can be modified by prescribers to use in their own practices.

Initial Evaluation for Chronic Noncancer Pain Flowsheet

Name:	Medical record #:
History	
Pertinent illness/pain history[a]	
Prior therapy for pain (effectiveness)	
Family or personal history of alcohol or drug misuse	
Social substance use history (including tobacco)	
Prior pain specialist assessment	
Other	
Relevant physical findings	
X-ray or other findings	
Assessment(s)	
Diagnosis causing pain	
Concomitant diagnoses	
Plan(s)	
Further psychiatric or substance misuse evaluation(s)	
Physical therapy or other functional assessments and/or treatments	
Nonopioid analgesic and/or adjuvant therapies	
Opioid therapy[b]	
Recommended treatment plan	

[a] For new patients, consider only limited (if any) controlled substance prescriptions until all past medical records are obtained and reviewed.
[b] Consider using an informed consent agreement in addition to an opiate treatment contract to increase patient awareness of the potential adverse effects of opioid therapy.

2 Evaluations for Chronic Noncancer Pain Continued

Interim Evaluation for Chronic Noncancer Pain Flowsheet—Follow-up

Name:	Medical record #:
	Visit Date:

Accurate Medical History	
Current diagnosis	
Interim history since last visit (eg, X-rays)	
Routine laboratory test results	
Urine drug screen results	
Analgesia	
Medication list	
Pain control	
Adverse Events	
Medication side effects	
Activities	
Day-to-day functional status	
Social history	
Affect	
Psychiatric status and/or test results	
Ambiguous Drug-Taking	
External feedback[a]	
Treatment concerns	
Follow-up	

[a] External feedback from coworkers, family, law enforcement, other health care providers.

Preventing Drug Misuse and Diversion

Section Three

Section 3 Topics

Prescription Drug Misuse Trends

Prescription Drug Monitoring Programs

Prescriber Safeguards Against Drug Diversion

Recognizing a Patient with a Substance Use Disorder

Terminology Associated with Chronic Pain Management and Substance Use Disorders

3 Prescription Drug Misuse Trends

Prescription drug misuse is the nation's fastest growing drug problem. In 2014, about 10.3 million people reported nonmedical use of prescription opioids and 1.9 million people either abused or were dependent on prescription opioid pain relievers.[1,2] Heroin use and related overdose deaths have more than tripled since 2010.[5] Four out of 5 heroin users started on prescription opioids.

Illicit Fentanyl

Death by prescription opioid overdose, which includes natural, semi-synthetic and synthetic opioids, increased by 16% from 2013 to almost 19,000 people in 2014.[3] The CDC reports that a significant part of the increase in deaths was due to synthetic opioids; in particular illicit fentanyl, not prescribed fentanyl.[3] Non-pharmaceutical fentanyl availability and use has been on the rise. This type of fentanyl is illegally manufactured, and is often mixed with heroin and/or cocaine in order to increase the drug's effect. This also increases potency and raises the risk of overdose. Confiscations of illicit fentanyl have increased by nearly 7 times from 2012 to 2014.[4]

The National Drug Early Warning System

Timely surveillance of these types of emerging trends may help facilitate effective response and prevent fatal overdoses.[4] The National Drug Early Warning System (NDEWS), sponsored by the National Institute on Drug Abuse, is a network that identifies and monitors patterns of drug misuse, trends, and emerging drug problems nationally and locally. NDEWS has established a virtual community of scientists, government officials, public health experts, and law enforcement representatives for sharing local research. The system uses innovative methods to scan social media and Web platforms, collaborates with the American Association of Poison Control Centers and uses national- and local-level data to identify new or potential drug trends. Real-time exchange of this surveillance information allows stakeholders to make better informed and actionable public health policy decisions.[6] Geographic drug trends can help a prescriber respond faster to emergencies, create goal-oriented treatment protocols for patients and employ targeted interventions like UDS as a part of pain management if misuse is suspected.[4,6]

Resources

- For real-time information on drug misuse trends and problems, please regularly visit the NDEWS website at **https://www.drugabuse.gov/drugs-abuse/emerging-trends-alerts.**
- For information on commonly misused prescription opioids and other illicit drugs and street names for these drugs, visit **https://www.drugabuse.gov/drugs-abuse/commonly-abused-drugs-charts.**
- Your state PDMP can also provide invaluable patient data for your practice. To learn more about a specific state PDMP, please visit **http://www.pdmpassist.org/content/state-profiles.**

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3 Prescription Drug Monitoring Programs

A Prescription Drug Monitoring Program (PDMP) is a state-administered electronic database that tracks data on controlled prescription drugs dispensed in a state.[1,2] PDMPs are an effective way to identify and prevent drug diversion such as prescription fraud or forgeries, doctor shopping, and improper prescribing and dispensing.[1,2] PDMPs do not interfere with lawful prescribing, dispensing, or procurement of controlled substances.[1] On the contrary, PDMP records provide key real-time data to physicians, pharmacists, third party payers, law enforcement and state agencies to help improve outcomes related to medical care and rates of addiction, overdose, and death.[2,3]

Currently, 49 states have an operating PDMP.[3] Missouri is the only state that has not yet enacted legislation for a PDMP. State boundaries present opportunity for diversion and misuse. Many who obtain prescription drugs illicitly utilize providers in multiple states. Many states are now sharing their data at various levels with other states to allow a more complete view of a patient's controlled substance use.[3]

Benefits of Prescription Drug Monitoring Programs

- PDMP records enable prescribers to survey the movement of controlled substances and change prescribing habits.[2,4]
- Community drug abuse prevention programs can track abuse trends and create targeted interventions.[2]
- PDMP officials can identify geographical areas of high prescription drug abuse, prescribers of controlled substances outside the scope of standard medical practice (pill mills), or patterns suggesting patient "doctor shopping."[2,4]
- Law enforcement agencies can more efficiently investigate drug diversion. This may help lower the costs of investigations, prosecutions and incarcerations.[2]
- States, drug courts and third party payers may reduce the financial burden of drug and medical costs related to inappropriate prescribing, misuse and diversion utilizing PDMP data.[2]

PDMP Enhancements to Encourage Prescriber Utilization

Although a majority of primary care physicians report being aware of a PDMP in their state, prescribers consult PDMP data in less than 25% of instances when they prescribed opioids to patients. Some barriers to PDMP use include the time-consuming nature of registration and information retrieval and poor data format.[4] To encourage utilization, many states are rolling out the following enhancements to PDMPs.

- Making PDMP data real-time and available through electronic health records so clinicians may spend less time checking a patient's PDMP report before prescribing or dispensing controlled substances.[1,3]
- Streamlining the process to register with a PDMP.[4,5]
- Permitting physicians and pharmacists to appoint staff delegates from their practice to access PDMP data to reduce workload and seamlessly integrate into clinical workflow.[1,3-5]
- Mandating prescribers to query the PDMP for patient information triggered by predetermined circumstances, decided by each state (i.e. requirements to access PDMP prior to initially prescribing a schedule II, III or IV controlled substances, in worker's compensation cases, etc.).[1,3-5]
- Distributing unsolicited and solicited reports to inform prescribers, dispensers or law enforcement about patients who may be engaged in doctor shopping or who may be at risk of overdose.[5,6]
- Distributing "prescriber report cards" to physicians that summarize their prescribing patterns in relation to the average data of other prescribers in the same specialty. This allows prescribers the opportunity to self-examine prescribing habits and realize prescription outliers. The intent of the report card is to positively influence controlled substance prescribing patterns and promote following best practice guidelines for their specialty.[6]

3 Prescription Drug Monitoring Programs Continued

Using the Prescription Drug Monitoring Programs to Make Informed Treatment Decisions

The table below outlines some fictional but likely case examples demonstrating how physicians can maximize the utility of a PDMP, pursuant to applicable state guidelines.

Case Examples	
Case 1	**Patient A** is new to your practice. He presents with a medical problem suggesting the need for an opiate prescription. Review of the PDMP database before you prescribe could identify other clinicians that have recently prescribed the same or other opiate prescriptions that were not disclosed by the patient.
Case 2	**Patient B** is an *established* patient. She is known to your practice and has never been suspected of abusing opioids. She is receiving chronic treatment with high doses of opioid analgesics. Regular monitoring of the PDMP for other sources of opioids to calculate the patient's total morphine milligram equivalents (MME) per day is recommended to help assess overdose risk. If warranted, you should discuss the increased risk for respiratory depression, taper or discontinue therapy and/or prescribe naloxone to ensure the patient's safety.
Case 3	**Patient C** is an *established* patient being treated for chronic pain. You suspect the patient is doctor shopping and diverting his opioid prescription instead of taking it. There is a patient contract in place that obliges the patient to take random UDS and not to share or sell his medications. The combination of a negative UDS and review of the PDMP for other sources of opioids could help confirm misuse and identify violations of the contract.
Case 4	**Patient D** is being treated with Suboxone for opiate addiction. Concurrent use of other opioid analgesics would be a violation of the labeled and intended use for Suboxone. PDMP records enable you to track the patient's prescription history and ensure you are the only one prescribing opioid therapy.

- For FAQs and more information about PDMPs in the state(s) in which you practice visit the PDMP Training and Technical Assistance Center website at **http://www.pdmpassist.org**.
- For an annual review of changes made to PDMPs across the country and other relevant information for your practice, visit the National Alliance for Model State Drug Laws website at **http://www.namsdl.org/prescription-monitoring-programs.cfm**.

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3 Prescriber Safeguards Against Drug Diversion

There are a number of practice parameters prescribers can adopt to prevent medication diversion. The table below offers some guidance.

Use available technology[1]

- Prescribe drugs electronically via a certified and secure system, pursuant to applicable state laws. This reduces the potential for phony call-in prescriptions, forged and altered prescriptions, and stolen prescription pads.
- Utilize a PDMP

Use patient medication agreements[2]

A signed informed-consent medication agreement outlines the goals of therapy, overall therapeutic plan, and other conditions for treatment. See the sample pain care agreements in Section 2 of the Toolkit.

Work closely with local pharmacies[2]

- Often it is the pharmacist who first detects a diversion attempt.
- A patient attempting to divert medications may try to call in his or her own prescriptions by claiming to represent a physician's office and providing the patient's personal telephone number for call-back confirmation.
- A close, working relationship between the physician's office and local area pharmacies may help to prevent diversion attempts from succeeding.

Involve your office staff[2]

- Staff members are also important allies in preventing diversion, especially since patients trying to divert medications will likely be on their best behavior when they are in your presence.
- Ask staff members to pay attention to what patients say and how they behave in the office and promptly report any suspicions.

Be aware of diversion tactics[2]

Diverters may:

- Try to steal blank prescription pads or alter physicians' written prescriptions.
- Write their own prescriptions, write new prescriptions for fictitious patients, or photocopy or scan blank prescriptions to have an unlimited supply of prescription forms.
- Remove physicians' writing with solvents and then write new prescriptions.

Monitor all prescription pads[2,3]

- Use tamper-resistant prescription pads with the following features: serial numbers, prescriber information, watermarks, intricate lines, and/or heat- or light-sensitive messages.
- Keep prescription pads in a locked area and minimize the number of pads in use.
- Use prescription pads only for prescriptions. Use other stationary for notes or patient instructions.
- Never sign blank prescriptions in advance.
- Do not leave the refill space blank or fail to circle the number of refills on a prescription.
- Use sequentially numbered prescription pads to help detect missing forms.
- Record the name of the medication, the dose strength, the number of pills dispensed, and the dosing frequency in the patient's chart.
- Contact the nearest DEA field office regarding suspicious prescription activities. To access local field offices, visit http://www.deadiversion.usdoj.gov/offices_n_dirs/fielddiv/index.html.

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3 Recognizing a Patient With a Substance Use Disorder

Diagnostic and Statistical Manual of Mental Disorders (5th ed.)
Opioid Use Disorder Diagnostic Criteria[1]

A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least 2 of the following, occurring within a 12-month period:

- Opioids are often taken in larger amounts or over a longer period than was intended.
- There is persistent desire or unsuccessful efforts to cut down or control opioid use.
- A lot of time is spent in activities necessary to obtain and use the opioid and recover from its effects.
- Craving, or strong desire or urge to use opioids.
- Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
- Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
- Important social, occupational, or recreational activities given up or reduced because of opioid use.
- Recurrent opioid use in situations in which it is physically hazardous.
- Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
- Tolerance,* as defined by either of the following:
  - A need for markedly increased amounts of opioids to achieve intoxication or desired effect.
  - A markedly diminished effect with continued use of the same amount of an opioid.
- Withdrawal,* as manifested by either of the following:
  - The characteristic opioid withdrawal syndrome.
  - Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms.

*This criterion is not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

3 Recognizing a Patient With a Substance Use Disorder Continued

Approaches to Treating a Patient Suspected of Misusing Drugs[2]	
DO	**DON'T**
Perform a thorough exam appropriate to the condition	"Take their word for it" when you are suspicious
Document exam results and questions you asked the patient	
Request identification and social security number; photocopy all documents and include in patient's record	Prescribe, dispense, or administer drugs just to get rid of the patient
Consult a PDMP or call a previous practitioner, pharmacist, or hospital to confirm patient's history and status	Prescribe, dispense, or administer controlled substances outside the scope of your professional practice or in the absence of a formal practitioner-patient relationship
Confirm telephone numbers	
Confirm current address at each visit	
Write prescriptions for limited quantities	

Evidence-Based Treatment Programs

Modes of treatment vary depending on the type of drug addiction and the characteristics of the patient. Seek programs that provide a combination of therapies and services that meet the needs of your patient. Clinicians should also have access to an up-to-date network of behavioral health professionals to ensure seamless transitions in care.

Treatment Facility Locator

For more information on locating physicians and treatment programs authorized to treat opioid addiction and dependence, visit **http://www.samhsa.gov/find-help** on the Substance Abuse and Mental Health Services Administration (SAMHSA) website.

References

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3 Terminology Associated with Chronic Pain Management and Substance Use Disorders

Accurate use of terminology is essential and inconsistent use of language associated with pain management and substance use disorders may result in misunderstandings and stigmas among regulators, health care providers, patients, and the general public.[1,2] However, terminology in these areas are changing.[1,2]

Diagnostic and Statistical Manual of Mental Disorders (5th ed.) Restructuring of Substance Use Disorders to Clarify Terms[1]

In the 5th edition of the *American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders* (DSM-V), substance use disorder is a new overarching category, replacing the old categories of substance abuse and substance dependence. The specific substance is used to define the specific disorder (eg, alcohol use disorder or opioid use disorder). This was done in hopes of reducing misunderstanding regarding certain terms. For example, "dependence" and "addiction" were frequently confused, yet the terms "tolerance" and "withdrawal" that previously defined dependence are actually very normal responses to prescribed medications that affect the central nervous system and do not necessarily indicate the presence of an addiction.

Definitions of Terms Associated with Chronic Pain Management

The APS position statement, *Definitions Related to the Use of Opioids for the Treatment of Pain*, published jointly with the AAPM and the American Society of Addiction Medicine, thoughtfully distinguishes relevant pain management terms.[3] Please check the APS website to ensure you are using the most current definitions.

Definitions of Terms Associated with Chronic Pain Management	
Addiction	A primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include 1 or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.
Physical dependence	A state of adaptation that is manifested by a drug class–specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.
Pseudoaddiction	A term that has been used to describe patient behaviors that may occur when pain is undertreated. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated.
Tolerance	A state of adaptation in which exposure to a drug induces changes that result in a diminution of 1 or more of the drug's effects over time.

Adapted from: *Definitions Related to the Use of Opioids for the Treatment of Pain*[3]

3 Terminology Associated with Chronic Pain Management and Substance Use Disorders Continued

A Guide to the Use of Language Associated with Substance Use Disorders and Treatment

Using the right language with patients with substance use disorders is central to a positive treatment experience. The SAMHSA Center for Substance Abuse Treatment composed a language guide with a list of selected terminology that may be stigmatizing and misinforming. Utilization of the suggested alternative terms can help foster better communication and trust between patient and prescriber. It may also minimize the chance for negative bias that is often associated with substance use disorders and treatment.

Some of the words in the following table, "Words that Work," are a part of regular pain treatment vernacular and are not necessarily considered stigmatizing. However, they can sometimes cause confusion when used in certain contexts. The next table, "Words to Avoid," lists selected terms that are considered stigmatizing or unhelpful and should be replaced with preferred terms when appropriate.[3,4]

Words that Work

Terminology	Why It Works	Caveats
Chronic disease	Identifies a substance use disorder not as an acute condition, but one that requires continued management just as other chronic conditions (eg, heart disease and hypertension).	Some view the term "chronic" as one that justifies failure and presumes a negative end result.
Medication-assisted treatment	Is a practical, accurate, and nonstigmatizing term to describe the path of recovery via medically monitored pharmacological agents (eg, methadone, naltrexone, buprenorphine).	
Misuse	Offers the same intended meaning as "abuse," but without the stigma and judgmental implication.	Some argue that one does not misuse a substance when it is used as intended (eg, marijuana is produced and purchased for the intention of being smoked, so technically it is not misused)."
Relapse	Is a recognized term to describe the recurrence of symptoms and behaviors of substance use disorders following a period of remission.	The term has negative connotations. Some recommend the term recurrence, as is used with other chronic illnesses.

Adapted from: *Substance Use Disorders*[4] *and Language, Substance Use Disorders, and Policy*[5]

3 Terminology Associated with Chronic Pain Management and Substance Use Disorders Continued

Words to Avoid		
Terminology	**Problems With the Terminology**	**Preferred Terminology**
Abuse	Although "abuse" is a clinical diagnosis, it can be stigmatizing because: (1) it negates the fact that addictive disorders are a medical condition; (2) it blames the illness solely on the individual, ignoring environmental, genetic, and chemical factors; (3) it absolves those selling and promoting addictive substances; and (4) it feeds into the stigma experienced by individuals with addictive disorders and their family members and the addiction treatment field.	Misuse, harmful use, inappropriate use, hazardous use, problem use, risky use
Abuser, addict	These terms are demeaning because they label a person by his or her illness, and these labels can imply a permanency to the condition, leaving no room for a change in status. It can also compromise the quality of medical care and may create unintended barriers to self-disclosure and treatment engagement for those with a substance use disorder.	"Person first" language: Person with alcohol/drug disease, person with a substance use disorder, person using for non-medical reasons
Habit, drug habit	Calling a substance use disorder a habit denies the medical nature of the condition and implies that resolution of the problem is simply a matter of willpower.	Substance use disorder, drug disorder, drug disease
Self-help groups	The term is a misnomer because such groups are formed for the express purpose of providing an environment for individuals to support one another.	Recovery support groups, mutual aid groups

Adapted from: *Substance Use Disorders*[4] *and Language, Substance Use Disorders, and Policy*[5]

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Clinical Areas of Focus

Section Four

Section 4 Topics

Adverse Effects and Safety Concerns with Use of Opioid Therapy

Balancing Short-acting and Long-acting Analgesics

Dosing Guidelines with Acetaminophen Therapy

Treatment with Buprenorphine

Challenges with Methadone for Pain Management

Opioid Conversion and Morphine Milligram Equivalents

4 Adverse Effects and Safety Concerns with Use of Opioid Therapy

Adverse Effects[1]

Opioid side effects are well known. With chronic use, many unwanted effects subside.

Constipation	Itching/dry skin	Respiratory depression
Dizziness	Nausea	Sleep apnea
Hormonal effects	Opioid-induced hyperalgesia	Somnolence/sleep disturbances
Impaired cognition	Vomiting	

Opioid-Induced Constipation (OIC)[2,6]

OIC often remains problematic and may require a bowel regimen. Guidelines recommend prophylactic treatment with increased fluid intake, dietary changes, exercise, and over-the-counter stool softeners, and laxatives to be used in patients receiving long-term opioid treatment. Failure of these options to provide relief should be followed with OIC diagnosis using the Bowel Function Index. This tool is a three-question assessment that asks patients to quantify ease of defecation, sense of incomplete bowel evacuation, and personal feelings regarding constipation during the previous week. A score ≥30 would warrant a prescription medication, such as Amitiza® (lubiprostone), Movantik® (naloxegol), or Relistor® (methylnaltrexone), for the treatment of OIC in patients already receiving prophylactic and first-line therapy.

Safety Issues with Meperidine Therapy

Meperidine usage continues to be a health safety issue despite continued warnings on overdose. Normeperidine, the primary active metabolite of meperidine, tends to accumulate with repeated doses or with large quantities of meperidine.[5] Build up of normeperidine can result in anxiety, tremors, myoclonus and generalized seizures. Naloxone does not reverse these adverse effects. Meperidine should not be prescribed for treatment of chronic pain due to the risk of toxicity. The drug should only be reserved for post operative shivering.[6] The American Geriatrics Society recommends that meperidine should be avoided in older adults, and especially in individuals with chronic kidney disease. Common oral dosages of meperidine may confer a higher risk of neurotoxicity, including delirium, compared to other opioids in the elderly. Safer alternatives are available to relieve pain in older adults.[7]

Concurrent Use of Benzodiazepines and Opioids

Clinicians should avoid prescribing opioids and benzodiazepines concurrently whenever possible. The additive effects of respiratory depression and sleep-disordered breathing from concurrent use can increase the risk for overdose. Before prescribing opioids, clinicians should review PDMP data for benzodiazepines the patient might be receiving from other prescribers.[6,8]

Opioid Overdose Reversal

Naloxone, in addition to emergency care, reverses potentially fatal respiratory depression caused by acute opioid toxicity. Naloxone can also be used in opioid overdose situations in pregnant women. With the rise in opioid-related deaths, many stakeholders support expanding laws to ensure ready access to naloxone.[9]

4 Adverse Effects and Safety Concerns with Use of Opioid Therapy Continued

Today, laws allow a patient to obtain naloxone via a prescriber, standing order and in some states, at a pharmacy without a prescription.[9,10] Prescribers are encouraged to provide education on overdose prevention and naloxone use to patients receiving naloxone prescriptions and to members of their households.[8]

Guidelines recommend prescribers provide a prescription for naloxone along with an initial prescription of an opioid pain reliever to patients who are at risk for overdose. Some candidates are those who are using high doses of opioids for long periods of time; have a history of opioid abuse, dependence or overdose; are receiving prescription opioid therapy with concomitant use of alcohol, benzodiazepines, or other sedatives; enrolled in opioid dependence programs; receiving rotating opioid medication regimens; or discharged from emergency medical care following opioid intoxication or poisoning.[8,11,12]

A majority of states now allow for prescription of naloxone products based on a standing order, without a physician examining the individual patient.[9] Many pharmacies, including CVS Health, are also utilizing a standing order with a physician in a state that permits pharmacists to dispense naloxone to patients without an individual prescription.[10] And finally, many states also permit third-party prescriptions that are written for individuals other than the patient so that naloxone can be readily accessed and administered in the event of overdose.[9,11]

Patient Information

Section 5 of the Toolkit contains patient-friendly information about opioid medications and adverse effects.

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4 Balancing Short-acting and Long-acting Analgesics

Opioids may be an appropriate treatment option for some patients with chronic noncancer pain when other therapies have failed. Initial choice of opioids and dosing should be based on therapeutic goals, patient needs, scale of pain perception and intensity, previous exposure to opioids, and any other concomitant illnesses that may perpetuate the pain.[1,2,3]

Opioid Selection for Noncancer Chronic Pain

Short-acting Opioids

Short-acting (SA) opioids are recommended when opioid therapy is being initiated for the first time in opioid naïve patients.[3] They have a shorter half-life and may be associated with a lower risk of inadvertent overdose. For acute pain, prescribe the lowest effective dose of SA opioids at a quantity no greater than needed for the expected duration of pain. Three days or less is recommended; more than 7 days of opioids will rarely be needed.[2] For selected opioids like transmucosal immediate-release fentanyl (TIRF), the risk of serious adverse events, including death, is high as a result of improper patient selection (eg, use in opioid naive patients) and/or improper dosing.[4] TIRF formulations are reserved for the management of breakthrough pain in patients with cancer who have already received and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.[4] Use of TIRF products in any other scenario is not recommended.[4]

Long-acting and Extended-release Opioids

In certain scenarios, the proposed benefits of transitioning from SA to long-acting and extended-release (LA/ER) opioids include more consistent control of pain, improved adherence, and lower risk of addiction or misuse.[1] However, there is a disproportionate number of safety problems associated with the improper use of LA/ER products, including overdose and death.[6] Additionally, there is no evidence that initiating treatment with LA/ER opioids is more effective than SA opioids for the relief of chronic noncancer pain. Consequently, LA/ER opioids should not be used for as needed pain relief and should be prudently used for chronic pain.[2,3]

Concurrent Use of LA/ER and SA Opioids

For those with cancer pain, a long-acting opioid is recommended to cover around-the-clock pain, and the short-acting medication is used for breakthrough pain.[3,7] However, patients with chronic **noncancer** pain present with longer lasting flares which are not analogous to cancer breakthrough pain. Because of the disparity in presentation of breakthrough pain, using the cancer pain strategy of combining a LA/ER opioid with a SA opioid is not preferred and may result in unnecessary adverse events.[3]

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4 Dosing Guidelines with Acetaminophen Therapy

Acetaminophen-Induced Hepatotoxicity

Liver injury resulting from chronic use and/or high daily doses of acetaminophen is a serious concern. The effects of liver damage may range from feeling nauseous or ill to permanent liver damage and possibly death.[1] In a study of patients who suffered acute liver failure after unintentional acetaminophen overdose, 63% had been using a combination prescription opioid-acetaminophen medication and 38% took two or more acetaminophen products simultaneously.[2] Another study confirmed elevations in liver enzymes in patients using 4,000 mg of acetaminophen per day for up to 14 days.[3] Given the research on dosing behaviors, safety and risk factors associated with exceeding certain acetaminophen thresholds, the FDA recommends the maximum daily safe dosage of acetaminophen to be ≤ 4,000 mg in a 24-hour period.[1] The American Liver Foundation states that short-term use (≤ 14 days) of 4,000 mg per day is acceptable but that patient dosage should not exceed 3,000 mg of acetaminophen per day for any **prolonged period of tim**e. Additionally, acetaminophen may be considered a first-line medication in patients with liver disease not actively drinking alcohol as long as the dose is reduced to 2,000-3,000 mg per day for long-term use.[4]

The FDA and manufacturers of prescription and over-the-counter (OTC) acetaminophen have taken various actions to increase patient safety.[1]

- Manufacturers of prescription combination products with acetaminophen have limited the amount of acetaminophen to no more than 325 mg in each tablet, capsule, or other dosage unit. OTC acetaminophen products are **not** affected by the 325 mg limit.[5]
- Some manufacturers have voluntarily reduced the recommended maximum daily dosage for certain OTC acetaminophen products from 4,000 mg to 3,000 mg.[6]
- FDA has required all manufacturers of OTC acetaminophen products to use revised labeling language that informs consumers about the risk of liver injury when using acetaminophen.[6] Manufacturers can label the risk as either a maximum daily dosage of 4,000 mg in a 24-hour period or specify the daily maximum number of tablets or dosage units for the product.[7]
- Most manufacturers have also removed the "APAP" abbreviation for acetaminophen from their products and instead use the full spelling of acetaminophen. This was done to help reduce the potential for confusion caused by the use of abbreviations.[1]

What This Means to You

- When prescribing combination products containing acetaminophen, take into account the total daily dosage of acetaminophen the patient may be receiving from other medications (prescription or OTC) that contain acetaminophen. Educate patients about the importance of reading all medication labels to ensure they are not taking multiple acetaminophen-containing products.[1]
- Talk to patients about taking too much acetaminophen at one time and taking the next dose too soon if they are struggling to manage their pain.[1] For those taking a combination prescription product, you can remind them that there are no data that indicate that taking a medicine with more than 325 mg of acetaminophen per dosage unit provides more pain relief.[5]

4 Dosing Guidelines with Acetaminophen Therapy Continued

What This Means to You Continued

- Use the word "acetaminophen" instead of "APAP" when counseling patients. This will help ensure that patients understand what they are taking when reading labels on acetaminophen products.[1]
- Advise patients not to drink alcohol while taking acetaminophen-containing medications.[1,4]

Patient Information

Section 5 of the Toolkit contains patient-friendly information about acetaminophen and its proper use.

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4 Treatment with Buprenorphine

Buprenorphine for the Treatment of Opioid Use Disorder

Buprenorphine partially blocks the mu-opioid receptor thus limiting the effects of subsequently administered opioid agonists or antagonists.[1,2] The drug's "ceiling effect" appears to confer a higher safety profile and milder withdrawal symptoms after long-term administration compared to full opioid agonists. The addition of naloxone to buprenorphine serves as a deterrent to injection misuse while maintaining buprenorphine efficacy when taken sublingually. For this reason, a buprenorphine-naloxone combination product is preferred for most patients for whom current guidelines recommend use of the monoproduct.[1,2]

Several buprenorphine-containing products are on the market and considered equivalent with respect to safety and efficacy.[1] Prescribers should consider cost and formulation appropriateness for an individual patient.[1] Transdermal and buccal formulations of buprenorphine are indicated for the treatment of pain severe enough to require daily, around-the-clock therapy and are not appropriate for the treatment of opioid dependence.[5,6]

If a prescriber is unable to provide treatment themselves, arrangements should be made for the patient to receive care from a substance use disorder treatment specialist or SAMSHA-certified opioid treatment program.[3] For pregnant women with opioid use disorder, medication-assisted treatment with buprenorphine monoproduct or methadone has been associated with improved maternal outcomes.[3]

Drug Addiction Treatment Act of 2000[1]

DATA 2000 legislation permits qualified physicians to receive a waiver from the Controlled Substances Act registration requirements and prescribe and dispense FDA-approved Schedule III, IV, or V narcotic medications for the treatment of opioid dependence in office-based settings. Physicians must meet certain requirements detailed in the DATA 2000 as well as obtain a waiver from SAMHSA. If approved, a special DEA identification will be issued.

For additional details, please refer to SAMHSA's Buprenorphine Waiver Management Web page (**http://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management**).

Treatment of Pain in Patients Receiving Buprenorphine

Combining buprenorphine with other opioids for the treatment of pain is considered inappropriate; there is limited evidence demonstrating efficacy and patient safety concerns are real.[2] Because buprenorphine blocks the analgesic effect of subsequently administered opioids in a dose-responsive manner, achieving adequate analgesia with full opioid agonists can be challenging. Patients are at an increased risk of respiratory depression and death when buprenorphine is combined with other central nervous system (CNS) depressants, including full opioids.[2]

4 Treatment with Buprenorphine Continued

The SAMHSA Treatment Recommendations for Patients Receiving Buprenorphine for Opioid Dependence

Treatment of Acute Pain[2]	• Initiate therapy with a nonopioid analgesic, if not contraindicated. • If nonopioid analgesics fail, employ usual and aggressive pain management, which may include use of single-agent, short-acting opioid analgesics. • Buprenorphine should generally be discontinued when opioid therapy is added. • Larger-than-normal doses of opioids may be needed until buprenorphine is cleared from the body. Titrate doses as appropriate.

Treatment of Chronic Pain	• Discontinue buprenorphine in patients who require end-of-life opioid analgesia unless buprenorphine provides adequate relief.[2] • Use nonopioid analgesics, adjuvant medications, and nonpharmacologic therapy as appropriate for pathophysiology.[4] • Treat psychiatric comorbidities.[4] • Initiate opioid therapy with extreme caution if the potential benefits outweigh risk. Monitor for benefit and discontinue as soon as possible.[4] • Scheduled, around-the-clock methadone, or another long-acting full opioid, may be considered for patients with severe chronic pain and who are opioid addicted.[2]

Risk Evaluation and Mitigation Strategies (REMS) for Buprenorphine Containing Products

The FDA has instituted REMS for many buprenorphine containing products to help ensure benefits of medication use outweigh risks associated with the products.

Please refer to the following website to determine if a particular product is subject to REMS.
http://www.accessdata.fda.gov/scripts/cder/rems/

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4 Challenges with Methadone for Pain Management

Methadone is still one of the top three most common drugs involved in prescription opioid overdose deaths.[1] A disproportionate number of deaths are reported relative to the frequency with which methadone is prescribed for pain.[2] Consequently, methadone should be prescribed cautiously and by clinicians familiar with its use and risks. Several guidelines are available that discuss key steps to ensure safe use of methadone for both treatment of chronic pain and addiction.

- Methadone for Pain Management: Improving Clinical Decision Making. Recommended Prescriber Practices from the American Academy of Pain Medicine[3]
- Federal Guidelines for Opioid Treatment Programs from SAMHSA[4]
- Methadone Safety: A Clinical Practice Guideline from the American Pain Society and College on Problems of Drug Dependence, in Collaboration With the Heart Rhythm Society[5]

FDA approved indications of methadone are:[6]

- Management of pain severe enough to require daily, around-the clock, long-term opioid treatment and for which alternative treatment options are inadequate or not tolerated.
  - Methadone is NOT indicated as an as-needed analgesic
- Detoxification treatment of opioid addiction (heroin or other morphine-like drugs)
- Maintenance treatment of opioid addiction (heroin or morphine-like drugs) in conjunction with appropriate social and medical services

Boxed Warnings[6]: See full prescribing information for complete boxed warning

Addiction, Abuse, and Misuse
Methadone exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk before prescribing, and monitor regularly for development of these behaviors or conditions.

Life-Threatening Respiratory Depression
Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase.

Life-Threatening QT Prolongation
QT interval prolongation and serious arrhythmia (torsades de pointes) have occurred during treatment with methadone. Closely monitor for changes in cardiac rhythm during initiation and titration.

Accidental Ingestion
Accidental ingestion of methadone, especially in children, can result in fatal overdose of methadone.

Neonatal Opioid Withdrawal Syndrome (NOWS)
Prolonged use of methadone during pregnancy can result in NOWS, which may be life-threatening if not recognized and treated. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of NOWS and ensure that appropriate treatment will be available.

Conditions For Distribution and Use of Methadone Products For the Treatment of Opioid Addiction
For detoxification and maintenance of opioid dependence, methadone should be administered in accordance with the treatment standards cited in 42 CFR Section 8, including limitations on unsupervised administration.

4 Challenges with Methadone for Pain Management Continued

Pharmacokinetics

Methadone should not be the first choice for an LA/ER opioid. Only clinicians who are familiar with the drug's unique risk profile should consider prescribing methadone for pain.[2] The pharmacokinetic profile of methadone include high interpatient variability in absorption, metabolism, and relative analgesic potency. Methadone also has a narrow therapeutic index, especially when combined with other drugs. Therefore, extreme caution and a highly individualized approach are required when prescribing the drug.[6]

- Steady-state plasma concentrations and full analgesic effect are usually not attained until 3 to 5 days of dosing, and may take longer in some patients.
- The duration of analgesic activity of methadone typically lasts 4 to 8 hours, but the plasma elimination half-life is 8 to 59 hours.
- With repeated dosing, methadone may be retained in the liver and slowly released. This can prolong the duration of methadone action and potential toxicity.
- The peak respiratory depressant effect of methadone occurs later and persists longer than its peak therapeutic effect.

Treatment of Pain[6]

- When selecting an initial dose of methadone, attention should be given to
  - The total daily dosage, potency, and special characteristics of the opioid the patient had been taking previously, if any.
  - The relative potency estimate used to calculate an equianalgesic starting methadone dosage; in particular, whether it is intended for use in acute or chronic methadone dosing.
  - The patient's degree of opioid tolerance.
    - The age, general condition, and medical status of the patient
    - Concurrent medications, particularly other CNS and respiratory depressants
    - The type, severity, and expected duration of the patient's pain
    - The acceptable balance between pain control and adverse side effects
- Always round the dose down, if necessary, to the appropriate methadone strength(s) available.
- Published equianalgesic conversion ratios between methadone and other opioids are imprecise. Many commonly cited equianalgesia tables greatly underestimate the analgesic potency of methadone and its potential for adverse effects in repeated-dose settings.
- Methadone is most safely initiated and titrated using small initial doses and gradual dose adjustments. For breakthrough pain, provide an immediate-release opioid rescue medication. With repeated dosing, the potency of methadone will eventually increase due to systemic accumulation. Monitor for sedation.

4 Challenges with Methadone for Pain Management Continued

Morphine to Methadone Conversion for Chronic Administration[a]	
Total Daily Baseline **ORAL MORPHINE** Equivalent Dose (mg)	Estimated Daily **ORAL METHADONE** Requirement as a Percentage of Total Daily Morphine Equivalent Dose (%)
<100	20–30
100–300	10–20
300–600	8–12
600–1,000	5–10
>1,000	<5

a This is not a table of equianalgesic doses. Equianalgesic dosing conversions to methadone show large inter- and intrapatient variability, depending on baseline morphine dose; therefore, methadone dosing should not be solely based on this information. Methadone conversion and dose titration methods should be individualized after considering the patient's prior opioid exposure, general medical condition, concomitant medication(s), and anticipated breakthrough pain medication use. This table cannot be used to convert from methadone to another opioid.

Adapted from: Dolophine® (methadone hydrochloride) tablets [package insert].[6]

Additional Patient Resources

Public education material, called *Follow Directions: How to Use Methadone Safely*, has been developed jointly by SAMHSA, Center for Substance Abuse Treatment, and the FDA. Clinicians can use this document to educate and counsel patients prior to the first prescription of methadone and regularly during treatment. The publication is available at **http://store.samhsa.gov/shin/content//SMA09-4409/SMA09-4409.pdf.**

References

1. Centers for Disease Control and Prevention. Prescription Opioid Overdose Data. Updated: June 21, 2016. http://www.cdc.gov/drugoverdose/data/overdose.html. Accessed June 28, 2016.
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5. Chou R, Cruciani RA, Fiellin DA, et al. Methadone Safety: A Clinical Practice Guideline from the American Pain Society and College on Problems of Drug Dependence, in Collaboration With the Heart Rhythm Society. *J Pain*. 2014 Apr;15(4):321-37.
6. Dolophine® (methadone hydrochloride) tablets [package insert]. Columbus, OH: Roxane Laboratories; May 2016.

4 Opioid Conversion and Morphine Milligram Equivalents

Opioid Rotation and Conversion Risks

The 2016 CDC Guideline found no studies evaluating opioid rotation versus maintenance of current therapy on pain, function, quality of life or abuse-related outcomes.[1] Additionally, an increasing body of literature suggests that opioid rotation practices, including the use of dose conversion ratios found in equianalgesic tables, may be an important contributor to increased opioid-related mortality.[2]

Equianalgesic conversion tables and procedures for conversion vary among publications.[2] Dose conversion guidelines in medication prescribing information are also inconsistent. These guides often are based on studies that used single dose or a relatively limited range of doses of a specific route and therefore may not be applicable to chronic dosing or other routes of administration. Finally, there is great variability in how individual patients respond to opioid therapy and incomplete cross-tolerance. Thus opioid rotation and switching should be approached with extreme caution.[2]

Morphine Milligram Equivalents

Calculating the total daily dose of opioids may help identify patients for whom close monitoring, tapering of opioids, prescribing of naloxone, or other measures to reduce risk of overdose may be of benefit.[1,3] For patients taking more than one opioid product, the total daily dose of each opioid must be determined, then converted into MME by multiplying by conversion factors; the individual MMEs can then be summed.[3] The 2016 CDC Guideline suggests using extra precaution when increasing patients' opioid regimen above 50 MME/day and avoiding or carefully justifying the use of more than 90 MME/day.[1,3] The state of Washington spearheaded this movement with the publication of *Interagency Guideline on Opioid Dosing for Chronic Noncancer Pain*.[4] This guideline recommends not prescribing average daily morphine equivalent doses greater than 120 mg unless the patient has demonstrated an improvement in function or pain or the prescriber has obtained a consultation from a pain management expert. The 2015 *Interagency Guideline* maintains these recommendations though acknowledged some guidelines have lower dose thresholds.[4]

MMEs are NOT intended to determine dosage for directly converting one opioid to another.[1] Conversion factors should be used as a general guide; dosage of the new opioid should be lowered to avoid unintentional overdose.[1]

Safely Transitioning From One Opioid to Another

As a prescriber, it is important that you are aware of the different procedures for safely transitioning a patient from one opioid to another. We encourage you to continuously educate yourself in this area as well as follow the recommendations of your practice site.

References

7. Centers for Disease Control and Prevention. Prescription Opioid Overdose Data. Updated: June 21, 2016. http://www.cdc.gov/drugoverdose/7. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016. MMWR Recomm Rep. 2016 Mar 18. 65 (1):1-49.

8. Webster LR, Fine PG. Review and critique of opioid rotation practices and associated risks of toxicity. *Pain Med*. 2012 Apr;13(4):562-570.

9. Calculating Total Daily Dose of Opioids for Safer Dosage. Atlanta, GA: Centers for Disease Control and Prevention; 2016. http://www.cdc.gov/drugoverdose/prescribing/resources.html. Accessed July 22, 2016.

10. Washington State Agency Medical Directors' Group. Interagency guideline on opioid dosing for chronic non-cancer pain: an educational aid to improve care and safety with opioid treatment. Olympia (WA): Washington State Department of Labor and Industries; 2015. http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf. Accessed July 28, 2016.

Patient Handouts

Section Five

Section 5 Topics

The tools in this section are intended to assist your patients with the day-to-day management of their chronic pain. Please feel free to copy these materials and share them with your patients as you deem appropriate.

Questions and Answers: Opioid Pain Medicines

Questions and Answers: Acetaminophen and Your Liver

Pain Medicine Safety

Daily Pain Diary

5 Questions and Answers: Opioid Pain Medicines

Q:	A:
What are opioid pain medicines?	Opioid pain medicines, or simply opioids, have been used for hundreds of years to relieve pain. The term opioid comes from opium, which is an extract from the poppy plant. Opioids are sometimes called narcotics. There are many prescription opioids available. They are used to treat moderate-to-severe pain. How quickly they start to relieve pain and for how long they relieve it are different for each one. Opioids are available as both short-acting and long-acting medicines. Some opioids are used around the clock, while others are used as needed only when you feel pain (breakthrough pain).
Is it true that I will become addicted to opioid pain medicine?	Many patients fear becoming addicted to opioids. Addiction and physical dependence are not the same. Any person who takes enough doses of certain drugs (such as opioids) for a certain length of time can have withdrawal symptoms if the drug is stopped. This can mean physical dependence, but does not mean addiction. Addiction is the unstoppable craving for, the loss of control over the use of, and the compulsive and continued use of a drug, despite its harm. The risk of addiction is not just because of the properties of the opioid. It is also because of the hereditary, psychological, and situational factors of the person taking the opioid. Opioid Use Disorder is another term a health care provider may use for addiction. Most people will not become addicted to their prescribed pain medicine. That said, opioids still should only be taken for the time that they are needed and at the lowest dose needed.
What if my opioid medicine is not working?	Talk to your health care provider if you are not getting pain relief from your opioid, or if you have signs or symptoms that are unpleasant to you. There are many different opioids available. You may need to try several to find the right one for you.
What else should I know about taking opioids?	• Make sure you understand exactly how you are supposed to take your medicine. • Call your health care provider before you take your opioid in greater amounts or more often than it was prescribed. • Keep your opioid medicine in a safe place. Safely dispose of unused medicine. • Tell all your health care providers that you are taking an opioid. • Do not drink alcohol while you are taking opioids. • Tell all your health care providers about all the medicines and supplements you take.

5 Questions and Answers: Opioid Pain Medicines Continued

What are the most common side effects of opioids?

The most common side effects of opioid therapy are constipation, drowsiness, nausea, vomiting, and itching. Most of these side effects will go away with time, but some will not. Listed below are some possible side effects of an opioid and tips on how to manage them.

Constipation	• Constipation means having hard or dry bowel movements. • For almost everyone taking opioids, constipation is one side effect that will not go away. • Ask your health care provider which laxative or stool softener may help you. These products are available at most drug and grocery stores. • You may also want to make changes in your diet to help you have normal bowel movements while you are taking opioids: - Eat more fiber (dried and raw fruits, raw vegetables, whole-grain bread and cereals). - Drink plenty of liquids, such as water and juices, if you are not on a diet that restricts liquids. • If you still have constipation after changing your diet and trying over-the-counter medicines, tell your health care provider. You may need to take a prescription medicine to get relief.
Drowsiness	• It is common to be drowsy for the first few days after starting an opioid, or after a dose is increased. Do not drive or operate machinery as long as you are drowsy from opioids. Drowsiness often goes away after 2 to 3 days.
Nausea and Vomiting	• Nausea and vomiting are very common early side effects from taking opioids. You may need to take another medicine to help you control nausea. • If you are very nauseated, you can try drinking only clear liquids, such as water or weak tea.
Itching	• Sometimes using a mild anti-itch medicine will do the trick, and the itching will stop. • Other times, the anti-itch medicine does not stop the itching, and your health care provider may change the opioid you are using to one that may not cause itching. • It is important to keep track of the opioids you have used that made you itch, so your health care provider will not prescribe them again.
Dry Mouth	• You can help dry mouth by drinking plenty of fluids. Also, eating pineapple chunks, popsicles, shakes, yogurt, or sugarless gum may help you keep your mouth moist. • Take care of your teeth and gums. Mouth dryness will affect your tongue, teeth, and gums. Brush your teeth regularly, and rinse your mouth often.

5 Questions and Answers: Acetaminophen and Your Liver

Q:	A:
What is acetaminophen?	Acetaminophen is the active ingredient found in Tylenol®. It is a medicine used to treat fever and pain. Acetaminophen is found in hundreds of prescription and over-the-counter (OTC) products, either alone or combined with other medicines.
When can acetaminophen hurt you?	Acetaminophen is safe when you take only the amount you have been told to take and for only the amount of time you have been advised to take it. Using too much acetaminophen can cause liver damage. Drinking alcohol while using acetaminophen can also hurt your liver. The effects of liver damage may range from feeling nauseous or ill to permanent liver damage and possibly death.
How much acetaminophen is okay for you to take?	The US Food and Drug Administration (FDA) recommends taking less than 4,000 milligrams (mg) per day if you use acetaminophen regularly.[1] Talk to your doctor or pharmacist if you have any questions.
What steps can you take to use acetaminophen safely?	1. Follow the directions exactly as they are explained. Make sure you understand how much acetaminophen you can take at each dose, how often to take it, and when to stop. 2. Remember, if you take acetaminophen regularly, do so under the care of your doctor. If you are using OTC acetaminophen for just a couple of days, carefully read and follow the directions on the medicine label. 3. Take only one medicine at a time that has acetaminophen in it. Read all ingredients on your prescription and OTC medicines. Talk to your doctor or pharmacist about which of your medicines have acetaminophen in them and how much is in each dose. 4. Avoid taking the next acetaminophen dose too soon if you are struggling to manage your pain. Instead, talk to your doctor about changing your treatment routine to get more pain relief. 5. Do not drink alcohol while taking acetaminophen.
What should you do if you think you have taken more acetaminophen than directed?	In case of overdose, you should call 911 for medical help right away or contact the Poison Control Center at **1-800-222-1222.**

5 Pain Medicine Safety

You are responsible for taking steps to protect the children and others in your home.

- ☐ Keep all pain medicines locked in a safe place at all times.
- ☐ Make sure only those people who are allowed to open the lock to the medicine can do so.
- ☐ Keep track of every dose you take and how many doses are left in the container each time.
- ☐ Never share your pain medicine.

You are responsible for taking steps to protect yourself.

- ☐ Only take pain medicine that is prescribed for you, exactly as your doctor told you. Never change the amount you take or how often you take it without first talking with your doctor.
- ☐ Keep a list of all medicines you take, including over-the-counter medicines (OTC). Share this list with your doctor and pharmacist. They can make sure all your medicines can be taken together safely.
- ☐ Never take sleep or anti-anxiety medicine while you are taking pain medicine. Ask your doctor or pharmacist if you are not sure if you take these medicines.
- ☐ Never drink alcohol while you are taking pain medicine.
- ☐ Take a Urine Drug Screen (UDS) if your doctor asks you. An UDS is a tool many doctors use with all of their patients who take opioid pain medicines. This tool may help your doctor choose the right amount of the right pain medicine for you and help prevent a drug overdose.

You are responsible for safely throwing out all unused medicine.

- ☐ **Check the papers that came with your medicine**—Follow the directions on how to throw away your medicine exactly. Ask your pharmacist if you have any questions.
- ☐ **Use a medicine take-back program**—Ask your pharmacist or your trash and recycling service if there is a medicine take-back program in your community. A take-back program collects the medicine and takes care of throwing it away safely.
- ☐ **Safely throw out your medicine in the household trash**
  1. Take the medicine out of the bottle or package. Do NOT crush tablets or capsules. Mix the medicine with something that no one would eat or want to touch such as kitty litter or used coffee grounds.
  2. Place the mixture in a plastic bag or other container that you can close up tightly and won't leak.
  3. Throw the closed-up container in your household trash.
  4. Before throwing out your empty pill bottle or other empty medicine package, scratch out all information on the prescription label so no one can read it.
- ☐ **Only flush certain medicines**—Do not flush your old medicine down the sink or toilet unless you are supposed to. There are only a few very harmful medicines that should be flushed as soon as they are no longer needed and when they cannot be given to a medicine take-back program.

  Visit **http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/** for a list of medicines that should be flushed when they are no longer needed.

5 Daily Pain Diary

Use this diary to record details about your pain, including how you treated it and if the treatment worked. This will help you keep track of what works and what doesn't. Show this to your doctor at your next appointment. It will help your doctor better understand your pain level and what you're doing about it. Use this scale to rate the severity of your pain.

Pain Diary for the week of:

0	1	2	3	4	5	6	7	8	9	10
0=No pain		1 to 3=Mild pain		4 to 5=Moderate pain		6 to 8=Severe pain			9 to 10=Worst possible pain	

Day	Time of day	Where is the pain on your body? How does it feel (sharp, dull, burning)?	Rate the pain (0 to 10) and describe it.	What were you doing when the pain started or increased?	Did you take pain medicine or supplements? What did you take and how much?	What other therapies have you tried (heat, ice, rest, etc.)?	One hour after taking the medicine, rate the pain.	Additional comments	Overall, how was your pain today?
SUN									
MON									
TUE									
WED									
THU									
FRI									
SAT									

Adapted from: Daily Pain Diary. American Cancer Society website. http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-033203.pdf. Accessed September 15, 2016.

Additional Information

Section Six

Section 6 Topics

Abbreviations and Acronyms

Physician Response Form

Personal Notes

6 Abbreviations and Acronyms

AAPM	American Academy of Pain Medicine
APAP	Acetaminophen
APS	American Pain Society
ASIPP	American Society of Interventional Pain Physicians
CAGE	Cut-down, annoyed, guilt, eye-opener
CAGE-AID	CAGE adapted to include drugs
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
CNS	Central nervous system
COMM	Current opioid misuse measure
CT	Computed tomography
DATA 2000	Drug Addiction Treatment Act of 2000
DSM-V	The 5th edition of the *American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders*
ER	Extended release
FDA	US Food and Drug Administration
GC-MS	Gas chromatography/mass spectrometry
IR	Immediate release
LA	Long acting
MED	Morphine equivalent dose
MME	Morphine milligram equivalents
MRI	Magnetic resonance imaging
NDEWS	National Drug Early Warning System
NOWS	Neonatal opioid withdrawal syndrome
OIC	Opioid Induced Constipation

6 Abbreviations and Acronyms Continued

ORT	Opioid Risk Tool
OTC	Over the counter
PADT	Pain Assessment and Document Tool
OUD	Opioid Use Disorder
PDMP	Prescription Drug Monitoring Program
PDQ	Physician Data Query—National Cancer Institute's Comprehensive Cancer Database
PMQ	Pain Medication Questionnaire
PQA	Pharmacy Quality Alliance
REMS	Risk Evaluation and Mitigation Strategies
SAMHSA	Substance Abuse and Mental Health Services Administration
SOAPP-R	Screener and Opioid Assessment for Patients in Pain–Revised
STAR	Screening Tool for Addiction Risk
TIRF	Transmucosal immediate–release fentanyl
UDS	Urine drug screen
VA/DoD	Department of Veterans Affairs and Department of Defense

6 Physician Response Form

Please take a few moments to answer the following questions. This information will help us with future communications to you. For each statement, please check only one answer.

Please fax this completed survey to 1-866-249-6157.

1. These sections of the Opioid Prescriber Toolkit were useful:			
General Opioid Prescribing Principles and Pain Guidelines	☐ Agree	☐ Neutral	☐ Disagree
Physician Tools for the Day-to-Day Management of Patients with Chronic Pain	☐ Agree	☐ Neutral	☐ Disagree
Preventing Drug Misuse and Diversion	☐ Agree	☐ Neutral	☐ Disagree
Clinical Areas of Focus	☐ Agree	☐ Neutral	☐ Disagree
Patient Handouts	☐ Agree	☐ Neutral	☐ Disagree
2. When dealing with patient cases complicated by the use of controlled substances, what do you find most challenging?			
3. What can we change or add to the Opioid Prescriber Toolkit to make it more useful to you?			
4. Is there anything further we can do to help you address issues of controlled substance fraud, waste, and misuse?			
5. Please comment on the overall usefulness of the Opioid Prescriber Toolkit.			

Physician Name .....

Office Address .....

City ..... State..... Zip.....

Specialty..... Phone.....

Office Email.....

6 Personal Notes

Opioid Prescriber Toolkit

CVS caremark™

Exhibit 4

64B8-9.013 Standards for the Use of Controlled Substances for the Treatment of Pain.

(1) Pain management principles.

(a) The Board of Medicine recognizes that principles of quality medical practice dictate that the people of the State of Florida have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

(b) Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agencies for prescribing, dispensing, or administering controlled substances including opioid analgesics, for a legitimate medical purpose and that is supported by appropriate documentation establishing a valid medical need and treatment plan. Accordingly, these standards have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

(c) The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The medical management of pain including intractable pain should be based on current knowledge and research and includes the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

(d) The Board of Medicine is obligated under the laws of the State of Florida to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

(e) The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

(f) Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these standards, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs including any improvement in functioning, and recognizing that some types of pain cannot be completely relieved.

(g) The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors. The following standards are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

(2) Definitions.

(a) Acute Pain. For the purpose of this rule, "acute pain" is defined as the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma, and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

(b) Addiction. For the purpose of this rule, "addiction" is defined as a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

(c) Analgesic Tolerance. For the purpose of this rule, "analgesic tolerance" is defined as the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

(d) Chronic Pain. For the purpose of this rule, "chronic pain" is defined as a pain state which is persistent.

(e) Pain. For the purpose of this rule, "pain" is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

(f) Physical Dependence. For the purpose of this rule, "physical dependence" on a controlled substance is defined as a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

(g) Pseudoaddiction. For the purpose of this rule, "pseudoaddiction" is defined as a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

(h) Substance Abuse. For the purpose of this rule, "substance abuse" is defined as the use of any substances for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

(i) Tolerance. For the purpose of this rule, "tolerance" is defined as a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

(3) Standards. The Board has adopted the following standards for the use of controlled substances for pain control:

(a) Evaluation of the Patient. A complete medical history and physical examination must be conducted and documented in the medical record. The medical record shall document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also shall document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy, if necessary, to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(c) Informed Consent and Agreement for Treatment. The physician shall discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient shall receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician shall employ the use of a written agreement between physician and patient outlining patient responsibilities, including, but not limited to:

1. Urine/serum medication levels screening when requested,
2. Number and frequency of all prescription refills; and,
3. Reasons for which drug therapy may be discontinued (i.e., violation of agreement).

(d) Periodic Review. Based on the individual circumstances of the patient, the physician shall review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage and related treatment plans.

(e) Consultation. The physician shall be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention must be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.

(f) Medical Records. The physician is required to keep accurate and complete records to include, but not be limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence, as appropriate,
2. Diagnostic, therapeutic, and laboratory results,
3. Evaluations and consultations,

4. Treatment objectives,

5. Tiscussion of risks and benefits,

6. Treatments,

7. Medications (including date, type, dosage, and quantity prescribed),

8. Instructions and agreements,

9. Drug testing results; and,

10. Periodic reviews. Records must remain current, maintained in an accessible manner, readily available for review, and must be in full compliance with Rule 64B8-9.003, F.A.C, and Section 458.331(1)(m), F.S.

Records must remain current and be maintained in an accessible manner and readily available for review.

(g) Compliance with Controlled Substances Laws and Regulations. To prescribe, dispense, or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual: An Informational Outline of the Controlled Substances Act of 1970, published by the U.S. Drug Enforcement Agency, for specific rules governing controlled substances as well as applicable state regulations.

Rulemaking Authority 458.309(1), 458.331(1)(v) FS. Law Implemented 458.326, 458.331(1)(g), (t), (v) FS. History–New 12-21-99, Amended 11-10-02, 10-19-03, 10-17-10.

Exhibit 5

64B8-9.013 Standards for the Prescribing of Controlled Substances for the Treatment of Acute Pain.

The standards of practice in this rule do not supersede the level of care, skill and treatment recognized in general law related to healthcare licensure. All physicians and physician assistants who are authorized to prescribe controlled substances shall comply with the following:

(1) Definitions.

(a) Acute Pain. For the purpose of this rule, "acute pain" is defined as the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness. The term does not include pain related to:

1. Cancer.

2. A terminal condition. For purposes of this subparagraph, the term "terminal condition" means a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered to be reversible without the administration of life-sustaining procedures, and will result in death within 1 year after diagnosis if the condition runs its normal course.

3. Palliative care to provide relief of symptoms related to an incurable, progressive illness or injury.

4. A traumatic injury with an Injury Severity Score of 9 or greater.

(b) Prescription Drug Monitoring Program (PDMP) or "the system." For the purpose of this rule, the prescription drug monitoring system is defined as the Florida Department of Health's electronic system to collect and store controlled substance dispensing information as set forth in section 893.055, F.S.

(c) Substance Abuse. For the purpose of this rule, "substance abuse" is defined as the use of any substances for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

(2) Standards. The nature and extent of the requirements set forth below will vary depending on the practice setting and circumstances presented to the clinician. The Board has adopted the following standards for the prescribing of controlled substances for acute pain:

(a) Evaluation of the Patient. A medical history and physical examination appropriate for the patient's clinical condition must be conducted and documented in the medical record. The medical record also shall document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written treatment plan shall indicate if any further diagnostic evaluations or other treatments are planned including non-opioid medications and therapies if indicated. After treatment begins, the physician shall adjust medication therapy, if necessary, to the individual medical needs of each patient.

(c) Informed Consent and Agreement for Treatment. The physician shall discuss the risks and benefits of the use of controlled substances including the risk of abuse and addiction as well as physical dependence with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The discussion shall also include expected pain intensity, duration, options, use of pain medications, non-medication therapies, and common side effects. Special attention must be given to those pain patients who are at risk of misuse or diversion of their medications.

(d) Periodic Review. Based on the circumstances presented, the physician shall review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not achieved, despite medication adjustments, the physician shall reevaluate the patient and determine the appropriateness of continued treatment. The physician shall monitor patient compliance of medication usage and related treatment plans.

(e) Consultation. The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.

(f) Medical Records. The physician is required to keep accurate and complete records to include, but not be limited to:

1. The medical history and a physical examination, including history of drug abuse or dependence, if indicated;

2. Diagnostic, therapeutic, and laboratory results;

3. Evaluations and consultations;

4. Treatment objectives;

5. Discussion of risks and benefits;

6. Treatments;

7. Medications (including date, type, dosage, and quantity prescribed);

8. Instructions and agreements;

9. Drug testing results if indicated;

10. Justification for deviation from the 3-day prescription supply limit for a Schedule II opioid controlled substance for acute pain;

11. Outline of problems encountered when attempting to consult the Prescription Drug Monitoring Program (PDMP) or its successor, if the system was non-operational or the clinician, or his or her designee, is unable to access the PDMP due to a temporary technological or electrical failure; and

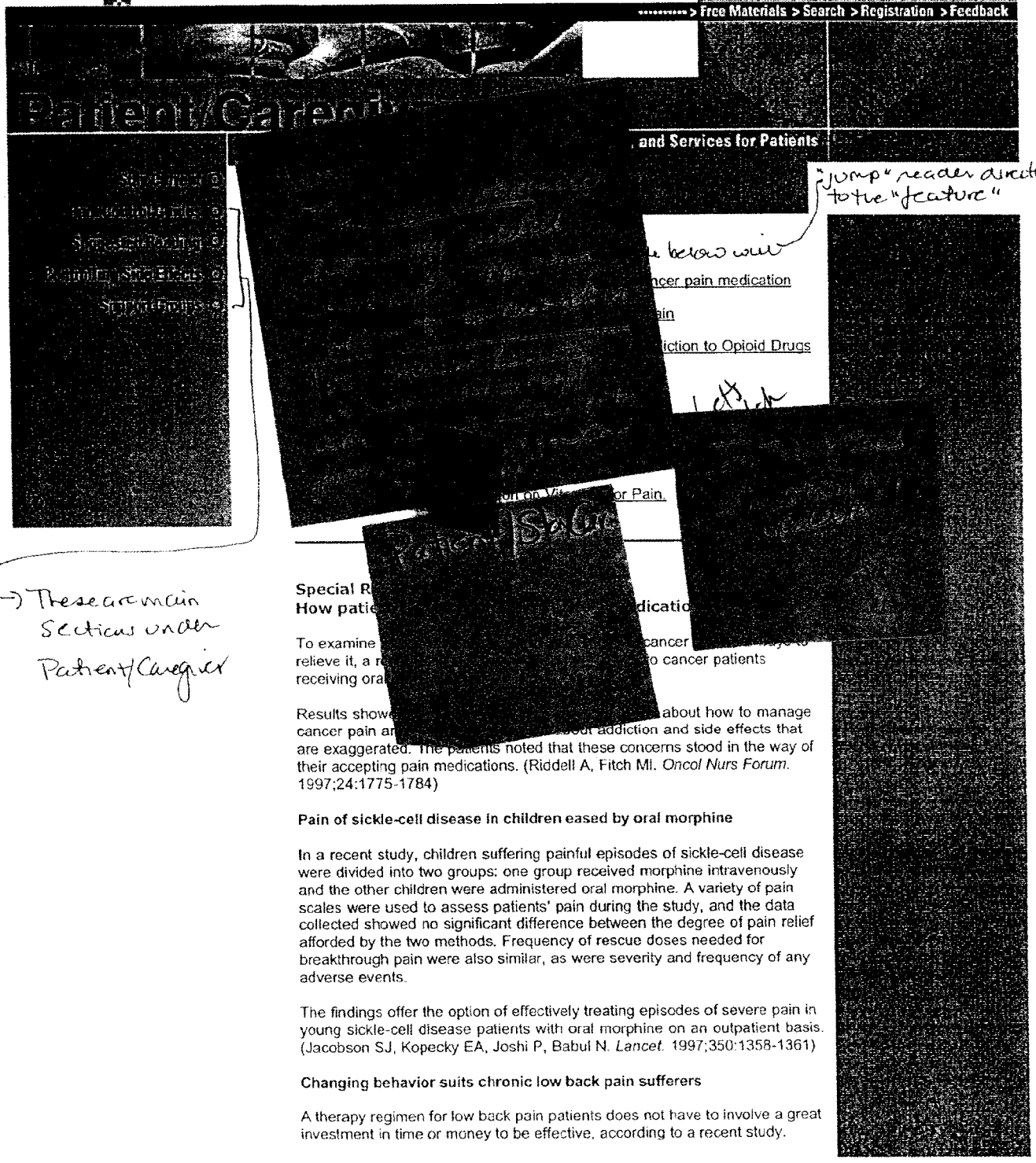
12. Periodic reviews. Records must remain current, maintained in an accessible manner, readily available for review, and must be in full compliance with rule 64B8-9.003, F.A.C., section 456.057, F.S., and section 458.331(1)(m), F.S.

(g) Compliance with Laws and Rules. Physicians and physician assistants shall at all times, remain in compliance with this rule and all state and federal laws and regulations addressing the prescribing and administration of controlled substances.

Rulemaking Authority 456.44(4), 458.309(1), 458.331(1)(v) FS. Law Implemented 456.44, 458.326, 458.331(1)(g), (t), (v) FS. History–New 12-21-99, Amended 11-10-02, 10-19-03, 10-17-10, 2-21-19.

Exhibit 6

PARTNERS AGAINST PAIN



"jump" reader directly to the "feature"

→ These are main Sections under Patient/Caregiver

Special R
How pati **dicatio**

To examine cancer relieve it, a r o cancer patients receiving ora

Results show about how to manage cancer pain ar addiction and side effects that are exaggerated. The patients noted that these concerns stood in the way of their accepting pain medications. (Riddell A, Fitch MI. *Oncol Nurs Forum.* 1997;24:1775-1784)

Pain of sickle-cell disease in children eased by oral morphine

In a recent study, children suffering painful episodes of sickle-cell disease were divided into two groups: one group received morphine intravenously and the other children were administered oral morphine. A variety of pain scales were used to assess patients' pain during the study, and the data collected showed no significant difference between the degree of pain relief afforded by the two methods. Frequency of rescue doses needed for breakthrough pain were also similar, as were severity and frequency of any adverse events.

The findings offer the option of effectively treating episodes of severe pain in young sickle-cell disease patients with oral morphine on an outpatient basis. (Jacobson SJ, Kopecky EA, Joshi P, Babul N. *Lancet.* 1997;350:1358-1361)

Changing behavior suits chronic low back pain sufferers

A therapy regimen for low back pain patients does not have to involve a great investment in time or money to be effective, according to a recent study.

Pain Control Guides

How You Can Be a Partner Against Pain® and Gain Control Over Your Own Pain

You are the pain authority.

There are many types of pain, just as there are many causes of pain. Fortunately, now doctors have ways to greatly reduce pain. Most patients with pain can get adequate pain relief.
You are the expert on your own pain. We all need the help of doctors, nurses, pharmacists, and others when we are in pain. But for them to help you, you must tell them about your pain. Together you will cooperate as "partners against pain."

Partners Against Pain®

The Partners Against Pain program was created to encourage talk among patients and their caregivers. Caregivers include the patient's family and all the doctors, nurses and pharmacists who help fight pain. The Partners Against Pain program reaches both caregivers and patients to help ensure that every patient receives maximum pain relief.
Now, let's look at some of the most frequently asked questions about pain and pain medicines.

Q. Is controlling pain complicated?

A. No. Today doctors can control pain through the relatively simple means of pain medications. And taking them is not complicated – your doctors and nurses will teach you everything you need to know. Your job is to tell your healthcare team how you feel and to follow doctors' instructions.
There are two steps in controlling pain with medicine. The first step is to learn what is the correct amount of medicine you are taking to relieve your pain.
The second step, pain experts agree, is to take that dose at the prescribed times every day. Taking medicine at the same times each day keeps a constant level of pain-relieving medicine in the body, which is an important step in preventing pain from coming back. Usually this medicine can be taken by mouth, which is the easiest way for most people to take medicine.

Q. Will I need a doctor's prescription for my pain medicine?

A. For treating mild pain, over-the-counter drugs that don't require a prescription may relieve the pain. But for more severe pain, stronger medicines may be needed. Strong medicines include morphine (say: more-FEEN) and oxycodone (ox-ee-KOH-dohn). These medicines, called opioids (OH-pee-oydz), always require a doctor's prescription.

Q. Will I have to take pain pills every few hours?

A. Until recently most medicines to relieve pain provided relief for only a few hours. Today, scientists have developed long-acting medicines which remain effective much longer. For example, long-acting opioid tablets for pain relief are usually taken only twice a day (every 12 hours).
Taking pain medicine only twice a day permits a full night's rest. The pain

doesn't wake you up, and you don't have to wake up to take pain medicine. Follow your doctor's orders when taking any medicine, including those to relieve your pain.

Q. There are times when my pain is worse than at other times. What can be done about this?

A. Occasionally, even when your pain is relieved, you may feel pain during certain activities. This is called "incident pain." Or at the end of a tiring day, the pain may seem to "break through." For incident pain and breakthrough pain, your doctor will prescribe a fast-acting "rescue" pain-reliever to provide fast relief. Follow your doctor's orders in using this medicine too.
If you see that the pain regularly breaks through during, say, increased activity, fast-acting pain medicine can be taken an hour or so before the activity to prevent even this type of pain from occurring.
Remember that increasing pain does not necessarily mean worsening disease. Pain can sometimes be caused by the various treatments for the disease. Sometimes it's caused by factors completely unrelated to the disease.

Q. Aren't these pain medicines addictive? I don't want that to happen.

A. Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking the pain medication for medical purposes. The medical purpose is clear and the effects are beneficial, not harmful.
True addiction very rarely occurs when opioids are being used properly under medical supervision to relieve pain. If your pain gets better, your doctor can reduce the amount you take. Follow your doctor's orders for taking less medicine, just as you do if the amount is increased.

Q. Does taking opioids mean the end is near?

A. Taking opioids does not mean you are about to die. Many patients take opioids for years to control pain. They will not shorten your life. They will allow you to live with less pain and improve your quality of life.

Q. What should I do if my pain gets worse when I'm taking opioid medication?

A. With opioids, if the prescribed dosage level is inadequate, usually all it takes to get pain relief is to increase the dose after a careful assessment by your doctor.

Q. Won't these pain medicines eventually lose their effect?

A. No. An opioid will not lose its effect if you take it for a long time. Opioids can be taken for months or years, and they will continue to relieve pain. And if your pain worsens, the amount you take can be increased by your doctor to control the additional pain.

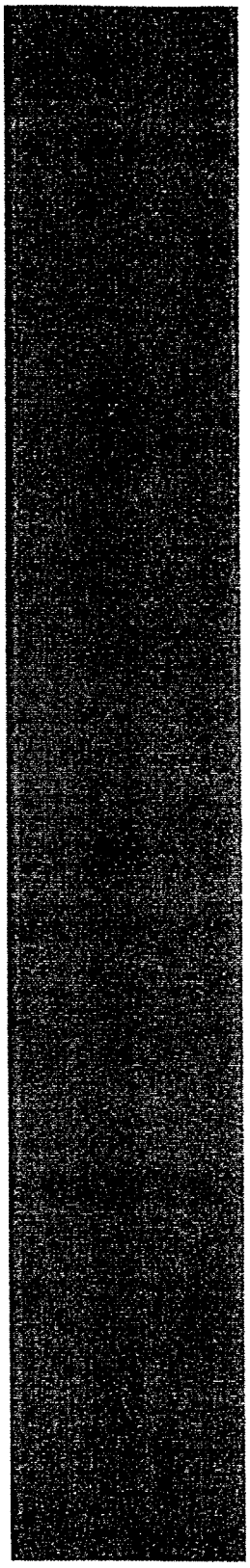
Q. Isn't pain an unavoidable consequence of my illness? Shouldn't the doctor be focusing on treating my disease?

A. Pain may be caused by your disease, but it's not unavoidable. Don't think you have to accept the pain to be a "good patient." Having pain under control helps in the treatment of the primary disease.
With pain under effective control, you may enjoy a better quality of life. You can eat, sleep, perform daily activities, and relate to your family and friends more normally. Patients who are strong and rested are better able, both mentally and physically, to fight disease and actively participate in treatment.

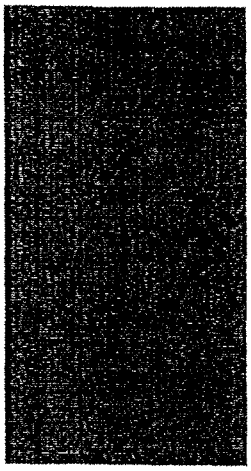
Q. My doctor says my pain is due to cancer. Can cancer pain be relieved too?

A. Yes, it can. In approximately 90% of patients, cancer pain can be controlled through relatively simple means – such as oral pain medicine. The other 10% of patients may require using other methods to successfully relieve pain. Your medical team will help you find the best way to control your individual type of pain.

Q. I know my loved ones want to help. What can they do?



A. Most likely, your family and friends want to help. But you may have to tell them how they can help. While it's not easy to ask others for help, there is a lot that they can do to help make your life easier. In addition to running errands and helping around the house, they can help you keep your journal and other written records of your medicines and your pain.
You are the leading expert on your own pain. When you feel pain, your pain is real. You know what it is, what it feels like, and how it affects your life. Share your thoughts and feelings with your doctors and nurses. If you are feeling pain, it is important for you to describe it to those who are trained to help you. Remember: You have every right to ask them to help you relieve the pain as much as possible.



| Go Back |

Exhibit 7

Date: Monday, March 18 2013 05:42 PM

Subject: PROP/Feinstein

From: Rosen, Burt <Burt.Rosen@pharma.com>

To: <Stew.Leavitt@Pain-Topics.org> <Stew.Leavitt@Pain-Topics.org>;

CC: RKirch@CANCER.ORG; Tom O'Donnell <TOdonnell@NACDS.org>; Dr. Alfred Anderson <aanderson@medpainmanagement.com>; Ashli Douglas <adouglas@sjm.com>; Adriane Burke <Adriane.Burke@Cancer.org>; Anita Ducca <aducca@hdmanet.org>; Amy Goldstein <agoldstein@aapainmanage.org>; Alyson Lewis <alewis@madisonassoc.com>; Aaron Gilson <amgilson@wisc.edu>; Andrea Best <andrea.best@abbott.com>; Alice Mead <apm@gwpharm.com>; Anita Roach <aroach@ichelp.org>; Alec Stone <astone@ons.org>; Robert Twillman <btwillman@aapainmanage.org>; Byrne, Timothy <Byrne.Timothy@endo.com>; Claudia Campbell <campbecfun1@yahoo.com>; Windy Y. Carson-Smith <carsonco@aol.com>; Cathrine Dratz <catherine.dratz@abbott.com>; Chrissy Kopple <CKopple@NACDS.org>; Caroline Schellhas <cmoody2@corus.jnj.com>; Cindy Steinberg <csteinberg@rcn.com>; Catherine Underwood <cunderwood@amctec.com>; Dara Mann <dara.mann@abbott.com>; David Swankin <davidswankin@cacenter.org>; David Woodmansee <david.woodmansee@cancer.org>; Dee Delezene Browers <dee@uspainfoundation.org>; Darrel C. Jodrey <djodrey@its.jnj.com>; Donna Kalauokalani <dkalauokalani@yahoo.com>; Haddox, Dr. J. David <Dr.J.David.Haddox@pharma.com>; Elizabeth Ernst <elizabeth.ernst@boehringer-ingelheim.com>; Whitney Englander <englander@harmreduction.org>; Eric Rasmussen <erasmussen@pattonboggs.com>; Erin Morton <erin.morton@dbr.com>; Felix Lara <Felix.lara@grunenthal.com>; Gail Amalia B. Katz <gamaliabkatz@gmail.com>; Regina Kaurich <gina@nadona.org>; Greg Hicks <greg.hicks@boehringer-ingelheim.com>; Paul, Ilisa Halpern <ilisa.halpernpaul@dbr.com>; Jack Kalavritinos <jack.kalavritinos@covidien.com>; James Lavery <james.lavery@abbott.com>; Janet McUlsky <janet.mculsky@pfizer.com>; Janet Favero Chambers <jan.chambers@fmcpaware.org>; Joy Buck <jbuck@hsc.wvu.edu>; Justine Coffey <jcoffey@ashp.org>; Erensen, Jennifer <Jennifer.Erensen@pharma.com>; Jeremy Scott <jeremy.scott@dbr.com>; Jerry Hall <jerry.hall@abbott.com>; Jillian Manley <jillian@aapainmanage.org>; Jonathan Keyserling <jkeyserling@nhpco.org>; June Dahl PhD <jldahl@wisc.edu>; Judi Lund Person <jlundperson@nhpco.org>; Jody Green <jody.green@rmpdc.org>; David E. Joranson <joranson@wisc.edu>; Jerold Roschwalb <jroschwalb@msn.com>; Jim Broatch <jwbroatch@aol.com>; Jewell Wellborn Cosgrove <jwellborn@hdmanet.org>; Karina Tabor <Karina.Tabor@cancer.org>; Kathy Sapp <kathy.sapp@tevapharm.com>; Kendra Calhoun <kcalhoun@amputee-coalition.org>; Karen Davis <kdavis@nhpco.org>; Keysha Brooks-Coley <keysha.brooks-coley@cancer.org>; Kristen Freitas <kfreitas@hdmanet.org>; Kaelan Hollon <khollon@phrma.org>; Tiller, Kimberley <Kimberley.Tiller@pharma.com>; Kim Elting <kim.elting@sjmneuro.com>; Kitlinski, Linda <Kitlinski.Linda@Endo.com>; Kevin Nicholson <KNicholson@NACDS.org>; Kristen Pulatie <kpulatie@connect2amc.com>; Kristin Recchiuti <KRecchiu@its.jnj.com>; Kristen Hedstrom <kristen.hedstrom@bsci.com>; Katherine Sharpe <ksharpe@cancer.org>; Kathleen Strauser <kstrauser@highwaterpartners.net>; Kathryn Tucker <ktucker@compassionandchoices.org>; Kevin L. Zacharoff <kzacharoff@inflexxion.com>; Lee Claassen <LClaassen@ichelp.org>; Lenore Duensing <lduensing@aapainmanage.org>; Libby.Terry@ltcpa.org; Loyce Pace <loyce.pace@livestrong.org>; Lisa Robin <lrobin@fsmb.org>; Luke Poppish <luke.poppish@rmpdc.org>; Lisa Pearlstein <l.pearlstein@asawash.org>; Marcia Lee Taylor <marcialee_taylor@drugfree.org>; Marta Sokolowska <Marta.Sokolowska@grunenthal.com>; Matt Gunderman <matthew.gunderman@bsci.com>; Marcie Bough <mbough@aphanet.org>; Myra Christopher <mchristopher@practicalbioethics.org>; Meredith Smith <meredith.smith@abbott.com>; Mike Hall <mhall@madisonassoc.com>; Mike Heffernan <mheffernan@collegiumpharma.com>; Michael Mattoon <michael.mattoon@bsci.com>; Micke Brown <micke.a.brown@gmail.com>; Michael Klimaszewski <mklimaszewski1202@gmail.com>; Maegan Martin <mmartin@fsmb.org>; Malcolm Monaghan <MMonagh4@its.jnj.com>; Marsha Stanton <mstanton@horizonpharma.com>; Crystal Muilenburg <muilenburg_crystal@allergan.com>; Munroe, Brian <Munroe.Brian@Endo.com>; Natalie Hamm <natalie.hamm@cancer.org>; Nicole Kelly <nicolekelly@verizon.net>; Natacha Pires <npires@neuropathy.org>; Bennett, Pamela (Gov't Affairs) <Pamela.Bennett@pharma.com>; Penney Cowan <pcowan@pacbell.net>; Peggy Tighe <Peggy.Tighe@PPSV.com>; Paul Arnstein <pmarnstein@partners.org>; Philip Saigh Jr. <psaigh@connect2amc.com>; Paul Scott O'Neill <pso@dcbalaw.com>; Peter VanPelt <pvanpelt@aphanet.org>; Patrick Toalson <p.toalson@lilly.com>; rhauser@ncpanet.org; Ron Kuntz <rkuntz@its.jnj.com>; Robert Saner <robert.saner@ppsv.com>; Robert Falb <rob.falb@tevapharm.com>; Ronna Hauser <ronna.hauser@ncpanet.org>; Rosemary Garza <rosemary.garza@medtronic.com>; Robert Radie <rr@egalet.com>; Sally Welsh <sallyw@hpna.org>; Sara Rosta <Sara.Rosta@PPSV.com>; Stacey Beckhardt <sbeckhardt@healthac-llc.com>; Sharon Brigner <SBrigner@phrma.org>; Scott M. Fishman <smfishman@ucdavis.edu>; Shaw, Solana <Solana.Shaw@pharma.com>; Sharon Stancliff <stancliff@harmreduction.org>; Steve LaPierre <Steve.LaPierre@bsci.com>; Sue Thau

<suerthau@aol.com>; Susan Rogers <susan.k.rogers@verizon.net>; Tamara Sloan <tamara@valinet.com>; Theresa Connor <tconnor@compassionandchoices.org>; Thomas, Greg <Thomas.Greg@endo.com>; Christy Torkildson <torkc@sbcglobal.net>; Trzaskawka, Catharine <traz.cathy@endo.com>; Tina Tockarshewsky <ttockars@neuropathy.org>; Patrick Coyne <user479069@aol.com>; Paul Gileno <uspainfoundation@gmail.com>; Wade Delk <wdelk@goAMP.com>;

Attachments: image001.gif; image001.png

Burt – if you have not already seen, thought this would be of interest. May want to distribute to PCF members.

Physicians for Responsible Opioid Prescribing (PROP)
and
Senator Dianne Feinstein
Chairman of the
Senate Caucus on International Narcotics Control
present a briefing
"OVERVIEW OF THE PRESCRIPTION OPIOID EPIDEMIC"
Data from the Substance Abuse and Mental Health Services Administration (SAMHSA)'s National Survey on Drug Use and Health<http://www.oas.samhsa.gov/nhsda.htm> (NSDUH) showed that nearly 2.6 million people aged 12 and over reported the first time non-medical use of a prescription drug in 2010 with a mean age of this cohort consistently in their teen years. The Centers for Disease Control and Prevention (CDC) has classified prescription drug abuse as an epidemic while the Drug Enforcement Administration (DEA) has been sounding the alarm bell acknowledging that the United States is creating a new generation of drug abusers. We will explore the epidemic from the perspective of a medical professional specializing in the treatment of addiction.

When: Tuesday, March 19, 2013<x-apple-data-detectors://1>
Time: 11:00 am – 12:00 pm<x-apple-data-detectors://2>
Where: Room G11 of the Dirksen Senate Office Building
Guest Speaker:
Andrew Kolodny, MD
Chairman of Psychiatry,Maimonides Medical Center Inc.
<http://investing.businessweek.com/research/stocks/snapshot/snapshot.asp?capId=4204978>
President, Physicians for Responsible Opioid Prescribing (PROP)

Dr. Andrew Kolodny is the Chair of Psychiatry at Maimonides Medical Center in Brooklyn, NY. Board certified in Psychiatry and Addiction Medicine, Dr. Kolodny is a national expert on the opioid addiction epidemic. In his clinical practice, he specializes in the treatment of opioid addiction.

Dr. Kolodny has a long-standing interest in public health and community psychiatry. He is currently President of Physicians for Responsible Opioid Prescribing (PROP) and was previously the Medical Director for Special Projects in the Office of the Executive Deputy Commissioner for the New York City Department of Health and Mental Hygiene. For New York City, he helped develop and implement multiple programs to improve the health of New Yorkers and save lives, including city-wide buprenorphine programs, naloxone overdose prevention programs and emergency room-based screening, brief intervention and referral to treatment (SBIRT) programs for drug and alcohol misuse.

All Senate and House Staff Invited

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Robert J. Falb Director, Government and Public Affairs Dept
Tel: 202 639 3800 <tel:202%20639%203800> Cell: 202 320 7602<tel:202%20320%207602> Fax: 816 508 8160
<mailto:[fax:816%20508%208160]>
25 Massachusetts Ave, NW, Suite 440, Washington, DC 20001<x-apple-data-detectors://5/1>
Rob.Falb@tevapharm.com<mailto:Rob.Falb@tevapharm.com>

Sent from my iPhone

On Mar 18, 2013, at 1:07 PM, "Stew.Leavitt@Pain-Topics.org<mailto:Stew.Leavitt@Pain-Topics.org>" <Stew.Leavitt@Pain-Topics.org<mailto:Stew.Leavitt@Pain-Topics.org>> wrote:

I think that if members of Congress are listening to the evidence-distorting messages of PROP (Kolodny) — without any fair-balanced discussion of the evidence regarding opioids for pain — there is much more to worry about in addition to the rescheduling of hydrocodone combination products. Admittedly, Kolodny does a convincing presentation, IF one is uneducated in what the evidence actually says; as was evident in his presentation to the Pain Care Forum.

Will anyone be present at the Feinstein briefing? And, might there then be opportunities at a later time for a more fair-balanced, truly evidence-based briefing of her group?

Stew

Stewart B. Leavitt, MA, PhD
Executive Director
Pain Treatment Topics
202 Shermer Road | Glenview, IL 60025
Phone: 847-724-3091
e-Mail: Stew.Leavitt@Pain-Topics.org<mailto:Stew.Leavitt@Pain-Topics.org>
> Pain-Topics.org<http://pain-topics.org/>
> UPDATES.Pain-Topics.org<http://updates.pain-topics.org/>
> Opioids911.org<http://opioids911.org/>

<image001.gif>

From: RKirch@CANCER.ORG<mailto:RKirch@CANCER.ORG> [mailto:RKirch@CANCER.ORG]
Sent: Monday, March 18, 2013 11:30 AM
To: Tom O'Donnell
Cc: 'Dr. Alfred Anderson'; 'Ashli Douglas'; 'Adriane Burke'; 'Anita Ducca'; 'Amy Goldstein (agoldstein@aapainmanage.org <mailto:agoldstein@aapainmanage.org>)'; 'Alyson Lewis'; 'Aaron Gilson'; 'Andrea Best'; 'Alice Mead'; 'Anita Roach'; 'Alec Stone'; 'Robert Twillman'; 'Rosen, Burt'; 'Timothy Byrne'; 'Claudia Campbell '; 'Windy Y. Carson-Smith'; 'Cathrine Dratz'; Chrissy Kopple; 'Caroline Schellhas'; 'Cindy Steinberg'; 'Catherine Underwood'; 'Dara Mann'; 'David Swankin'; 'David Woodmansee'; 'Dee Delezene Browers'; 'Darrel C. Jodrey'; 'Donna Kalauokalani'; 'Haddox, Dr. J. David'; 'Elizabeth Ernst'; 'Whitney Englander'; 'Eric Rasmussen'; 'Erin Morton'; 'Felix Lara'; 'Gail Amalia B. Katz'; 'Regina Kaurich'; 'Greg Hicks'; 'Paul, Ilisa Halpern'; 'Jack Kalavritinos'; 'James Lavery'; 'Janet McUlsky'; 'Janet Favero Chambers'; 'Joy Buck'; 'Justine Coffey'; 'Erensen, Jennifer'; 'Jeremy Scott'; 'Jerry Hall'; 'Jillian Manley'; 'Jonathan Keyserling'; 'June Dahl PhD'; 'Judi Lund Person'; 'Jody Green'; 'David E. Joranson'; 'Jerold Roschwalb'; 'Jim Broatch'; 'Jewell Wellborn Cosgrove'; 'Karina Tabor'; 'Kathy Sapp';

'Kendra Calhoun'; 'Karen Davis'; 'Keysha Brooks-Coley'; 'Kristen Freitas'; 'Kaelan Hollon'; 'Tiller, Kimberley'; 'Kim Elting'; 'Linda Kitlinski'; Kevin Nicholson; 'Kristen Pulatie'; 'Kristin Recchiuti'; 'Kristen Hedstrom'; 'Katherine Sharpe'; 'Kathleen Strauser'; 'Kathryn Tucker'; 'Kevin L. Zacharoff'; 'Lee Claassen'; 'Lenore Duensing'; 'Libby.Terry@ltcpa.org <mailto:Libby.Terry@ltcpa.org >'; 'Loyce Pace'; 'Lisa Robin'; 'Luke Poppish'; 'Lisa Pearlstein'; 'Marcia Lee Taylor'; 'Marta Sokolowska '; 'Matt Gunderman'; 'Marcie Bough'; 'Myra Christopher'; 'Meredith Smith'; 'Mike Hall'; 'Mike Heffernan'; 'Michael Mattoon'; 'Micke Brown'; 'Michael Klimaszewski'; 'Maegan Martin'; 'Malcolm Monaghan'; 'Marsha Stanton'; 'Crystal Muilenburg'; 'Brian Munroe'; 'Natalie Hamm'; 'Nicole Kelly'; 'Natacha Pires'; 'Bennett, Pamela (Gov't Affairs)'; 'Penney Cowan '; 'Peggy Tighe'; 'Paul Arnstein'; 'Philip Saigh Jr.'; 'Paul Scott O'Neill'; 'Peter VanPelt'; 'Patrick Toalson'; 'rhauser@ncpanet.org <mailto:rhauser@ncpanet.org >'; 'Ron Kuntz'; 'Robert Saner'; 'Robert Falb'; 'Ronna Hauser'; 'Rosemary Garza'; 'Robert Radie'; 'Sally Welsh'; 'Sara Rosta'; 'Stacey Beckhardt'; 'Sharon Brigner (SBrigner@phrma.org<mailto:SBrigner@phrma.org >)'; 'Scott M. Fishman'; 'Shaw, Solana'; 'Sharon Stancliff'; 'Steve LaPierre'; 'Stewart Leavitt'; 'Sue Thau'; 'Susan Rogers'; 'Tamara Sloan'; 'Theresa Connor'; 'Greg Thomas'; 'Christy Torkildson'; 'Cathy Trzaskawka'; 'Tina Tockarshewsky'; 'Patrick Coyne'; 'Paul Gileno'; 'Wade Delk'
Subject: Re: Letter to Congress on Hydrocodone Rescheduling

Tom,
Bob Twillman and I just discussed concerns about tomorrow's Hill briefing Senator Feinstein is hosting with PROP. Given that timing and the urgency Congress is building around the hydrocodone legislative initiative, we might consider it important and useful to get this letter circulating on the Hill today to inform staff in offices that there is more to the story than just addiction and overdose. The people with pain side of the story will not be addressed in tomorrow's briefing -- that appears to feature only Dr. Kolodny, so we need to broadcast our message through this letter and follow up meetings to be heard.

Thanks for considering this. Rebecca and Bob
Rebecca Kirch, JD | Director, Quality of Life & Survivorship

American Cancer Society, Inc.

555 11th St. NW, Suite 300

Washington, DC 20004

Phone: 202 661 5725 | Mobile: 202 277 5912 | Fax: 202 661 5750

cancer.org<http://www.cancer.org > | 1.800.227.2345

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[http://lnimages.cancer.org/images/twitter.jpg] <http://www.twitter.com/americancancer?societysignature=twitter >
[http://lnimages.cancer.org/images/youtube.jpg]
<http://www.youtube.com/user/AmerCancerSociety?societysignature=youtube >
[http://lnimages.cancer.org/images/linkedin.jpg] <http://www.linkedin.com/company/american- cancer-society?societysignature=linkedin >

[http://lnimages.cancer.org/images/esig_rev%20with%20registration.gif]

From: "Tom O'Donnell" <TOdonnell@NACDS.org<mailto:TOdonnell@NACDS.org>>
To: Date: 03/18/2013 12:15 PM
Subject: Letter to Congress on Hydrocodone Rescheduling

Friends –

Good Afternoon. Please find enclosed the letter to Congress on Hydrocodone rescheduling we had circulated earlier. Due to editing and our association fly-in last week, we had to delay this.

My goal is to get it out this on Thursday, March 21st and to have the final deadline be COB this Wednesday, March 20th. If you would like to sign the letter, please let me know by then.

Also, the below organizations agreed to sign the original draft:

American Cancer Society Cancer Action Network, Inc.
Long Term Care Pharmacy Alliance
Massachusetts Pain Initiative
National Association of Chain Drug Stores
National Community Pharmacists Association
National Fibromyalgia & Chronic Pain Association
US Pain Foundation
Virginia Cancer Pain Care Initiative
Wisconsin Pain Initiative

Since we made a minor edit in the letter (its noted in the draft), please review once more and let me know if your organization would still like to sign on to the letter.

Thanks again.

Tom

Tom O'Donnell
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www.twitter.com/@NACDS <http://www.twitter.com/@NACDS>

[attachment "Draft Hill Hydrocodone Rescheduling letter Final.docx" deleted by Rebecca Kirch/NA/ACS/US]

Exhibit 8

From:	Kevin Nicholson <KNicholson@NACDS.org>
To:	Albert Garcia; Bob Egeland; Chuck Reed; Dale Masten; Dan Salemi; Debbie Garza; Dennis Wiesner; Fred Ottolino; Jennifer Speares; John Carlo; John Fegan; Jonathan Thacker; Karen Mankowski; Kate Coler; Kevin Connor; Burton, Larry; Marc Baer; Mark Gregory; Mark Pilkington; Mark Polli; Mike Podgurski; Raymond McCall; Rick Chambers; Sandra Kinsey; Steve McCann; Susanne Hiland; Suzanne Hansen; Tim Weber; Tim Weippert; Gibbons, Thomas J.; Vic Curtis; Yong Choe
CC:	Alethia Jackson; Alex Adams; Horne, Allen K.; Anika Hagenson (anika.hagenson@target.com); Jenkins, Ann; Anne Fellows; Arianna Daoulas; Beth Cieslik; Beth Zander; Bobbie Riley; Brad Dayton; Files, Brian; Carol Kelly; Carolyn Steinberg; Charlie.Oltman; Chris Krese; Chrissy Kopple; Christie Boutte; Connie Woodburn; Craig Norman; Dave Fitzsimmons; Dave Sencabaugh; Diane Darvey; Dimos, Chris; Don Bell; Ed Kaleta; Elisa Muller; Douglas, Eric; Eric Juhl; Ghassan Hourani; Gregg Jones; Heidi Ecker; 'Ileana.Mcalary@meijer.com' (Ileana.Mcalary@meijer.com); Isaac Reyes; Jay Bogdan; Jill McCormack; Jim Tsipakis; Joe Montoto; Joel Kurzman; Jon McArthur; Flum, Josh M.; Joyce Robertson; Julie Philp; Karen White; Kathleen Jaeger; Katie Anderson; Kevin Nicholson; Laura Asbury; Laura Miller; Leigh Knotts; Lis Houchen; Lisa Boylan; Marc Schloss; Schlaifer, Marissa C; Mary Diggs; Mary Ellen Kleiman; Mary Staples; Melanie Grenier; Michael Mone; Michelle Cope; Ayotte, Michael J.; Mike Cantrell; Sargent, Michael D.; Ronald Richmond; Sandra Guckian; Sheree Barton; Steve Anderson; Steven Gregory; Susan Flack; Tedria Hampton; Tom O'Donnell; Tony Unan
Sent:	8/14/2013 3:00:01 PM
Subject:	NACDS Policy Council Call - Aug 16 @ 11:00 a.m. EDT
Attachments:	DEA Rule Excerpts Recordkeeping Final.docx; FW: pharmacy lock-in programs; Hydrodocodone Rescheduling - Copy.pdf; SEATTLE-#365324-v1-291159__NACDS_QUESTION_SET.DOCX

We will have a Policy Council call this week. Call in number and agenda below. Thanks.

1-888-450-5996

608936#

AGENDA:

Update

1. NACDS member plans for communicating info about ACA Health Insurance Info - Chrissy Kopple

2. CA Update - Mary Staples

Discussion

1. Hydrocodone Compromise from AAPM - Kevin -- AAPM is floating a compromise alternative to rescheduling combination hydrocodone products into Schedule II

AAPM's Proposal (also see attachment):

§ Allow hydrocodone combination products to remain in Schedule III;

§ Change the limits on called-in or faxed-in prescriptions for Schedule III medications, such that the total amount allowed to be prescribed through this means is no greater than the supply needed to provide for the patient's needs until he or she is able to visit the prescriber (likely a 3 - 7 day supply; the exact number is negotiable). No refills would be

allowed for such a prescription; and

§ Limit the total amount of medication available through the original hydrocodone combination product prescription plus refills to no more than a 90 - day supply.

§ Per AAPM, his would ensure that the prescriber has an opportunity to see patients using this medication at least every three months. AAPM believes this modification to the laws governing Schedule III prescriptions would totally avoid the increased costs associated with necessary changes to the wholesale and retail pharmacy distribution system; address concerns related to prescribers providing many months' supply with one prescription; minimize the increased number of office visits necessary; and increase control over subsequent prescription fills on the part of prescribers and dispensers.

2. GAO Study on Prescription Drug Abuse - Kevin -- Please see the attached questions from GAO

3. Medicare Lock In - Kevin -- See the attached email

4. DEA Recordkeeping - Kevin - Please see below and attached

At the direction of the Policy Council, members of the New & State Initiatives workgroup identified the following priorities for where DEA should revise their rules to accommodate the current technologies that pharmacies use for recordkeeping. Both the requirement for pharmacies to maintain original hard copy prescription records, which do not allow pharmacies to maintain scanned prescriptions (21 CFR 1304.04); and the central fill recordkeeping requirements (21 CFR 1306.15 & 21 CFR 1306.27) were identified as being the two highest priority rules that DEA should revise. That said, the workgroup did recognize that getting DEA to allow pharmacies to maintain scanned prescriptions and associated records in lieu of hard copy prescriptions and associated records is unlikely since DEA prefers the original hard copy for investigational purposes. Additionally, the New and State Initiatives workgroup identified the daily printout requirement for electronically maintained refill records (21 CFR 1306.22) as being another (although lower) priority issue.

Beyond these, there were numerous other provisions of the DEA rules that require pharmacies to maintain certain records in hard copy form, although these rules were ranked as low priority by the members of the New & State Initiatives workgroup.

FYI - ACA and Medicaid

Recently, A new online tool released by the Kaiser Family Foundation provides detailed projections of the impact of the Affordable Care Act on Medicaid enrollment and the uninsured in local communities across the nation. Zooming In On Health Reform: Understanding the Potential Impact of the ACA on Medicaid and the Uninsured at the Local Level, the new interactive infographic, reveals substantial geographic variations in the law's impact. The tool's interactive maps allow users to identify communities that could experience the largest declines in the uninsured and where the remaining uninsured populations are likely to be concentrated, as well as to identify key local areas for enrollment outreach. Users can enter zip codes or place names to compare different states, counties, and localities, and to examine the characteristics of the changing Medicaid and uninsured populations by race, age, gender and language spoken at home. The tool's estimates reflect the projected impact if all states were to undertake the expansion. NACDS has reviewed the tool and found it to be a sound tool.

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Exhibit 9

From:	Kevin Nicholson <KNicholson@NACDS.org>
To:	Albert Garcia; Bob Egeland; Chuck Reed; Dale Masten; Debbie Garza; Dennis Wiesner; Fred Ottolino; Jennifer Speares; John Carlo; John Fegan; Jonathan Thacker; Karen Mankowski; Kate Coler; Kevin Connor; Burton, Larry; Marc Baer; Mark Gregory; Mark Pilkington; Mark Polli; Mike Podgurski; Raymond McCall; Rick Chambers; Riley, Bobbie (Bobbie.Riley@albertsons.com); Sandra Kinsey; Steve McCann; Susanne Hiland; Suzanne Hansen; Tim Weber; Tim Weippert; Gibbons, Thomas J.; Vic Curtis; Yong Choe
CC:	Alethia Jackson; Alex Adams; Horne, Allen K.; Anika Hagenson (anika.hagenson@target.com); Jenkins, Ann; Anne Fellows; Arianna Daoulas; Beth Cieslik; Beth Zander; Brad Dayton; Files, Brian; Bryan Dunwoody; Carol Kelly; Carolyn Steinberg; Charlie.Oltman; Chris Krese; Chrissy Kopple; Christie Boutte; Christopher Smith; Connie Woodburn; Craig Norman; Dan Salemi; Dave Fitzsimmons; Diane Darvey; Dimos, Chris; Don Bell; Ed Kaleta; Elisa Muller; Douglas, Eric; Eric Juhl; Gregg Jones; Heidi Ecker; 'Ileana.Mcalary@meijer.com' (Ileana.Mcalary@meijer.com); Isaac Reyes; Jay Bogdan; Jill McCormack; Jim Tsipakis; Joe Montoto; Joel Kurzman; Jon McArthur; Flum, Josh M.; Joyce Robertson; Julie Philp; Karen White; Kathleen Jaeger; Katie Anderson; Kevin Nicholson; Laura Asbury; Laura Miller; Leigh Knotts; Lis Houchen; Lisa Boylan; Marc Schloss; Schlaifer, Marissa C; Mary Diggs; Mary Ellen Kleiman; Mary Staples; Melanie Grenier; Michael Mone; Michelle Cope; Ayotte, Michael J.; Mike Cantrell; Sargent, Michael D.; Ronald Richmond; Sandra Guckian; Sheree Barton; Steve Anderson; Steven Gregory; Susan Flack; Tedria Hampton; Tom O'Donnell; Tony Unan
Sent:	11/13/2013 3:35:43 PM
Subject:	No Policy Council Call this Week - Please Read Email
Attachments:	Joint Rescheduling Letter to HHS 10-2013.pdf

We will not have a Policy Council call this week.

Please see the attached letter from pharmacy associations to HHS opposing FDA's recommendation to reschedule combination hydrocodone products. The letter was sent to HHS this week. NACDS signed the letter, along with AMCP, APhA, ASCP, NASPA, and NCPA.

Thanks, Kevin

KEVIN N. NICHOLSON, R.PH., J.D.
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Exhibit 10

Message

From: Marc Schloss [/O=NACDS/OU=NACDS_DOMAIN/CN=RECIPIENTS/CN=MSCHLOSS]
Sent: 6/8/2012 6:32:44 PM
To: Carol Kelly [ckelly@nacds.org]; Kevin Nicholson [knicholson@nacds.org]; Julie Philp [jphilp@nacds.org]
CC: Chris Krese [ckrese@nacds.org]
Subject: Fwd: Urgent: AAPM/ACSCAN Sign on letter opposing federal hydrocodone rescheduling amendement

Please see the attached letter and chain. The attached is a draft letter against reclassifying combination hydrocodone and there are many PhRMA, GPhA and patient care groups like the American Cancer Society listed. I let Harkin staff know the letter was in the works. The patient groups will be very powerful tamping down Manchin.

Begin forwarded message:

> **From:** "Wellborn, Jewelyn" <jwellborn@hdmanet.org>
> **Date:** June 8, 2012 2:27:44 PM EDT
> **To:** Marc Schloss <MSchloss@NACDS.org>
> **Subject: Fwd: Urgent: AAPM/ACSCAN Sign on letter opposing federal hydrocodone rescheduling amendement**
>
> Here is their letter and message through a group we monitor. Mind you we raised this with them when the amendment was being floated and they are just now getting involved.
>
> Sent from my iPhone
>
> Begin forwarded message:
>
> > **From:** "Rosen, Burt" <Burt.Rosen@pharma.com>
> > **Date:** June 8, 2012 11:43:39 AM EDT
> > **To:** Aaron Gilson <amgilson@wisc.edu>, Adam Chrisney <Adam.Chrisney@ppsv.com>, Adam Clark <adam.clark@laf.org>, Alec Stone <astone@ons.org>, Alice Mead <apm@gwpharm.com>, Alyson Lewis <alewis@madisonassoc.com>, Andrea Best <andrea.best@abbott.com>, Andrew Bertagnolli <andrew.bertagnolli@kp.org>, Anita Ducca <aducca@hdmanet.org>, Ashli Douglas <adouglas@sjm.com>, Barbara Gordon <bgordon@ichelp.org>, "Bennett, Pamela (Gov't Affairs)" <Pamela.Bennett@pharma.com>, Bobby Clark <bobby.clark@tevapharm.com>, Brian Gallagher <bgallagher@aphanet.org>, Brian Munroe <munroe.brian@endo.com>, Caroline Schellhas <cmoody2@corus.jnj.com>, Cate Dillon <catherine.dillon@abbott.com>, Catherine Underwood <cunderwood@amctec.com>, Cathy Trzaskawka <trzaskawka.catharine@endo.com>, Christy Torkildson <torkc@sbcglobal.net>, Cindy Steinberg <csteinberg@rcn.com>, "Claudia Campbell " <campbecfun1@yahoo.com>, Crystal Muilenburg <muilenburg_crystal@allergan.com>, Dara Mann <dara.mann@abbott.com>, "Darrel C. Jodrey" <djodrey@its.jnj.com>, "David E. Joranson" <joranson@wisc.edu>, David Swankin <davidswankin@cacenter.org>, David Woodmansee <david.woodmansee@cancer.org>, Dee Delezene Browers <dee@uspainfoundation.org>, Donna Kalauokalani <dkalauokalani@yahoo.com>, "Dr. Alfred Anderson" <aanderson@medpainmanagement.com>, Elizabeth Ernst <elizabeth.ernst@boehringer-ingelheim.com>, "Erensen, Jennifer"

<Jennifer.Erensen@pharma.com>, Erin Morton <erin.morton@dbr.com>, "Gail Amalia B. Katz" <gamaliabkatz@gmail.com>, Greg Hicks <greg.hicks@boehringer-ingelheim.com>, Greg Thomas <thomas.gregory@endo.com>, Jack Kalavritinos <jack.kalavritinos@covidien.com>, James Lavery <james.lavery@abbott.com>, Janet Favero Chambers <jan.chambers@fmcpaware.org>, Janet McUlsky <janet.mculsky@pfizer.com>, Jason Byrd <j.byrd@asawash.org>, Jason Grove <jason.grove@abbott.com>, Jeremy Scott <jeremy.scott@dbr.com>, Jerold Roschwalb <jroschwalb@msn.com>, Jerry Hall <jerry.hall@abbott.com>, Jewell Wellborn <jwellborn@hdmanet.org>, Jillian Manley <jillian@aapainmanage.org>, Jim Broatch <jwbroatch@aol.com>, Jody Green <jody.green@rmpdc.org>, Jonathan Keyserling <jkeyserling@nhpco.org>, Joy Buck <jbuck@hsc.wvu.edu>, Judi Lund Person <jlundperson@nhpco.org>, Judy Lentz <judyl@hpna.org>, June Dahl PhD <jldahl@wisc.edu>, Justine Coffey <jcoffey@ashp.org>, Karen Davis <kdavis@nhpco.org>, Karina Tabor <Karina.Tabor@cancer.org>, Katherine Sharpe <ksharpe@cancer.org>, Kathleen Strauser <kstrauser@highwaterpartners.net>, Kathryn Tucker <ktucker@compassionandchoices.org>, Kathy Sapp <kathy.sapp@tevapharm.com>, Kendra Calhoun <kcalhoun@amputee-coalition.org>, "Kevin L. Zacharoff" <kzacharoff@inflexxion.com>, Keysha Brooks-Coley <keysha.brooks-coley@cancer.org>, Kristen Freitas <kfreitas@hdmanet.org>, Kristen Hedstrom <kristen.hedstrom@bsci.com>, Kristen Pulatie <kpulatie@connect2amc.com>, Kristin Recchiuti <KRecchiu@its.jnj.com>, Lenore Duensing <lduensing@aapainmanage.org>, Linda Kitlinski <Kitlinski.Linda@Endo.com>, Lisa Pearlstein <l.pearlstein@asawash.org>, Lisa Robin <lrobin@fsmb.org>, Luke Poppish <luke.poppish@rmpdc.org>, Maegan Martin <mmartin@fsmb.org>, Malcolm Monaghan <MMonagh4@its.jnj.com>, Marcia Lee Taylor <marcialee_taylor@drugfree.org>, Marcie Bough <mbough@aphanet.org>, Marsha Stanton <mstanton@horizonpharma.com>, Mary Pat Aardrup <mpaardrup@yahoo.com>, Matt Gunderman <matthew.gunderman@bsci.com>, Meredith Smith <meredith.smith@abbott.com>, Michael Mattoon <michael.mattoon@bsci.com>, Mike Hall <mhall@madisonassoc.com>, Mike Heffernan <mheffernan@collegiumpharma.com>, Myra Christopher <mchristopher@practicalbioethics.org>, Natacha Pires <npires@neuropathy.org>, Natalie Hamm <natalie.hamm@cancer.org>, Nicole Kelly <nicolekelly@verizon.net>, Patrick Coyne <user479069@aol.com>, Patrick Toalson <p.toalson@lilly.com>, Paul Arnstein <pmarnstein@partners.org>, Paul Gileno <uspainfoundation@gmail.com>, Paul Scott O'Neill <pso@dcbalaw.com>, "Paul, Ilisa Halpern" <ilisa.halpernpaul@dbr.com>, "Penney Cowan " <pcowan@pacbell.net>, Peter Slone <peter.b.slone@medtronic.com>, Peter VanPelt <pvanpelt@aphanet.org>, Philip Saigh Jr. <psaigh@connect2amc.com>, Piran Farhadieh <pfarhadieh@sjm.com>, Rebecca Kirch <rkirch@cancer.org>, Regina Kaurich <gina@nadona.org>, Robert Saner <robert.saner@ppsv.com>, Robert Twillman <btwillman@aapainmanage.org>, Robyn Kohn <RKohn@its.jnj.com>, Ronna Hauser <ronna.hauser@ncpanet.org>, Rosemary Garza <rosemary.garza@medtronic.com>, "Rosen, Burt" <Burt.Rosen@pharma.com>, "Westberry, Ryan" <ryan.westberry@rmpdc.org>, "Scott M. Fishman" <smfishman@ucdavis.edu>, Sharon Stancliff <stancliff@harmreduction.org>, "Shaw, Solana" <Solana.Shaw@pharma.com>, Stacey Beckhardt <Stacey.beckhardt@tevapharm.com>, Stephen Porada <sp@paineducators.org>,

Steve LaPierre <Steve.LaPierre@bsci.com>, Stewart Leavitt <stew202@comcast.net>, Sue Thau <suerthau@aol.com>, Susan Rogers <susan.k.rogers@verizon.net>, Tamara Sloan <tamara@valinet.com>, Theresa Connor <tconnor@compassionandchoices.org>, "Tiller, Kimberley" <Kimberley.Tiller@pharma.com>, Timothy Byrne <Byrne.Timothy@endo.com>, Tina Tockarshewsky <ttockars@neuropathy.org>, Valerie Volpe <valerie_volpe@merck.com>, Wade Delk <wdelk@goAMP.com>, Whitney Englander <englander@harmreduction.org>, "Windy Y. Carson-Smith" <carsonco@aol.com>
Subject: FW: Urgent: AAPM/ACSCAN Sign on letter opposing federal hydrocodone rescheduling amendement

Please see request from Rebecca.

From: RKirch@CANCER.ORG [mailto:RKirch@CANCER.ORG]
Sent: Friday, June 08, 2012 11:42 AM
To: Rosen, Burt
Cc: btwillman@aapainmanage.org; Keysha.Brooks-Coley@cancer.org; blair.horner@cancer.org; David.Woodmansee@cancer.org
Subject: Urgent: AAPM/ACSCAN Sign on letter opposing federal hydrocodone rescheduling amendement
Importance: High

Burt, For circulation please asap to Pain Care Forum membership:

Dear Pain Care Forum participants:

The American Academy of Pain Management and American Cancer Society Cancer Action Network teamed up to prepare the attached letter to communicate our concerns in response to the federal hydrocodone rescheduling amendment (bumping combination products up to Schedule II from current Schedule III). This amendment was passed in the Senate recently in the context of PDUFA reauthorization. The House-passed bill does not include this hydrocodone amendment language, so the issue will be decided through conference within the next few weeks. We are facing a difficult situation here given the momentum this amendment has behind it, so it is essential to get on record with the community's concerns made clear.

ACS CAN has been communicating directly with key House and Senate Hill staff about these concerns, and will be sending the attached letter early next week to House Energy and Commerce Staff and Senate HELP Committee staff who will be conferencing to negotiate the final bill. We welcome other patient and professional organizations participating in the Pain Care Forum to sign on to this letter. **Timing is critical and short before conference, however, so we will need your response by 3pm on Monday, June 11 if your organization wants to be listed on the letter.**

Please reply directly to Keysha Brooks-Coley at keysha.brooks-coley@cancer.org if you want your group included.

We are also preparing a similar joint AAPManagement/ACSCAN letter for use in New York State, where the legislature is actively pursuing prescription monitoring program changes together with rescheduling hydrocodone combination products to Schedule II. ACS CAN state lobbyists have been actively communicating with NY legislative and Governor's office about our concerns and opportunities to ensure a balanced approach to the legislation, including emphasis on the importance of using an expert advisory group to guide implementation and evaluation of the PMP and other regulatory changes. We will circulate that letter separately and soon so you can make determination about signing

on to that as well.

Please feel free to contact Bob Twillman at AAPM (btwillman@aapainmanage.org) or Rebecca Kirch at ACS (rkirch@cancer.org) with any substantive questions about the information in the letter, and contact Keysha Brooks-Coley at ACSCAN (keysha.brooks-coley@cancer.org) with questions about the federal legislative activities underway.

Thanks very much for your consideration. -- Rebecca

-

(See attached file: AAPM ACS Hydrocodone letter June 2012kbc-dw.docx)

Rebecca Kirch | Director, Quality of Life & Survivorship
National Home Office | American Cancer Society, Inc.
555 11th Street NW, Suite 300, Washington, DC 20004 | **cancer.org**
202.661.5725 | mobile: 202.277.5912 | fax: 202.661.5750

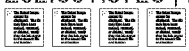

Exhibit 11

a1
a15

Managing Opioids in the Community Pharmacy Setting: Balancing Risks and Benefits

Background

Does it seem like you're seeing more opioid prescriptions than in the past? According to the Office of National Drug Control Policy, you probably are. In 2010, prescription opioid use in the U.S. translated into 693 mg of morphine per person. This compares to 369 mg per person in 2007. The country with the next highest use per capita is the United Kingdom, where each person used less than half the amount of their U.S. counterparts (335 mg) in 2010. And Canada has now surpassed the United States in per capita use of opioids. Compared to 693 mg of morphine per person in the U.S., in Canada this number is 753 mg.[1] To gain perspective on the magnitude of opioid prescribing, it's useful to consider how prescriptions for popular opioids stack up against other prescription drugs. In 2012 there were over 128 million prescriptions dispensed for hydrocodone/acetaminophen in the U.S., compared to around 98 million prescriptions for levothyroxine.[2]

removed

With the large quantities of opioids in circulation, prescription drug abuse is at epidemic levels. About 8 million people in the U.S. age 12 and older are using prescription drugs for nonmedical reasons.[3] Drug overdoses are the leading cause of death in 29 states...and this overlaps with the spike in *OxyContin*, *Percocet*, and *Vicodin* abuse.[4] The misuse and abuse of prescription drugs costs the country an estimated $53.4 billion a year in lost productivity, medical costs, and criminal justice costs.[4] Deaths from opioid overdose have more than tripled in the past 20 years... 100 people in the U.S. die from drug overdoses every day.

In Canada, the 2012 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) reported that abou 410,000 Canadians admitted abusing psychoactive pharmaceuticals in the past year, more than double th number in 2011. And about 1 million Canadian youth, aged 15 to 24 years, reported having used a psychoactive drug in the past 12 months, with over 20% admitting to abusing them.[5] Deaths from overdoses in Canada now greatly outnumber deaths from HIV and most of the overdoses involve opioids.

removed

On the other hand, chronic pain is extremely common and often requires opioids for management. In the U.S. there are approximately 26 million patients with diabetes, 23 million with coronary artery disease or stroke, and 12 million with cancer, but about 100 million with chronic pain...more than cancer, diabetes, and heart disease combined![6]

Added line ba

Prescription Drug Abuse

Just about every pharmacist has a story to tell about being duped into dispensing an opioid to an abuser. It's human nature to resent being conned, and most pharmacists try hard to avoid dispensing opioids to con artists and abusers.

In fact, the problem of diversion and abuse is so prevalent that pharmacists often look askance at any patient with an opioid prescription.[7] The desire to avoid being conned sometimes becomes a larger focus than the call to provide relief from pain and suffering.

Slide 1

a1 All sections in red should be removed.
All sections that mention Canada should be removed

anelson, 5/25/2015

a15 all sections in Red should be removed
anelson, 5/25/2015

Pharmacists are often the last line of defense against prescription drug abuse. They need to be diligent to prevent abuse and diversion, but to do so in a manner that doesn't unnecessarily restrict access for patients who need pain relief. In addition, it's important to identify patients who may be addicted so they can get appropriate treatment. Addicted patients are adept at concealing their problem, while rationalizing and minimizing it. Family and friends often fear getting involved. Even when the patient agrees to get help, addiction treatment is challenging. Addiction is a chronic disease with no lasting easy cure. Even when a patient is in recovery, it's precarious, and relapse is a constant danger.

People from all walks of life suffer from pain. Many times individuals suffering from pain do not look their best, and can "look like an abuser." They may not speak or respond fluidly, and may "sound like an abuser." This makes it challenging to sort abusers from legitimate patients in pain.

If abuse is suspected, pharmacists may give the patient a harder time and/or refuse to fill their prescriptions. Often pharmacists also send word out to other pharmacies so when the patient enters the other pharmacy the patient is immediately "labeled" as an abuser.

removed

Striking the right balance between not contributing to prescription drug abuse and ensuring patients receive medically necessary pain management is a constant struggle. To do so requires an understanding of pain, pain treatment guidelines, the definitions of addiction and related conditions, the legal and regulatory constraints related to opioids, and the practical application of all these considerations.

Amanda is 23 years old and comes into your pharmacy every month to get her opioid prescription filled. Amanda says she's a student at the local university and is being treated for chronic back pain. Amanda seems to always drop off her prescription the hour before you close and is impatient if you can't fill it right away. She usually comes in with a "rough looking" male friend.

How do you assess Amanda's case? What things about her behavior, her dress, or her friends cause you to judge her and her need for chronic opioid therapy? Are you certain these judgments are accurate or appropriate?

Chronic Pain

Chronic pain, defined as pain that persists beyond normal tissue healing time, is a complex condition.[8,9,10] This is attributed to both the variability and subjectivity of pain itself, and to the social, legal, and economic aspects of pain treatment.[8] The costs are staggering. It's been estimated that almost $100 billion dollars is spent annually to treat chronic back pain in the U.S.[10] The cost to patient quality of life is also significant. Chronic pain has been described as "the most frightening, the most humiliating, and the most difficult ordeal" of one's life.[11] It is important that pharmacists focus on helping patients gain appropriate pain relief.

Pain is a widespread problem:[11,1,1]

- Up to 75% of cancer patients suffer pain.
- Up to 50% of cancer patients have moderate to severe pain.
- One in three cancer patients has severe pain.
- Over two-thirds of nursing home residents experience serious chronic pain.
- Around one in six adults experiences chronic pain.
- The elderly, minorities, women, and children have higher rates of undertreated pain than others.

In addition to cancer-related pain, many patients experience chronic pain secondary to other causes. Chronic noncancer pain includes back pain, fibromyalgia, headache, and osteoarthritis.[10]

Pain Management Terminology

Health care professionals and non-professionals often perpetuate myths and misconceptions about the use of opioid analgesics. Pharmacists can prevent misunderstandings by understanding and using the correct terminology.

Aberrant drug-related behavior: Any medication-related behaviors that depart from strict adherence to the prescribed therapeutic plan of care. Aberrant drug-related behavior covers a great deal of territory and can include anything from requests for early opioid refills to hoarding opioids, to selling prescription opioids on the street.

Addiction: Addiction is a primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following:

- impaired control over drug use (can't stop despite the intention to)
- compulsive use (e.g., chain smoking)
- continued use despite harm (e.g., driving while drunk or high)
- craving (always thinking about using the drug)

Addiction affects a patient's life...their job, family, relationships, etc. This term is not interchangeable with "tolerance." Many addicts do develop tolerance to their chosen drug, but this is expected with regular use.[8]

Diversion: Diversion is the redirection of a prescription drug from its lawful purpose to illicit use; whether or not there is criminal intent.

M**isuse:** Misuse is defined as the intentional or unintentional use of a medication other than as directed. It can include a patient taking more pain medication than prescribed to control inadequately controlled pain, or using an opioid prescribed for pain for insomnia, or to feed an addiction.

Psychological dependence: Psychological dependence is defined as a sense of "need" for a specific psychoactive substance, either for its enjoyable mental effects or to avoid negative effects such as withdrawal symptoms.

Physical dependence: Physical dependence is a state of adaptation that often includes tolerance and is manifested by a drug class–specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood levels of the drug, and/or administration of an antagonist. Physical dependence is a normal adaptation to the drug, reinforced by continued use.[8]

Substance use disorder: A substance use disorder is defined as a maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by a selection of the following symptoms, occurring within a 12-month period.
Mild: 2 to 3 symptoms; Moderate: 4 to 5 symptoms; Severe: 6 or more symptoms

- Recurrent substance use resulting in a failure to fulfill major role obligations at work, school, or home (e.g., repeated absences or poor work performance related to substance use; substance-related absences, suspensions, or expulsions from school; neglect of children or household).
- Recurrent substance use in situations in which it is physically hazardous (e.g., driving an automobile or operating a machine when impaired by substance use).

- Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance (e.g., arguments with spouse about consequences of intoxication, physical fights).
- Tolerance, as defined by either of the following:
    - A need for markedly increased amounts of the substance to achieve intoxication or desired effect
    - Markedly diminished effect with continued use of the same amount of the substance. (Note: Tolerance is not counted for those taking medications under medical supervision such as analgesics, antidepressants, anti-anxiety medications, or beta-blockers.)
- Withdrawal, as manifested by either of the following:
    - The characteristic withdrawal syndrome for the substance
    - The same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms. (Note: Withdrawal is not counted for those taking medications under medical supervision such as analgesics, antidepressants, anti-anxiety medications, or beta-blockers.)
- The substance is often taken in larger amounts or over a longer period than was intended.
- There is a persistent desire or unsuccessful effort to cut down or control substance use.
- A great deal of time is spent in activities necessary to obtain the substance, use the substance, or recover from its effects.
- Important social, occupational, or recreational activities are given up or reduced because of substance use.
- The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
- Craving or a strong desire or urge to use a specific substance.[12]

Tolerance: Tolerance is a state of adaptation in which exposure to a drug induces the need for an increased dosage to produce the same level of analgesia that previously existed. Tolerance is a physiologic alteration of metabolism (a change in how the body processes the drug).[8,12]

Remember that patients who are substance dependent (a term that can encompass addiction, substance abuse, and physical dependence) may experience severe pain unrelated to their dependence. Substance dependence should not be made an obstacle to treatment of pain.[13]

Keep in mind that patients may also need an increased dosage of their pain medication due to worsening of their disease. It's important to note these two different reasons pain medication dosages may be increased.

What are your pharmacy's policies concerning handling patients who may be addicted to opioids or possibly abusing or diverting opioids? How have you handled past cases where a patient appears to be addicted? How have you helped patients you've identified as potentially addicted?

Pain Treatment Guidelines

Cancer Pain: World Health Organization (WHO) Analgesic Ladder

The World Health Organization (WHO) analgesic ladder categorizes the treatment of cancer pain into three pain-intensity steps. The first step uses non-opioid analgesics for mild-to-moderate pain (e.g., acetaminophen, aspirin, NSAIDs). The second step uses a mild opioid (e.g., codeine) for pain of moderate-to-severe intensity, or pain that increases or persists despite therapy with a step-one agent. And the third step uses a stronger opioid (e.g., hydromorphone, morphine) for severe pain, or pain that increases or persists despite therapy with a step-two agent. The analgesic ladder also recommends around-the-clock dosing of analgesics and as-needed analgesics available for breakthrough pain.[13]

Around-the-clock dosing with a long-acting opioid (e.g., fentanyl transdermal patch, methadone, controlled-release formulations of opioids) with PRN doses of short-acting formulations (e.g., codeine, hydrocodone, morphine, oral transmucosal or buccal fentanyl, oxycodone, etc) for breakthrough pain provides consistent control of pain, improves adherence, and lowers the risk for addiction or abuse.[10,13]

Noncancer Pain

The American Pain Society and the Canadian National Opioid Use Guideline Group both recognize that there are research gaps and that evidence is weak supporting the use of opioid analgesics for the treatment of chronic noncancer pain. Most of the data that are available are from efficacy studies with highly selected patients and short-term follow-up. New research is focusing on longer-term follow-up and assessing the risks and benefits of specific therapeutic approaches (e.g., whether analgesic efficacy is maintained over time or whether quality of life is improved).[10,14]

Non-opioids should generally be maximized before opioids are tried. These include acetaminophen or NSAIDs for most types of pain; tricyclic antidepressants for neuropathic, back, or fibromyalgia pain; duloxetine or pregabalin for neuropathic or fibromyalgia pain; gabapentin for neuropathic pain; cyclobenzaprine for fibromyalgia; and topicals (e.g., lidocaine [*Lidoderm*, U.S. only], capsaicin, salicylates) for local neuropathic pain or arthritis.[15]

Available evidence supporting the effectiveness of opioids in reducing chronic noncancer pain and improving functional status for periods of six months or longer is variable. The choice of an opioid is based on pain severity. For mild to moderate pain, initial choices include codeine, tramadol (e.g., *Ultram*), and hydrocodone (U.S. only), but hydrocodone may have a higher abuse potential.[10,14] Consider using *Butrans* (buprenorphine) for patients who can benefit from a once-a-week patch for moderate pain.[16] Step-up therapy options include morphine, oxycodone, or hydromorphone. For severe pain, start with morphine, oxycodone, or hydromorphone, and reserve fentanyl or methadone as a step-up if necessary. Be sure that fentanyl patches and sublingual/transmucosal formulations are only used in patients who are opioid tolerant. Keep in mind that the quality of evidence is less for hydrocodone or methadone as next step options.[17] Also remember that methadone is difficult to titrate because it has a long half-life that can lead to accumulation.

Short-acting agents are probably safest for initial therapy.[29] Long-acting formulations can be used for maintenance to improve adherence and provide consistent analgesia.[10,29]

Guidelines for the treatment of noncancer chronic pain with opioid analgesics include a recommendation to assess the patient's risk for substance abuse, misuse, or addiction prior to starting chronic therapy. The benefits of chronic opioid use must be weighed against its risk. It's estimated that up to 60% of patients receiving opioids for chronic pain exhibit aberrant drug-related behaviors, drug abuse, and misuse.[10]

Whenever opioid analgesics are prescribed, check that the dose and drug selection are appropriate, especially for a patient who is just starting opioid treatment.

> How do you know if a patient is opioid tolerant? To be considered opioid tolerant, a patient must have used any of the following, or their dose equivalent, for at least one week:
>
> - Fentanyl 25 mcg/hr patch
> - Hydrocodone 60 mg/day
> - Morphine 60 mg/day
> - Oral hydromorphone 8 mg/day

Practical Points in Opioid Management

Opioid-related side effects create significant management problems. Of potential side effects, constipation is one of the most common. To prevent constipation, ensure opioid patients are taking an appropriate laxative (e.g., PEG, senna two tablets twice daily or bisacodyl 5 mg at bedtime plus docusate 100 mg to 200 mg daily).[18] Docusate should not be used alone. Only use it if hard stool continues to be a problem despite use of another laxative. Keep in mind that soft stool alone isn't enough for opioid patients. They also need to help move stool through the gastrointestinal tract.

Watch for potential drug interactions. Serotonergic drugs can increase the risk of seizures with tramadol. Combining opioids and benzodiazepines increases the risk of sedation, respiratory depression, cognitive impairment, overdose, and falls, especially in the elderly. Before starting an opioid, consider trying to discontinue benzodiazepines to reduce the risk of these adverse effects. One approach is to taper by 10% every one to two weeks until 20% of the original dose is reached. Then taper by 5% every two to four weeks.[14]

Also watch for CYP450-related interactions. CYP2D6 is involved in converting codeine, hydrocodone, and tramadol to active metabolites.[19,20] Several commonly used medications, including several antidepressants (e.g., fluoxetine, duloxetine, paroxetine) inhibit CYP2D6. Methadone interacts with CYP3A4 inhibitors and inducers and also appears to be affected by interactions mediated through CYP2B6. Oxycodone levels may be increased with CYP3A4 inhibitors such as clarithromycin, ketoconazole, and ritonavir and decreased with CYP3A4 inducers such as carbamazepine, phenytoin, rifampin, and St. John's wort. For drugs that may affect oxycodone and other opioids, see our *PL Chart*, *Cytochrome P450 Drug Interactions*.

If an opioid isn't helping or the patient complains of intolerable side effects, recommend switching to another opioid.[10] For help making the switch, see our PL Chart, *Equianalgesic Dosing of Opioids for Pain Management*. Keep in mind that methadone or buprenorphine may be useful when opioid-induced hyperalgesia (i.e., pain sensitization caused by chronic opioid use) is suspected. Other options for hyperalgesia include dose reduction or tapering and discontinuation, with the addition of non-opioid therapies.[21]

As a general rule of thumb, most chronic noncancer pain patients will not need more than 200 mg of morphine or its equivalent daily.[14] Encourage prescribers to re-evaluate therapy when patients reach a total daily opioid dose that is equivalent to 200 mg of morphine. The prescriber may need to reconsider the diagnosis, adequacy of pain control and functional improvement, adverse effects, and the possibility of misuse or hyperalgesia.[10,14]

Opioid Regulatory and Legal Issues

Have you had a patient you thought was abusing opioids who turned out to be a legitimate pain patient? How did this case make you change your view of opioid patients?

Known barriers to effective pain management include patients' misconceptions, non-adherence, and lack of communication; and health care professionals' inability to adequately assess pain, inadequate knowledge of pain management, and overestimated expectation of addiction or tolerance.[9] **Error! Bookmark not defined.**

Legal entities are concerned about impaired providers, those who are incompetent or fraudulent in their prescriptive practices and who might endanger patients, and those who prescribe controlled substances that can be diverted onto the street.[11] Activities undertaken to alleviate these concerns often discourage the provision of ethically and medically necessary care for patients who could legitimately benefit from treatment with opioid analgesics.[11]

Be mindful of the fraud and deception that surrounds the distribution of opioids, but make sure that this focus does not prevent appropriate therapy for appropriate patients. One good way to think about this is to put yourself in the patient's shoes. If you were suffering from pain, you would want relief as fast and as efficiently as possible. And if you were addicted to opioids, you might not like it initially, but ultimately you'd most likely be grateful that someone recognized your problem and took steps to help.

Protecting Your Patients and Yourself

Have you ever seen a forged prescription at your pharmacy? How was it handled? Has anyone ever diverted drugs from your pharmacy? What was done when they were found out?

Prescriptions for opioids and opioid/simple analgesic combinations are at an all-time high, yet the under treatment of treatable pain is a problem. These facts underscore the importance of the balance between careful management of opioids for pain relief and preventing their misuse and abuse.

Diversion of prescription drugs can happen anywhere from the manufacturing process to the patients they're prescribed for. Common techniques include doctor shopping, use of internet pharmacies, theft, prescription forgery, and illicit prescriptions by prescribers. More than half of the time, people who are using pain relievers for non-medical reasons get the drug for free from a friend or relative.[13] Doctor shopping appears to be the second most common source. Individuals don't always use the pills themselves, instead they may collect them to sell.[13]

Note that although this CE review focuses on the use of opioid analgesics, much of its content also often applies to other drugs of abuse such as stimulants (methylphenidate, etc) and CNS depressants (e.g., benzodiazepines, etc).

There's more pressure than ever on pharmacists to prevent opioid misuse and abuse, but identifying dishonest patients seeking opioids for abuse or diversion can be challenging. It's important to apply

criteria for identifying dishonest patients consistently and not allow biases based on race or socioeconomic status.

Universal Precautions

You'll hear the term "universal precautions" applied to opioid patient care.[22] Universal precautions originated as a concept designed to manage the risk of transmission of bloodborne infections when it's not possible to know who is infected. The assumption is that everyone IS infected, so everyone is handled as potentially infectious. In pain management, universal precautions refers to the assumption that all patients are at risk for using opioids inappropriately. As such, all patients should be assessed for misuse, abuse, and diversion. Ten steps are proposed in the opioid universal precautions approach:

1. Make a diagnosis and treat the underlying condition when possible
2. Perform a psychological assessment including an assessment for addictive disorders
3. Obtain informed consent
4. Develop a treatment agreement
5. Assess pain level and patient function before and after starting an opioid
6. Give an appropriate trial of therapy
7. Regularly reassess pain scores and functional status
8. Regularly reassess analgesia, activity, adverse effects, and aberrant behavior
9. Periodically reassess the diagnosis and assess for addictive disorders
10. Carefully document all evaluations

Using the universal precautions approach also requires categorizing patients as low-, moderate-, or high-risk for misuse, abuse, or diversion.[22]

Category 1 (low risk): No personal or family history of substance abuse, no major or untreated psychological disorders. Appropriate for treatment by their primary care provider.

Category 2 (moderate risk): Patients with a history of or significant family history of substance abuse, and/or past or comorbid psychological disorders. These patients are at higher risk for addiction and should be co-managed by their primary care provider and a specialist.

Category 3 (high risk): These patients have active substance abuse and/or addiction and may have a major untreated psychological disorder. Opioids should be avoided unless the patient has been sober for at least 6 months. Specialist care is strongly recommended when possible.

Pharmacists may get involved in a number of different ways. You may be part of the treatment agreement by performing pill counts, enforcing "no early refill" orders, monitoring to ensure the patient doesn't get opioids from other prescribers, or reminding patients that all their opioid prescriptions have to be filled at your pharmacy in order for them to stay compliant with the agreement. Another point of involvement is monitoring pain severity and functional status.

Monitoring the efficacy of opioid therapy previously focused primarily on findings from pain rating scales...the "on a scale of 0 to 10 how bad is your pain" approach. More recently monitoring has added functional status because, as an objective measure, it complements subjective pain assessments. Using an objective function-based monitoring parameter can also help sort out patients using their meds appropriately from those who aren't.

Typically, functional goals are set by determining key activities a patient finds their pain restricts them from performing. The goal should be a significant and realistic improvement in the patient's ability to perform the activity. Functional treatment goals should be specific, achievable, objective, and measurable. For example, being able to walk up a flight of stairs without stopping or being able to work at a desk for 3 hours are functional treatment goals. This subtly shifts the focus of therapy to improving quality of life instead of eliminating pain. Patients may question why you're focusing on their daily activities instead of

their pain, so it's important to educate them about realistic goals. Explain that their ability to perform daily activities is the ultimate goal, not eliminating their pain.

Monitoring for Misuse/Abuse/Diversion

Health care professionals all share in the responsibility for combating prescription drug abuse and diversion. Pharmacists are legally responsible for not knowingly dispensing prescriptions not issued in the usual course of professional treatment.[23]

Remember that the quantity of drugs prescribed and frequency of prescriptions filled are not, by themselves, indications of fraud or improper prescribing. This is especially true if a patient is being treated with opioid analgesics for pain management.[23] There's no "ceiling" opioid dose, where going above that dose should raise suspicion about abuse; however, there are other warning signs to stay alert for.

The Controlled Substances Act of 1970 permits pharmacists to dispense controlled substances when bona fide prescriptions are issued by practitioners authorized to prescribe controlled substances. Pharmacists who are familiar with these regulations are the most successful in complying. If you need more information, see the Controlled Substances Act and your state's laws on the use of controlled substances and pain management.[24]

a5

Watch for red flags such as patients who pay cash only for their opioid prescriptions or demand certain brands, frequent early refill requests, nonlocal prescribers or patients, doctor or pharmacy shoppers, inappropriate dosing, prescriptions outside the scope of practice of the prescriber, the patient's only prescription is an opioid or that's the only prescription they seem to be taking, patients presenting with several prescriptions at once that make no therapeutic sense (e.g., *OxyContin* and methylphenidate), etc.

Red Flags for Potential Opioid Misuse and Abuse

- Cash only customers
- Demands for certain brands
- Frequent early refill requests
- Nonlocal prescribers
- Nonlocal patients
- Doctor shopping
- Pharmacy shopping
- Inappropriate dosing
- Prescriptions that are outside the scope of practice of the prescriber
- Opioids seem to be the only prescription a patient is taking
- Patients with a constellation of prescriptions that don't make therapeutic sense

a7

A red flag is not a stop sign. But it can help you screen for abuse or diversion and delve deeper if needed. Talk to the patient, but avoid letting your own personal biases enter into the assessment. Ask patients about their symptoms, what they've tried, and what the prescriber told them. Keep in mind that you're looking for trends. One or two isolated red flag incidents isn't a trend. Realize there are behaviors that make you think twice, but are not as likely a sign of a serious abuse/misuse problem, such as aggressive complaining about pain and the need for medication, requests for a specific drug, limited duration unsanctioned dose escalations, hoarding pills, misusing a drug to treat a different sy drinking more alcohol when in pain.

After this paragraph we will be able to link out to the NABP red flag consensus document- Yeah!

Slide 9

a5 remove the box with Canada information- that is in the CE with questions.
anelson, 5/25/2015

a7 we would like to add a link that will go to the NABP red flag consensus guide - possible link out to a PDF.
NABP just created a guide in march 2015 of the challenges and "red flag" warning related to Prescribing and dispensing of control substances
anelson, 5/25/2015

The other side of the coin is behaviors that are more likely to point to addiction such as buying medicines from someone else, stealing money to pay for medicines, trying to get opioids from more than one prescriber, or forging prescriptions.

Don't underestimate the value of other approaches to curbing opioid abuse. Simply asking a pain patient about their pain can be very instructive both for monitoring progress and determining whether there's an abuse problem. A legitimate pain patient should, without pause, be able to point to where their pain is, explain what makes it better or worse, describe where it moves to and when, describe what they've tried in the past and how well it worked, describe adverse effects they're experiencing, tell you whether the pain comes and goes or is constant, how severe it is, and whether it's affecting their day-to-day life or their ability to sleep. If the answers don't add up or there are a lot of pauses, as if searching for an answer, then your radar should go off and you should explore the situation more deeply.

The U.S. Drug Enforcement Administration (DEA) cites the following as criteria that may indicate a prescription has not been issued for a legitimate medical purpose:[23]

- The prescriber writes significantly more prescriptions (or in larger quantities) compared to other prescribers in your geographic area.
- The patient is asking for refills too soon.
- The prescriber writes for antagonistic drugs, like depressants and stimulants (e.g., "uppers" and "downers"), at the same time.
- The patient presents prescriptions written in the names of other people.
- A number of people simultaneously appear, or within a short period of time, with similar prescriptions from the same prescriber.
- Numerous people who are not regular patrons or residents of your community suddenly show up with prescriptions from the same prescriber.

We need to keep this in the CE but he said that he would make it very small and put it wherever we wanted even the end. No wiggle room on this one.. I will explain when I talk to you

a8

Another resource to help pharmacists when they feel uncomfortable about dispensing a prescription is VIGIL (verification, identification, generalization, interpretation, and leg goal of this system is to shrink that gray area between legitimate and fraudulent opioid establish a set of standardized rules for opioid use based on a collaborative approach be the health care team.[25]

Step 1: Verification – The prescriber determines whether the patient can use the medication responsibly. The pharmacist verifies the prescription with the prescriber including what the medication is being used for.

Step 2: Identification – The individual receiving the opioid must produce government-issued identification, which is photocopied for pharmacy records.

Step 3: Generalization – Establish parameters for the provider-patient relationship. This can include pain management agreements where the provider acknowledges their responsibilities for treatment and the patient acknowledges their responsibility for handling controlled substances.

Step 4: Interpretation – This is the step where the pharmacist decides whether or not to fill the prescription. The decision may be helped by the patient's responses on one of the various questionnaires used to help predict the likelihood of abuse (e.g., Opioid Risk Tool, COMM, etc). In addition, the patient or a family member may be asked to keep a diary of the influence of the medication on the patient's behavior.

Step 5: Legalization – The health care team follows legal requirements for treating patients with opioids, including regular physical exams and discussion of risks and benefits of opioids.

Slide 10

a8 Remove Canada's drug strategy box in CE

also remove VIGIL- remove all the red highlight section
anelson, 5/25/2015

What questions do you ask yourself when presented with an opioid prescription? Which do you find most useful when trying to uncover addiction?

Monitoring for forged prescriptions is a daily challenge. Legitimate prescriptions for appropriate patients are likely to have the security features on the written prescription, as required by your state. Check for them.

Prescription forgery may include:[23]

- Altering a prescription
- Writing fake prescriptions (for real or fictitious patients) on stolen or fabricated prescription pads
- Calling pharmacies for prescriptions without authorization from the prescriber

DEA cites the following as potential characteristics of forged prescriptions:[23]

- Prescription looks "too good," the prescriber's handwriting is too legible
- Quantities, directions, or dosages differ from the usual medical usage
- Prescription does not comply with the acceptable standard abbreviations or appears to be a textbook presentation
- Directions written in full with no abbreviations
- Prescription written in different color inks or written in different handwriting
- Apparent erasure marks

Have you ever identified a forged prescription? What tipped you off?

a11

validating DEA Numbers

We have to keep this one in as well for CE – again we can make it smaller in font he said and move it

A survey of pharmacists showed that one in four does not regularly validate the prescriber's DI when dispensing a controlled drug. One in ten pharmacists say that they rarely or never validat prescriber's DEA number.

Some pharmacy computer systems will check the DEA number for you. But, here's a refresher validating DEA numbers, in case you need to do it by hand:

- The DEA number always has nine characters. The first two characters are letters, and the last seven are numbers.
- The first letter is always A, B, F, G, M, or X. There are no numbers left that start with A or B, as all possible numbers have been assigned, so F has been added as a possible first letter and G is now being used for prescribers who are contractors with the Department of Defense. Prescribers with a Drug Addiction Treatment Act (DATA) waiver will have DEA numbers that start with X. Mid-level practitioners' (physician assistants, nurse practitioners, etc) DEA numbers will start with M.
- The second letter of the DEA number is the first letter of the prescriber's last name (unless a prescriber has married and changed last names).
- Here's how to verify that a DEA number is authentic:
  - Add the first, third, and fifth digits together.
  - Add the second, fourth, and sixth digits together. Multiply this number by 2.
  - Add these two results together. The last digit on the right must match the last digit of the DEA number.

Get our *Technician Tutorial, Dispensing C-II Controlled Substances*, for additional tips.

Slide 11

a11 Remove how to validate DEA numbers- our system does that already and we do not want to have this in the CE.

Also in CE there is a box with Canada info- remove that section
anelson, 5/25/2015

Note that the requirement for registration with DEA is waived for Public Health Service or Bureau of Prisons officials and military physicians who prescribe, dispense, or administer, but do not procure or purchase, controlled substances in the course of official duties. These individuals must indicate their branch of service or agency along with their service identification number in lieu of a DEA number, when required on prescriptions. These prescriptions may be filled off base at community pharmacies.[26]

Prescription Drug Monitoring Programs (PDMPs)

The purpose of these programs is to reduce prescription drug abuse and diversion. States, not the DEA, run these programs. Pharmacists and dispensing prescribers may be required to report the controlled substances they dispense. Usually, only outpatient prescriptions must be reported, but the specifics vary by state. The drugs that are reported also vary depending on the state. Some states allow access to prescription monitoring programs in other states. In addition, health care professionals may only be able to access data for patients that are currently under their care. See the *PL Chart, Prescription Drug Monitoring Programs*, for information about the program in your state.

The information available through prescription drug monitoring programs and requirements for use vary by state. However, most reports will indicate the drug prescribed, the date prescribed, and the date filled. Some states are more comprehensive and also include information on the prescriber and filling pharmacy. This is useful so you know who to call if there are questions or a conflict between what the patient is saying and the report is showing.

Prescription payment information is included in some reports. This is useful to identify patients who may be doctor- or pharmacy-shopping. Patients who are doing this have figured out how to beat the pharmacy computer system by using their insurance card at one pharmacy and paying cash at another pharmacy. If a monitoring report is run prior to prescribing or dispensing an opioid, these "shoppers" can be caught and re-evaluated to determine their need for these medications.

The DEA reports that PDMPs do discourage drug diversion and the states that have implemented these programs report decreases in abuse and diversion of the drugs they're monitoring, and fewer patients entering treatment for opioid abuse. In addition, pharmacists that use these programs report that they feel more confident when dispensing controlled substances.[27]

Whom To Call and When

If in doubt about an Rx, call the prescriber. Keep in mind that individuals who forge prescriptions might give their own phone number or a friend's as a call-back number for confirmation. Instead, use your computer system, directory assistance, or a telephone book to find the number of the prescriber or clinic listed on the prescription.

When calling, do not let the patient overhear. Checking up on patients can be humiliating to legitimate patients in need of pain relief. They are suffering already. Do not add to their pain. If the Rx turns out to be fraudulent, there is also no need for the person to overhear how you operate. This could also make the patient agitated and they could threaten you or other pharmacy staff.

If you need to get proper identification from a patient presenting a prescription for an opioid, remember to do so professionally and in a manner that does not allow the patient to feel like a suspect. Be sure to follow your company's policy when requesting identification. If you believe that you have a forged, altered, or bogus prescription, follow company policy when deciding whether to call the police. If you suspect a pattern of prescription abuse, contact your state board of pharmacy or your local DEA office.[23]

Note that the requirement for registration with DEA is waived for Public Health Service or Bureau of Prisons officials and military physicians who prescribe, dispense, or administer, but do not procure or purchase, controlled substances in the course of official duties. These individuals must indicate their branch of service or agency along with their service identification number in lieu of a DEA number, when required on prescriptions. These prescriptions may be filled off base at community pharmacies.[26]

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a12

Food for thought...how would you maintain **good patient care and customer service** in the following

- You suspect a forged prescription, but are not 100% sure:
  - Call the prescriber after finding the number in an independent source such as the phone director
  - Look in your patient records for prior use.
  - Respectfully and privately, ask the patient several questions, such as how the drug is working, l pain is, what the doctor said about using the pain medication, does this one work as well as othe medications, and other questions that are likely to help you assess whether this is an appropriate
  - Document your efforts in your records.
  - If there is no obvious reason to refuse filling, dispense it.

- A long-time patient appears to have altered a prescription:
  - First talk with the patient. Give them a comfortable out.
  - Explain that the filling process flagged the Rx as being somewhat different than the doctor intended.
  - Don't accuse the person of any wrongdoing, and don't even say what the change might be. Explain that if any Rx goes into your process with any change on it that both you and the patient can have big problems.
  - Hand the Rx back to the patient and suggest that he or she take it back to the prescriber to get it worked out.
  - Document everything in your system.

- You are presented with a forged prescription, during a very busy time, when there are several patients in the vicinity:
  - If you are positive that you have a fraudulent Rx one method to discourage repeat offenders is to take the Rx behind the counter as if you are going to fill it and then tell the person it will be about an hour because some authorities are coming over to inspect the Rx. When an offender hears this, he or she is likely to make a quick exit. Other patients probably won't even pick up on the incident going down.

- A patient becomes angry about your refusal, or inability due to insurance limitations, to fill a prescription for an opioid analgesic, during a very busy time, when there are several patients in the vicinity:
  - First keep in mind that this might be a situation where an appropriate patient, who is likely in pain, is supposed to get an Rx to alleviate the pain. Don't treat this patient differently just because the Rx is for an opioid.
  - Talk with the patient. Find out if they have other pain meds they can use until the problems can be resolved. Ask if they are in pain at the moment.
  - If needed, work with the prescriber to get a different Rx that is covered. If needed use our *PL Chart, Equianalgesic Dosing of Opioids for Pain Management.*
  - Try to take the patient to a somewhat private area to hold a respectful, private conversation. Offer for them to go home and discuss with you by telephone, which can be more private and at a more appropriate time for both of you.
  - Do your best to get a painkiller that is covered for the patient. Let the patient see that you are trying on his/her behalf.

Removed red part and he loves the PERC information. I need to send him the meaning of each letter and he will create a separate section and extenuate this part

Slide 13

a12 Remove Canada box in CE and remove red highlighted section

What we would like to do with the Food for thought area is add in "PERC" and how to have the converstion with the customer.

(P) Professional
(E) Engage in the converstaion
(R) Respectful
(C) Clear communication

I would add more language to each Letter in "PERC" . Remove red highlighted sections
anelson, 5/25/2015

Food for thought...addressing the "stigma":

Think back to the example of Amanda at the beginning of this course. What judgments did you have about her? Do any of these fall into the following "stigmas"?

- Do you assume that people who regularly fill prescriptions for opioids are abusing or selling drugs?
  - Assumptions about the appropriateness of opioid prescriptions should not be made based on quantity of drug prescribed or frequency of filling alone.
- Do you assume that people who look a certain way are MORE likely to be abusing prescription drugs?
  - Remember that patients who are in pain may not look their best.
- Do you assume that people who look a certain way are LESS likely to be abusing prescription drugs?
  - Likewise, just because a person is dressed nicely or well-groomed doesn't mean that he or she is necessarily less likely to have a forged prescription, or to be using prescription drugs for nonmedical purposes. Be vigilant with all patients.
- Would you be MORE or LESS likely to suspect a forged prescription if a patient were dressed in a certain way, or came from a certain geographic location, etc?
  - Don't make assumptions based on a person's perceived social status.
- Are you MORE or LESS likely to spend time counseling patients or offering information based on assumptions about their likelihood of misusing prescription drugs?
  - All patients who fill prescriptions for opioids should receive counseling about proper use of their medications, and have their questions addressed.
- Has anyone ever had an incorrect preconceived perception about you based on your looks, demeanor, dress, home location, or other factor? How did it make you feel?

Who's at Risk for Abuse?

Watching for warning signs and using good judgment can identify patients who have an abuse problem, but it can be supplemented with questionnaire-based assessment tools to help identify patients at risk.

CAGE-AID is a modification of the CAGE assessment tool you're probably familiar with to identify alcohol abuse risks. It uses the same four questions, but adds a phrase about drug use. A positive response to one question indicates a potential abuse problem that merits close monitoring. Two positive responses indicate probable abuse and the need for referral to an addiction specialist.[28]

CAGE-AID

1. In the last three months, have you felt you should cut down or stop drinking or *using drugs*?
2. In the last three months, has anyone annoyed you or gotten on your nerves by telling you to cut down or stop drinking or *using drugs*?
3. In the last three months, have you felt guilty or bad about how much you drink *or use drugs*?
4. In the last three months, have you been waking up wanting to have an alcoholic drink or *use drugs*?

NOTE: *Drug use* includes illegal drug use and the use of prescription drugs other than as prescribed.

Another tool that helps identify individuals at risk for opioid abuse is the Opioid Risk Tool. Pain patients categorized as high-risk using this tool have an increased likelihood of future drug abuse-related behavior. Patients categorized as low-risk are unlikely to demonstrate aberrant opioid behaviors.[29]

Opioid Risk Tool

		If yes… Female	Mal e
Family History of Substance Abuse?	Alcohol	1	
	Illegal Drugs	2	3
	Rx Drugs	4	3
Personal History of Substance Abuse ?	Alcohol	3	4
	Illegal Drugs	4	3
	Rx Drugs	5	4
Age 16 to 45 years?		1	5
History of Preadolescent Sexual Abuse?		3	1
Psychological Disease?	Attention Deficit Disorder, Bipolar, Obsessive Compulsive Disorder, Schizophrenia, Depression	2	0 2
	TOTALS	___	___

Total score risk category:
Low risk 0-3
Moderate risk 4-7
High risk ≥8

The Current Opioid Misuse Measure (COMM) is a questionnaire that can be administered to patients currently taking an opioid for chronic pain. Using this tool helps identify patients exhibiting behaviors associated with the misuse/abuse of opioids. It's important to realize that COMM is not a lie detector test. If a patient is determined to hide their behavior, they will be able to "trick" the questionnaire. It's important to take the entire clinical picture into account when assessing a patient's case. It's also important to understand that this tool is designed to over identify patients. You'll have positive scores in some patients who are NOT misusing or abusing opioids. That's one reason why you still need to look at the entire clinical picture and talk to the patient. You can sign up to access the COMM questionnaire at http://www.painedu.org.

What to do with the results

If a patient screens as high risk of developing a misuse/abuse problem or as having developed a problem already, suggest considering discontinuation of the opioid or continuing the opioid, but implementing strategies to improve the control over it. These patients require more monitoring to ensure that they don't develop aberrant drug-related behaviors.

It's important to understand that these screening questionnaires are only a tool, not an absolute truth. Regardless of family history or presence or absence of mental health concerns, patients on chronic opioids misuse them quite often, including purposely over sedating (24%), concurrently using alcohol (32%), self-up-titrating their dose (37%).[30] An estimated 3.3% of patients using opioids for chronic noncancer pain abuse them or are addicted to them. And this is probably an underestimate, especially when other aberrant behaviors are included.[14]

Strategies to improve control over drug use

- Pain management contracts
- Prescribing smaller quantities of drug and requiring more frequent prescriber visits
- Mandating the use of one pharmacy, instituting pill counts, and a policy of no replacement pills or early refills
- Urine drug screening

Pharmacist's Role in Pain Management

The American Pain Society encourages a multidisciplinary approach to improving the adequacy of pain management.[9]

Laws at the state and federal level say that clinicians must be responsible for the use and prescribing of analgesic medications. The regulatory risk is low with responsible use of opioid analgesics, when appropriate procedures are both followed and documented.[31]

Pharmacists play a key role in ensuring that patients get the pain medications they need, while at the same time ensuring that patients who don't need a pain medication don't get one. In general, the tendency is to overestimate the likelihood of abuse and undertreat pain. It's important for pharmacists to maintain a

balance between their enforcement role and that of education, monitoring, and reinforcing the need for proper opioid disposal.

Monitoring Therapy

When monitoring patients on opioids, keep in mind[8,9]

- Pure opioid agonists (e.g., fentanyl, hydromorphone, morphine, etc) do not have a "ceiling effect" or maximum dose where their efficacy plateaus. As the dose is increased, the analgesic effect increases. The degree of analgesia is limited by the extent of adverse effects.
- Partial opioid agonists and agonist/antagonists (e.g., nalbuphine) have a ceiling effect to the degree of analgesia they can produce.

Short-term side effects of opioids[8]

- constipation
- dizziness
- restlessness
- euphoria
- nausea
- itching
- respiratory depression
- sedation

Long-term side effects of opioids[8]

- constipation
- hyperalgesia or increased pain (a gradual increase in neural response to repeated stimulation, treated with NSAIDs or opioid rotation)
- negative hormonal and immune effects

Get our *PL CE, Pain Management: Keeping Opioid Patients Safe,* for help managing opioid-related side effects and our *PL CEs, Overview of Long-acting and Extended-release Opioids: A Risk Evaluation and Mitigation Strategy (REMS) Course* and *Opioid Rotation: Meeting Patients' Needs for Pain Control,* for more information on appropriate opioid dosing and the role of opioid rotation in pain management.

Patient Education

Patient education is important to help patients adhere to their medication regimens and maximize benefits.[31] In the same way that hypertension, heart failure, diabetes, and asthma are chronic diseases, so is chronic pain. Information that patients must understand includes the type of, and reason for, the analgesic medication that's been prescribed, information on how to use and titrate the medication, instructions on storage of the medication, who to call if their pain isn't relieved or if side effects occur, and information about nondrug approaches that might be useful for pain relief.[31] But this is just the tip of the iceberg. Work to develop relationships, so patients understand what a valuable resource you can be. A side benefit is that you'll also be able to more easily identify problems when they develop.

It's also important for pharmacists to help manage patient expectations by explaining reasonable and unreasonable goals and reinforcing the role of functional goals. When appropriate, reinforce the positive impact exercise, physical therapy, and adequate rest can have on pain.

Get our *PL Patient Education Handout,* Getting the Most Benefit of Your Pain Medication, to provide general information on pain medications, and to help prompt patient questions.

Drug Disposal

Help patients get rid of medications that they no longer need. Give them our *PL Patient Education Handout*, *Medication Disposal Guide* for tips on safely disposing of unwanted medications. Direct them to prescription medication Take-Back programs in your area or direct them to the DEA website for information on National Take-Back programs.

The FDA recommends mixing unwanted drugs with unpalatable substances, such as coffee grounds or kitty litter, and placing in a non-descript container before discarding in the trash. However, FDA requires that long-acting opioids be disposed of by flushing them down the toilet rather than putting them in the trash. Long-acting opioids that should be flushed include morphine (*Avinza*, etc), oxycodone (*OxyContin*), oxymorphone (*Opana ER*), hydromorphone (*Exalgo*), methadone, fentanyl transdermal, and others.[32] For a complete list, see How to Dispose of Unused Medicines.

a14

Get our patient handout to help encourage your patients to properly dispose of prescription drugs.

Reassure patients concerned about polluting the environmental by flushing opioid products. Explain that the main way drugs enter water systems in the environment is by people taking medications and then eliminating them naturally.[33] There's no evidence that flushing unwanted medications has a significant negative impact on the environment above what's already occurring from excreting ingested medications. In addition, there's no evidence that drug residues in the environment have adverse health effects. However, FDA doesn't want to needlessly add to drug residues in water systems, so they've limited the list of flushable meds and continue to monitor and revise the list as necessary.

Conclusions

Dispensing opioid analgesics involves a challenging balancing act for pharmacists. The pressure to prevent misuse, abuse, and diversion is ever increasing, yet there are still many patients with poorly controlled pain. It's important for pharmacy professionals to develop a systematic approach for evaluating the validity of opioid prescriptions. Tools developed to help predict which patients have a greater likelihood of misusing or abusing opioids are helpful for prioritizing patients to monitor more closely. Prescription Drug Monitoring Programs can also help achieve balance in managing opioids.

Beyond identifying misuse and abuse, managing appropriate pain control provides a huge opportunity for pharmacists to make contributions to patient care.

See what your colleagues are doing about new policies being put into place that ban the dispensing of a long-acting opioid when a patient isn't getting an immediate-release opioid or start your own conversation at *PL Colleagues Interact*.

Slide 18

a14 Remove section with Canada info
All canada sections should be removed.
anelson, 5/25/2015

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Exhibit 12

IN THE CIRCUIT COURT OF THE SIXTH JUDICIAL CIRCUIT
IN AND FOR PASCO COUNTY, FLORIDA

STATE OF FLORIDA, OFFICE OF THE ATTORNEY GENERAL, DEPARTMENT OF LEGAL AFFAIRS,

Plaintiff,

v.

PURDUE PHARMA L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS INC., JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, CEPHALON, INC., TEVA PHARMACEUTICALS USA, INC., ALLERGAN FINANCE, LLC, ACTAVIS PHARMA, INC., ACTAVIS LLC, INSYS THERAPEUTICS, INC., AMERISOURCEBERGEN DRUG CORPORATION, CARDINAL HEALTH, INC., MCKESSON CORPORATION, MALLINCKRODT LLC, WALGREEN CO., CVS HEALTH CORPORATION, and CVS PHARMACY, INC.,

Defendants.

Case No. 2018-CA-001438

Expert Report of Matthew Perri III, BS Pharm, PhD, RPh

July 29, 2021

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INTRODUCTION

1. I was retained on behalf of the State of Florida to evaluate the record and ascertain the nature of Defendants' opioid marketing activities, and its impact on the prescribing and use of opioids in Florida.[1] This Report provides a detailed summary of my methodology, findings, and conclusions.

QUALIFICATIONS

2. My name is Matthew Perri III. I received my Bachelor of Science in Pharmacy from Temple University in Philadelphia, Pennsylvania in 1981. In 1985, I obtained my Doctor of Philosophy, with a dual concentration in Pharmacy and Marketing, from the University of South Carolina. I have held academic and administrative positions at the University of Georgia, College of Pharmacy, since 1985.

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[1] "Defendants" is used throughout this Report to refer to the manufacturing defendants, Teva, Endo and Allergan, and their related families of companies. I recognize business activities (e.g., mergers and acquisitions, licensing, divestments, and joint marketing activities) may impact ownership of the various entities for specific time periods; however, my focus is on product marketing not withstanding which Defendant owned a product at a point in time. Further, because of the impact all opioid manufacturers had on the marketing environment, including "spillover" effects, this report will refer in some instances to manufacturers not a party to this litigation.

A spillover arises when a marketer's action affects either an unintended audience, or the targeted audience, in an unintended manner. (Desiraju and Tran, Chapter 23: Spillovers and Other Externalities in Pharmaceutical Marketing, pp.673-700. In, M. Ding et al. (eds.), *Innovation and Marketing in the Pharmaceutical Industry.* International Series in Quantitative Marketing 20, DOI:10.1007/978-1-4614-7801-0_24, © Springer Science+Business Media New York 2014.)

Spillover effects are integral to marketing in that these effects are part of the internal and external marketing environment. For pharmaceuticals, Information disseminated in the marketplace by one firm educates *all* Customers about a company's product, but also the disease, and its treatment. This creates a spillover effect on Customers and competitors who are exposed to these efforts. Spillover impacts external (e.g., marketing, advertising, and promotion) and internal efforts (e.g., research and development, ideas, information, or patient outcomes). For example, a company's educational efforts aimed at improving patient outcomes through medication adherence (and to ensure more consistent product sales for the company) may benefit both the company (the marketer), competitors who may also see increased sales, and patients who may experience improved health.

3. I am Professor Emeritus in the Department of Clinical and Administrative Pharmacy at the University of Georgia College of Pharmacy. Over the last three decades I have been a member of the Graduate Faculty, Adjunct Faculty of Gerontology in the College of Public Health, and served as the Director of the Pharm D / Master of Business Administration (MBA) dual degree program. I am an invited member of the University of Georgia Teaching Academy where the University's best teachers are recognized for their contributions to education.

4. I have taught graduate and undergraduate courses in pharmaceutical and health care marketing, research methods, statistics, literature evaluation, health care systems, pharmacy management, patient communications, and pharmacy practice skills. Some of these courses have attracted students from the School of Public Health, the Terry College of Business, and the College of Education.

5. I have published articles in peer-reviewed journals such as Medical Care, Journal of Health Care Marketing, Health Marketing Quarterly, Value in Health, and the Journal of Health Communication. I have served as a peer-review referee for more than two dozen academic journals such as the Journal of Advertising, Clinical Therapeutics, Health Marketing Quarterly, the Journal of Health Care Marketing and Management, and Medical Care. I have also published articles written for health care professionals in professional publications such as Pharmaceutical Executive, Southern Medical Journal, Drug Store News, and The Consultant Pharmacist.

6. I have made numerous presentations to audiences including academicians, researchers, industry professionals, policy makers, healthcare professionals, civic organizations, and consumer groups. Many of these were peer-reviewed or invited presentations. I was also the invited keynote speaker at the Emory School of Medicine conference on

Geriatrics where I spoke on strategies to help physicians understand pharmaceutical marketing.

7. I have authored two books, Pharmaceutical Marketing and Financial Analysis in Pharmacy Practice, as well as book chapters, and monographs on topics related to marketing, management, and clinical pharmacy care.

8. I have conducted extensive original research as principal, co-investigator, or consultant related to pharmaceutical marketing and related policy analyses. My recent research includes two, multi-year grants from the National Institutes of Health (NIH) and the Substance Abuse and Mental Health Services Administration (SAMHSA). The NIH grant investigated the effects of Medicaid prescription drug benefit program policy changes on patient outcomes, including death, in the Medicaid population.[2] The SAMHSA grant was a training project that aimed to provide skills to pharmacists, social workers, psychologists, and other health professionals to proactively recognize patients who may be at higher risk for health problems due to substance abuse.[3]

9. I have been involved with various non-paid national and state service and consulting activities including, for example, longstanding work with Georgia Medicaid Drug Utilization Review Board,[4] service on the Boards of the Association for Marketing and Health Care Research, the Medical College of Georgia / Blue Cross Blue Shield Center for Healthcare Improvement, and the Board of Regents Drug Utilization Review

[2] Opioid Prescribing in Medicaid: Healthcare Utilization and Deaths from Overdose. Grant No: 1R01DA039930-01A1 2016-2019; $675,000 National Institutes of Health (NIDA), Principle-Investigator.

[3] UGA SBIRT Inter-Professional Training Program, Grant No: 1H79T1026457-01, 2016-2019; $851,016 Department of Health and Human Services, Co-Investigator.

[4] I was a Board member (2001-2012) and Chair (2004-2010) of the Georgia Department of Community Health, Drug Utilization Review Board (DURB). I was reappointed to the DURB in October of 2018. The DURB, which serves GA Medicaid, composed of pharmacists, prescribers, and patient advocates, is responsible for recommending the drugs listed on the State's preferred drug list for all State-funded health plans.

Committee.[5] I have also served as a consultant to the Georgia Senate Committee on Cost Controls in State Funded Health Plans. I have been an invited participant to the National Consumers League workshop on direct-to-consumer prescription drug advertising, and to the Agency for Healthcare Research and Quality/U.S. Food and Drug Administration "Think Tank" on current issues and future research agenda for the marketing and advertising of prescription medications.

10. I have been a paid marketing consultant to organizations, including hospitals and long-term care facilities, independent marketing research companies, pharmacy organizations, pharmaceutical companies, and chain and independent pharmacies. My consulting activities have also included work with the U.S. Department of Justice, Attorneys General for various states, and private attorneys in litigation related to the marketing and use of pharmaceutical products.

11. I have been a registered pharmacist since 1981 and am currently licensed to practice pharmacy in Georgia and South Carolina. In addition to my work as a community pharmacist since 1981 (Schedule 1), from 2002 until 2019, I served as a part-time volunteer pharmacist at the Mercy Health Center, an independent, not-for-profit, comprehensive health center. I am currently a member of the UGA Medical Reserve Corps where I volunteer my time to support community health.

12. Before becoming a registered pharmacist, I worked as a pharmaceutical sales representative for a multinational pharmaceutical company.[6]

[5] I currently Chair the Board of Regents Drug Utilization Review Committee.

[6] In 1979 and 1980, I was a Pharmacy Student Sales Representative (PSSR) for the Dome Division of Miles Laboratories. In this position, I was trained and detailed a line of dermatological products to dermatologists, obstetricians, gynecologists, and general practitioners. The PSSR program was a work-coop program, between Temple University School of Pharmacy and the Dome Division of Miles Pharmaceuticals.

METHODOLOGY

13. In my analysis of this case, I applied my education, training, and experience in teaching, research, consulting, and clinical pharmacy to formulate my opinions. My perspectives on pharmaceutical marketing are based on my marketing education and work in pharmaceutical marketing, including research, writing and publishing, consulting, teaching, and training of doctoral level graduate students, many of whom currently work in the pharmaceutical industry. I have subjected my research and conclusions regarding marketing issues to peer-review on numerous occasions.

14. I applied generally accepted principles of marketing to evaluate Defendants' marketing focused on the marketing mix variables (price, place, product, and promotion), and Defendants' marketing segmentation, targeting, and positioning strategies and tactics. Using this framework, I identified marketing behaviors and assessed the significance of these behaviors.

15. Specifically, I was asked to assess the significance, if any, of Defendants' marketing related to prescription opioids, particularly with respect to the state of Florida. This was the overarching research question and problem to be addressed in this case. In this regard, I was also asked to address the following questions:

- What is pharmaceutical marketing?
- What are the basic standards or rules that the companies which market prescription opioids should follow?
- What have been Defendants' marketing strategies with respect to prescription opioids?
- How have marketing strategies been implemented and marketing messages disseminated by Defendants with respect to prescription opioids?

- What have been Defendants' messages, frequency, and reach?
- What has happened because of opioid marketing?
- What remedial actions might be undertaken with respect to opioid marketing?

16. I used case study methods, grounded in marketing principles, to conduct an in-depth, empirical investigation into Defendants' marketing behavior. Marketing literature, in addition to my education, training and experience, was relied on to identify and operationalize the relevant set of marketing behaviors to be studied.[7] I systematically assembled and articulated information (data collection, analysis, and interpretation[8]) related to each Defendants' marketing activities.[9] These methods are used and relied upon by experts in marketing.

17. The case study approach is appropriate for this research for several reasons. First, Defendants' marketing must be examined in a real-world context to understand the practical aspects of it, and case study methods are ideal for this purpose.[10] In addition, the case study methodology is appropriate for this analysis because in many forms of research, control over subjects is required and that is not possible here. Further, an extensive body of literature exists related to pharmaceutical marketing which provides a

[7] Operational measures of marketing behaviors were adopted from basic marketing principles, lending enhanced construct validity to the case study. (See, e.g., Yin 2004 *infra*.)

[8] The interpretation of the data developed in a case study can also be described as inductively inferring meaning to the data.

[9] The unit of analysis was the individual company.

[10] See, e.g., related to the case study method, *Case Study Research Design and Methods*, Second Edition, Robert K. Yin, Sage Publications, 2004; Charles Schell, The Value of the Case Study as a Research Strategy, Manchester Business School, January 1992, available at http://www.psyking.net/HTMLobj-3844/Value_of_Case_Study_as_a_Research_Strategy.pdf (last accessed June 18, 2020); Yin, R. The Case Study Crisis: Some Answers. Administrative Science Quarterly, March 1981;26:58-65; David, D. Case Study Methodology: Fundamentals and Critical Analysis. Cognition, Brain, Behavior, 2007; 11:299-317; Gerring J. What Is a Case Study and What Is It Good For? American Political Science Review, May 2004; 98,2:341-354.

theoretical basis for explaining the impact of opioid marketing on the medical community. Finally, case study methods utilize the same rigorous research tools to ensure reliability, internal and external validity, and conclusions about causality as other research methodologies.[11] [12] These considerations validate the use of case study research to answer the questions posed in this matter. Finally, the case study method is widely accepted and utilized for research in, for example, education, business, and marketing applications, as well as within the medical community.[13] Case studies are used for educational and research purposes, and are replicable.

18. Guided by marketing principles, the pharmaceutical marketing literature, case study methods, and the research questions, I formulated propositions that were either supported or negated by the record (documents and testimony) creating data points.

[11] Reliability can be strengthened by carefully designing and following the case study protocol and through the creation of a case study database. Here, the database can be considered at two levels, the document database (the universe of all potential data points) and my report and schedules which list all the documents and testimony considered or relied on.

[12] Because the research questions posed include some related to the impact of Defendants' marketing, ensuring internal validity is important. Case study analyses may increase internal validity by addressing the same factors as other research methods such as, for example, history or maturation effects, selection bias, or experimental mortality. In this instance, because traditional statistical tests are not being used, the impact of multiple tests of significance is not a concern. Internal validity can be maximized by utilizing pattern matching (convergence of the data), triangulation, logic, explanation building, and consideration of rival explanations. External validity defines the universe to which the results may be generalized.

[13] See, e.g., Flyvbjerg B. Five Misunderstandings About Case-Study Research. Qualitative Inquiry, 2006; 12(2):219-245; Kunselman J, and Johnson K. Using the Case Method to Facilitate Learning. College Teaching, 52(3):87-92; Trejo-Pech C and White S. The use of case studies in undergraduate Business Administration. Revista de Administração de Empresas July 2017; 57(4):342-356; Bonoma T. Case Research in Marketing: Opportunities, Problems, and a Process. Journal of Marketing Research, May 1985; 26:199-208; Grigoryan, Y. Some aspects of teaching the history of medicine: the case study method. History of Medicine, 2017; 4(3):237-242; Bridgman T, Cummings S, and McLaughlin C. Restating the Case: How Revisiting the Development of the Case Method Can Help Us Think Differently About the Future of the Business School. Academy of Management Learning & Education, 2016; 15(4):724-741; David, D. Case Study Methodology: Fundamentals and Critical Analysis. Cognition, Brain, Behavior, 2007; 11:299-317.

These data points were then linked to the case study questions and interpreted in the context of the internal and external business environments (real-world context), and the literature on pharmaceutical marketing. My commentary, findings, and conclusions are documented in this Report.

19. The materials relied on or considered are documented in this Report, Schedule 3 (Facts or Data Considered MDL), Schedule 5 (Supplemental Facts or Data Considered), Schedule 5a (Florida documents) and other schedules, tables, and footnotes in this report.[14] Specific documents that are used as examples to support my opinions are cited by Bates numbers. My opinions in this Report focus on pharmaceutical marketing and Defendants' marketing activities and are stated to a reasonable degree of certainty in the field of marketing, and particularly with respect to pharmaceutical marketing.

COMPENSATION

20. I am being compensated at the rate of $500 per hour for my time. My curriculum vitae, which contains a list of my publications, is attached as Schedule 1. A list of cases in which I have testified in the previous four years is attached as Schedule 2.

OPINIONS

21. I hold the following opinions in this matter:

Opinion 1: Marketing is the process of creating value for customers through exchange. (In this Report, I will refer to customers of the pharmaceutical industry as "Customers."[15] When referencing general marketing principles, I will employ the term

[14] I have verified with the Plaintiff's attorneys that each document cited in this report has been produced in the Florida matter. Each deposition cited was also vetted as to its production in the Florida matter. The documents cited in the attached schedules are referenced by their MDL Bates numbers.

[15] The customers of a pharmaceutical company's marketing activities include patients, prescribers, insurers, third-party payers, pharmacy benefit managers, and others who impact medication use and sales (e.g., pharmacies, pharmacists, wholesale distributors). Prescribers

"customer.") Marketing is an integrated process of analysis, planning, implementation, and evaluation. Marketers analyze internal and external aspects of their businesses to identify opportunities in the marketplace. The marketer's goal is to create satisfaction and value for the customer and to increase sales.

Opinion 2: Defendants are sophisticated marketers who are skilled in applying marketing strategy and tactics to successfully target and reach their desired Customers. This sophistication is seen in Defendants' strategic orientation, Customer-focused philosophy, extensive Customer data, well-integrated marketing activities, and extensive internal marketing communication.

Opinion 3: Pharmaceutical marketing targets Customers with the most potential to increase the number of prescriptions sold for marketed products. Defendants targeted high frequency and other prescribers to increase market share of individual products and the total size of the market for opioids.

Opinion 4: Marketing principles establish standards, regardless of the type of product marketed. Pharmaceutical marketers should adhere to heightened standards of responsibility when marketing medicine, including:

a. Pharmaceutical marketers should support and promote the safe use of medicines, putting patient safety before profit.
b. Pharmaceutical marketing must always be truthful. A pharmaceutical marketer must never mislead the medical community, other stakeholders, or the public.
c. Pharmaceutical marketers must always accurately disclose information about the risks of their product, in addition to the benefits being marketed, in a fair and balanced manner.

includes all who can write prescriptions for patients, including physicians, nurse practitioners, physician assistants, dentists, and any others with prescribing authority.

d. Pharmaceutical marketing efforts should not be disguised as science or education.
e. Pharmaceutical marketing should be based on good science to provide an unbiased, non-commercial basis for the use of medication.
f. Pharmaceutical marketers should be transparent about who or what they financially support.

Opinion 5: Defendants failed to adhere to established industry standards in their marketing of opioids.

Opinion 6: Defendants' marketing strategies for opioids focused on three overarching untrue, false, misleading, and/or deceptive themes:[16]

a) Dependence, tolerance, addiction, and withdrawal should not be a concern in prescribing opioids.
b) Opioids are effective for, and improve functioning in, patients taking them for long-term and chronic use.
c) Opioids should be first-line therapy for pain.

Opinion 7: Defendants' integrated, consistent, and aggressive marketing and overpromotion of opioids created durable prescribing behaviors, and as a result, the market for prescription opioids expanded and persists.[17]

[16] Defendants employed multiple marketing messages associated with each of these themes. These messages are identified and discussed in Section III of this Report.

[17] Integrated marketing refers to the coordination of diverse marketing messages, through multiple channels, designed to create product position. Consistent marketing relates to the thematic approach (the themes are described in Section III) to marketing utilized by Defendants, and the extensive use of time-tested marketing techniques. Aggressive marketing has both lay and marketing term-of-art meaning and is defined below.

Opinion 8: Marketing by both branded and generic pharmaceutical manufacturers, including Defendants, contributed to the rapid growth and expansion of the opioid market.

Opinion 9: Corrective measures are needed to reverse decades of Defendants' marketing that used untrue, false, misleading, and/or deceptive messages to reposition opioids in the minds of prescribers.

BASIS AND REASONS FOR OPINIONS

I. MARKETING AND PHARMACEUTICAL MARKETING

A. Principles of Marketing

The Marketing Process

22. Marketing is the process of creating value for customers through exchange.[18] [19] It encompasses the full scope of activities, including advertising and promotion, aimed at informing or persuading customers. Marketers strive to illustrate the value of their products by communicating (e.g., providing information or engaging in persuasive activities) how those products can fulfill existing needs and wants to create demand for their products. If marketers are successful in creating demand for their product, they receive an exchange of money through sales. Value is a subjective evaluation made by customers, assessing how well the perceived benefits outweigh any perceived risks of

[18] See, e.g., Kotler, P and Armstrong, G. *Principles of Marketing*. 17th Ed. 2018, Pearson; Rollins, Brent L and Matthew Perri. *Pharmaceutical Marketing*. Jones & Bartlett Learning, 2014, p.4.

[19] In this discussion of the marketing process, I refer to the customer as anyone for which a marketer seeks to create value.

the product and deciding that, in the end, the product was worth the price paid (perceived costs).[20] In exchange for value, customers provide sales revenue.

23. Marketing is an integrated process reflecting strategic and operational planning and implementation. (Figure 1) The starting point in marketing is to understand the company's mission and vision. Once mission and vision are formulated, marketers analyze internal and external aspects of their businesses to identify opportunities in the marketplace.[21] The information developed from the pre-market analyses is used to segment and target customers, set marketing goals, and to develop marketing strategy. Marketing strategies are then implemented, and the results obtained are evaluated to provide feedback to the marketing planning process. The goal of the marketer is to solve customers' problems, create satisfaction and value, thus selling more product.[22] [23] The documents and testimony reviewed in this case study examined each component of Defendants' marketing process, creating data points that provided either support for or against propositions that ultimately describe Defendants' marketing behavior.

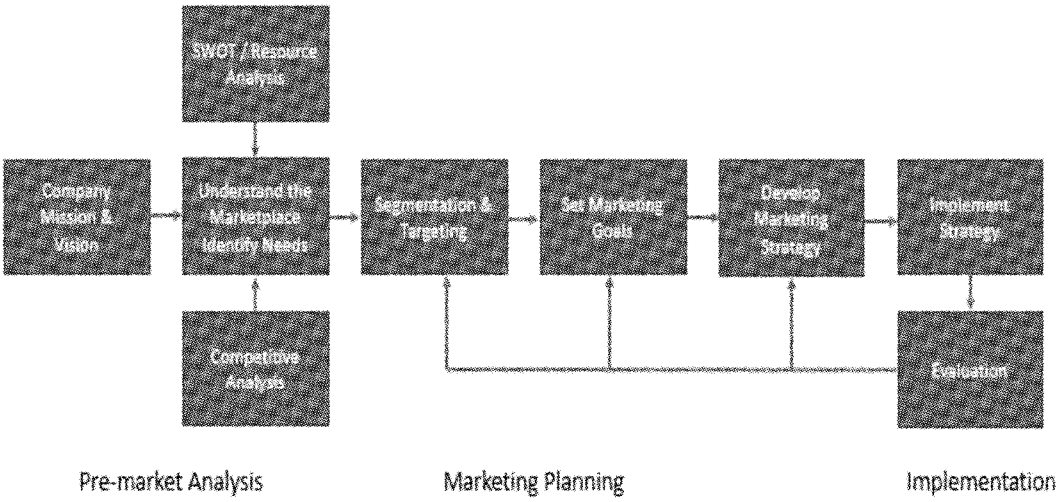
[20] Value may be represented as the subjective relationship between the perceived benefits and perceived costs of a product: Value = Perceived Benefit(s) / Perceived Cost(s). Higher value exists where the benefits are greater than the associated costs.

[21] This process is generally referred to as pre-market analysis. See, e.g., Kotler P. Marketing Mix Decisions for New Products. Journal of Marketing Research 1964; 1(1):43-49.

[22] Marketers seek to satisfy a customer need and in doing so, solve customers' problems. When the product does a good job of solving customers' problems, it may represent a good value and provide customer satisfaction. Value is assessed subjectively and relates to the trade-off between how well the product worked and the price paid.

[23] See, e.g., Kotler, P and Armstrong, G. *Principles of Marketing*. 17th Ed. 2018, Pearson; Kotler P and Keller K. *Marketing Management*. Boston: Pearson, 2016.

Figure 1: The Marketing Process



Creating Value with the "4Ps"

24. When creating value for customers, marketers make decisions that revolve around the basic principles, or cornerstones, of marketing: the product or what will be sold (product); its price (price); how and where it will be sold (place); and how customers will be informed and persuaded about the product (promotion). These principles are referred to by marketers as the four "Ps" (4Ps) of marketing or the "marketing mix" variables.[24] Each marketing decision is tethered to one or more of the 4Ps of the

[24] Some marketers like to consider additional "Ps" in the marketing mix, to include positioning, process (or packaging), and people. These product considerations are inherent to other marketing principles such as segmentation, targeting, and positioning and are therefore included in the "mix" regardless of how they are classified. See, e.g., Ahmad Kareh, Evolution of the Four Ps: Revisiting the Marketing Mix. Forbes. Jan 3, 2018.

marketing mix. Savvy marketers manipulate all the Ps of the marketing mix to maximize the effect of their marketing program.

Marketing Metrics

25. Marketers assess how well marketing is working using a variety of metrics such as sales, market share, customer satisfaction, or less tangible metrics like brand loyalty or goodwill. Marketing metrics provide an additional input to the marketing process so that plans can be revised and adjusted to ensure the desired results are obtained.[25]

Segmentation, Targeting, and Positioning

26. The 4Ps and target marketing, which includes segmentation, targeting, and positioning, provide the foundation upon which marketers build their programs and can be described as:

- ***Positioning:*** Positioning creates a perception in the minds of customers.[26] Positioning is critical to a product's success; the marketer's goal is for the product to be thought of first and favorably.[27] To achieve this, the marketer informs customers about product features and how these features translate into customer benefits to create the desired position in customers' minds.
- ***Segmentation:*** It may be difficult for one set of marketing decisions (revolving around the 4Ps) to create value for all customers. Therefore, marketers seek

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https://www.forbes.com/sites/forbesagencycouncil/2018/01/03/evolution-of-the-four-ps-revisiting-the-marketing-mix/#9c823aa11200 (last accessed June 17, 2020); Brian Tracy, The 7Ps of Marketing. Entrepreneur, May 17, 2004. https://www.entrepreneur.com/article/70824 (last accessed February 9, 2020).

[25] Seggie S, Cavusgil E, and Phelan S. Measurement of return on marketing investment: A conceptual framework and the future of marketing metrics. Industrial Marketing Management. 2007; 36:834-841. See also e.g., 2014 Performance Management Report, Day Matthew M., TEVA_MDL_A_08802273, p.2.

[26] Kotler and Armstrong, *supra,* Part 1, Chapter 2.

[27] Positioning statements are frequently communicated in the marketing and tactical plans identified in Schedule 6: Defendants' Marketing Plans.

groups of customers with similar needs (and wants) and group these customers together into market segments.[28] For each market segment, decisions can be made that will appeal to these groups (segments) of customers with homogeneous needs. Market segments are also evaluated for their potential success based on how easily the market can be measured, the size (or potential size) of the market, and accessibility. Some marketers also consider the durability of the market, or how long the market can be expected to be profitable.

- ***Targeting:*** Marketers have multiple segments of customers that can be considered for marketing efforts. A market segment that is selected to be the focus of marketing activities is considered a "target" customer. The selection of target customers and efforts to reach these customers is referred to as "targeting."

27. The "science" of marketing is complex and requires marketers to understand customers, what they "need," and how they will react to marketing efforts.[29] While the basic principles of marketing lay a foundation, effective marketing also requires an understanding of psychology, consumer behavior, quantitative methods and analysis, and the savvy to adapt as products, customers, and the marketplace change.

[28] See the discussion of "deciles" below. See also e.g., Actiq Physician Segmentation Guide, TEVA_FL_00001413; "Conservative & Careful, Open & Understanding, Experts" in Mission Actiq 2005, TEVA_MDL_A_000024688; Fentora Prescriber Analysis, TEVA_MDL_A_00500589.

[29] Marketing research, a part of which is consumer research, is an important subset of marketing. Without good consumer level research, marketers cannot accurately evaluate customers' needs or how their products can meet these needs. See, e.g., Blackwell R, Miniard P and Engel R. *Consumer Behavior*, Ohio: Thomson Learning, 2001. See also e.g., Patients. A Cephalon presentation analyzing the patient as a source of business, resources for informing and educating patients, and coupon and voucher use, TEVA_MDL_A_00500603; A Day in the Life of a Breakthrough Pain Patient: Final Report, May 21, 2010, MBS/Vox, TEVA_MDL_A_00500697.

B. Pharmaceutical Marketing

Why Pharmaceutical Marketing has a Heightened Standard

28. Pharmaceutical marketers rely on the same basic marketing principles as the marketers of other consumer goods, but pharmaceutical marketing has important differences, including:

- Pharmaceutical marketing carries with it a heightened responsibility, because the "products" affect public health, patient health, and can be a matter of life and death.
- Prescription drugs carry with them risks that are as important as the benefits. This is especially true when the product being marketed is, by definition, dangerous to use, such as a Schedule II or Schedule III narcotic, as is the case for most opioids. These drugs possess a high potential for abuse, may lead to psychological or physical dependence and serious side effects that include addiction and death.[30]
- The consumer (patient) who uses the product is not the person who selects the product; selection is made by a prescriber, as a Customer of the pharmaceutical marketer.
- Insurers, third party payers (TPPs), and pharmacy benefit managers (PBMs) influence the medication choices available to prescribers through formularies

[30] www.dea.gov/drug-scheduling (last accessed June 18, 2020). Consider also, these products are associated with Risk Minimization Action Plans (RiskMAPs) and Risk Evaluation and Mitigation Strategies (REMS), indicating there is high potential risk associated with the use of these medications. RiskMAPs may be voluntarily implemented when a manufacturer recognizes unusual risks and benefits of a drug. RiskMAPs use Customer education and pharmacovigilance (e.g., post-marketing surveillance) to minimize a drug's risks while allowing access to the possible benefits. RiskMAPs generally have evaluation plans to monitor the effectiveness of the RiskMAP. REMS are safety programs that are required by the FDA for certain drugs with safety concerns. REMS are intended to ensure that when a dangerous drug is used, the benefits will outweigh the risks. Both REMS and RiskMAPs are designed to reduce negative patient outcomes from the use of a medication with known, serious potential for harm.

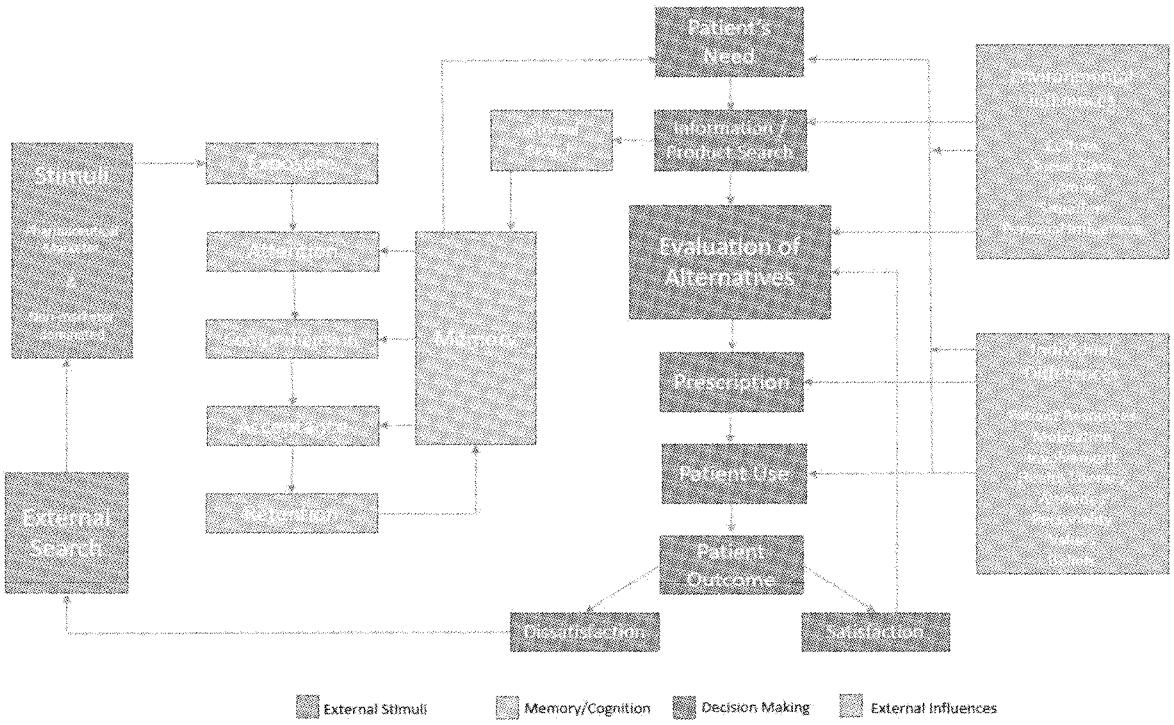
and preferred drug lists, which makes these stakeholders critically important to pharmaceutical marketers.

- Pharmaceutical marketers take advantage of the medical community's desire for scientific evidence by not only providing science-based messages directly through their marketing, but also through funding and sponsoring clinical research, clinical literature, clinical practice guidelines, and continuing medical education.

- Direct-to-consumer (DTC) prescription drug marketing seeks to influence patient demand for a medication by increasing patient awareness and creating the belief in patients' minds that they have a "need" and "right" to be treated with a specific medication.

- The decision to choose a medication is complex and influenced by marketers, the prescriber, the patient, environmental influences, and individual differences. (Figure 2: Physician Prescribing - Information Processing Model)

Figure 2: Physician Prescribing - Information Processing Model (Adapted)[31]



Concerns with Opioid Marketing

29. While pharmaceutical marketing itself is different than other product marketing, marketing for highly addictive Schedule II narcotics, such as opioids, has additional concerns not found with other medications with less serious consequences.

30. Because of the potentially dangerous nature of pharmaceuticals, pharmaceutical marketers are expected to put patient welfare first when making marketing decisions about prescription medicines. This is especially true for products like prescription opioids which should be marketed differently than other consumer products, or even

[31] Blackwell R, Miniard P and Engel R. *Consumer Behavior*. Ohio: Thomson Learning, 2001.

other prescription drugs, because of their serious side effects (including death) and the potential for addiction, abuse and diversion.[32] Given these concerns, Customers, including prescribers and formulary decision-makers (e.g., TPPs or PBMs), must have complete and accurate information to determine the appropriate use of opioids.[33]

31. Additionally, because prescription opioids may result in tolerance, dependence, and/or addiction, the overall "demand" for opioids is distorted by pharmaceutical marketing aimed at increasing the use of these drugs. I refer to this as a distortion because, whether due to tolerance, dependence, or addiction, some patients who use opioids require and/or seek more opioids over time. The properties of opioids may also stimulate some users to report successful treatment to prescribers due to a desire or need to keep taking the drug. Therefore, the use of opioids can result in an increase in demand for opioids. This increase in demand effectively expands the overall market for these drugs – in addition to creating market share for the advertised opioid product.

32. Pharmaceutical companies, including Defendants, employ marketing to achieve the sales objectives created for their businesses and products. Marketing principles are based on an extensive body of literature which analyzes and explains why marketing works to create value and sales. Marketing enables companies to capture market share and expand the overall size of a market. However, marketing in and of itself is a science-based tool, and as such, is without conscience, ethical, or moral values. Thus, marketing strategies and tactics must be used carefully by individuals who should consider the appropriateness of their actions.

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[32] See, e.g., Drug Scheduling https://www.dea.gov/drug-scheduling (last accessed July 29, 2021).

[33] See, e.g., Mintzes B, Lexchin J, Sutherland J, Beaulieu M, Wilkes M, Durrieu G, and Reynolds E. Pharmaceutical Sales Representatives and Patient Safety: A Comparative Prospective Study of Information Quality in Canada, France, and the United States. J Gen Intern Med 28(10):1368-75.

Standards that Apply to Pharmaceutical Marketing

33. In all pharmaceutical marketing activities, pharmaceutical marketers must comply with standards set by the government requiring them to work within their FDA-approved labeling when communicating marketing messages to Customers. In addition to existing laws or guidelines, multiple organizations and associations in the U.S. and around the world have published guidelines, opinions, and ethical principles that should be voluntarily followed by pharmaceutical companies to overcome the challenge inherent to this industry: how to put patient safety first while still making a profit for shareholders.[34]

34. Relying on these principles that have been published world-wide, and assembled here, pharmaceutical companies seeking appropriate medication use should all agree that the goal is for medications to be used correctly and to provide maximum benefit to patients. Therefore, companies seeking appropriate medication use should follow basic

[34] See, e.g., Editorial. Ethical challenges in the pharmaceutical industry. Prof. Jose Luis Valverde, Editor in Chief, Pharmaceuticals, Policy and Law. 2012; 14:123-127. "The ultimate ethical goal in the pharmaceutical industry is to discover and develop safe and efficacious drugs that allow patients to live longer, healthier and more productive lives, while making a profit to reward shareholders and to invest in research for the next generation of medicines." Haque, O, De Freitas J, Bursztajn H, Cosgrove I, Gopal A, Paul R, Shuv-Ami I, and Wolfman S. The Ethics of Pharmaceutical Industry Influence in Medicine. May 2013, UNESCO Chair in Bioethics Office, Publications Division, Ministry of Education, Israel (ISBN 9897-965-444-035-6).

standards, in addition to laws and guidelines in their marketing conduct. Those standards are summarized in the following statements:[35] [36]

- **Pharmaceutical marketers should support and promote the rational use of medicines and put patient safety before profit.**

[35] See, e.g., Laczniak G and Murphy P. Normative Perspectives for Ethical and Socially Responsible Marketing. Journal of Macromarketing 26(2):154-177; Haque, O, De Freitas J, Bursztajn H, Cosgrove I, Gopal A, Paul R, Shuv-Ami I, and Wolfman S. The Ethics of Pharmaceutical Industry Influence in Medicine. May 2013, UNESCO Chair in Bioethics Office, Publications Division, Ministry of Education, Israel (ISBN 9897-965-444-035-6); Editorial. Ethical challenges in the pharmaceutical industry. Prof. Jose Luis Valverde, Editor in Chief, Pharmaceuticals, Policy and Law. 2012; 14:123-127; Komesaroff P and Kerridge I. Ethical issues concerning the relationships between medical practitioners and the pharmaceutical industry. Medical Journal of Australia, 2002; 176:118-121; Association of the British Pharmaceutical Industry (ABPI). Code of practice for the pharmaceutical industry 2016. London: Prescriptions Medicines Code of Practice Authority, 2016; Code on Interactions with Healthcare Professionals. Pharmaceutical Research and Manufacturing Association (PHRMA). http://phrmadocs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008-1.pdf; CBS MoneyWatch, November 30, 2007, Understanding Marketing Ethics. https://www.cbsnews.com/news/understanding-marketing-ethics/ (last accessed June 18, 2020); Ethical criteria for medicinal drug promotion. Resolution WHA41.17, World Health Organization, Geneva, 1988, https://apps.who.int/iris/bitstream/handle/10665/38125/924154239X_eng.pdf;jsessionid=519140B102E90B412265013B0607D70F?sequence=1 (last accessed June 18, 2020); Pan American Network on Drug Regulatory Harmonization, Working Group on Medicines Promotion. Ethical criteria for the promotion, advertisement, and publicity of medicines. Pan American Health Organization/World Health Organization. https://www.paho.org/hq/dmdocuments/2013/PANDRH-12-Criterio-2013.pdf (last accessed June 18, 2020); International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practice 2012, Guiding Principles on Ethical Conduct and Promotion, https://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_Code_of_Practice_2012_new_logo.pdf (last accessed June 18, 2020).

[36] When asked, Defendants also provided support for these propositions. E.g., Boyer, Andrew (Teva) Deposition, p.305; Condodina (Teva) Deposition, pp.482-483; Barrett (Allergan) Deposition, p.32; Beckhardt, (Teva) Deposition, p.59.

- Pharmaceutical marketing must always be truthful. A pharmaceutical marketer must never make a false, misleading, or deceptive statement to the medical community, other stakeholders, or the public.
- Pharmaceutical marketers must always accurately disclose information about the risks of their drug, in addition to the benefits being marketed, in a fair and balanced manner.[37]
- Pharmaceutical marketing's promotional efforts should not be disguised as science or education.
- Pharmaceutical marketing should be based on good science[38] to provide an unbiased, non-commercial basis for the use of medication.
- Pharmaceutical marketers should be transparent about who or what they financially support.[39]

Pharmaceutical marketers must all comply with each of these basic propositions that describe the higher standard (as compared to many other consumer products) for pharmaceutical marketing conduct.

[37] See, e.g., https://www.fda.gov/media/76269/download Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion; https://www.fda.gov/media/81597/download Communicating Risks and Benefits: An Evidenced-Based User's Guide; https://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms#F Glossary, Fair Balance; https://www.fdli.org/2017/08/prescription-drug-advertising-promotion-regulations-enforcement-select-global-markets/ Prescription Drug Advertising and Promotion Regulations and Enforcement in Select Global Market, Food and Drug Law Institute (last accessed March 15, 2020).

[38] Good science is a term of art that refers to research that adheres to principles that protect it from threats to reliability, internal and external validity.

[39] For example, companies should be forthcoming about who is paid to endorse their products, what research they have funded, who has been paid to advocate for products, or diseases.

Defendants are Effective Pharmaceutical Marketers

35. Effective marketers routinely employ the basic principles of marketing. Sophisticated marketers additionally have a clear strategic orientation, a customer-oriented philosophy, ample information about their customers, a well-integrated company-wide marketing effort, and excellent intra-organizational efficiency (e.g., communication, coordination) regarding the entire marketing effort.[40]

36. I have reviewed an extensive record of documents and testimony related to each aspect of Defendants' marketing of opioids, reflecting an array of marketing efforts. It is my opinion that Defendants were adept in their application of marketing principles and strategies to generate demand (sales) for their opioid drugs. Defendants demonstrated high levels of strategic orientation, strategic planning, and integration of marketing within their organizations. Further, Defendants exhibited extensive intra-organizational communication regarding marketing activities and had a high level of focus on the Customer. In my opinion, Defendants were sophisticated in their application of proven marketing techniques to achieve their marketing goals.

[40] See, e.g., Kotler P. From sales obsession to marketing effectiveness. Harvard Business Review, 1977; (Nov-Dec):67-75; Kotler P. *Marketing Management: Analysis, Planning and Control.* Englewood Cliffs, NJ: Prentice Hall, 1988.

Setting Pharmaceutical Marketing Strategies

37. A marketing plan is a comprehensive description of the full scope of marketing activities, or the road map, used to achieve sales and profits. Marketing plans identify strategies, set goals, and plan for the implementation and evaluation of marketing activities and are developed at multiple levels within the organization. Marketers, including Defendants, base their plans on careful assessment of a company's strengths and weaknesses as well as the opportunities and threats (SWOT analysis) that exist within the business environment.[41] This information is integrated with resource analysis and the assessment of market potential, to identify areas of business opportunity and to formulate corporate marketing objectives.

38. Once corporate direction has been established, marketers develop organization-wide marketing planning efforts. These efforts range from the highest-level plans where corporate level strategy and tactics are set, to regional, territory, and even individual level plans. The mid- and lower-level plans are more operational and focus on implementation. All marketing planning activities, when considered together, create a purposeful and strategic action plan that a company will use to achieve its desired results.

39. Marketing plans are often iterative documents that change over time. The significance of data points contained in marketing plans – including drafts of marketing plans – can be analyzed and placed in context with respect to other marketing plans.

Pharmaceutical Marketing's Target Customers

40. Pharmaceutical marketers seek to drive the sales of prescription drugs by informing and persuading target Customers about the value of the marketer's drug. Target Customers

[41] E.g., Kaisen (Teva) Deposition, pp.124-126, and Exhibit 9, Actiq 2004 Marketing Plan; Pyfer (Teva) Deposition, p.228.

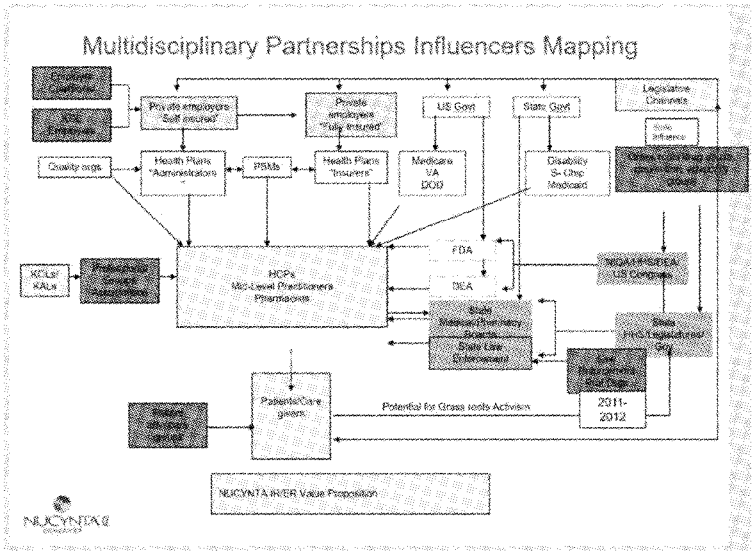
include prescribers, payers (e.g., insurers, TPPs, PBMs), sites of care (e.g., institutions, long term care, retail, or surgery centers), and influencers (e.g., professional and patient advocacy groups, employers, thought leaders, or policy makers, caregivers/families).[42] Physicians and other prescribers are primary targets of pharmaceutical marketing efforts because patients cannot write prescriptions, and, generally, do not possess the technical knowledge to diagnose a medical condition and choose between alternative prescription medications.[43] However, the pharmaceutical industry also employs DTC marketing that is used to create awareness of drugs, diseases, or other health concerns, and encourages patients to act on the information in these ads.[44] Janssen illustrated graphically its Customers and the interrelated nature of these customers (see insert below) on prescribing:[45]

[42] There are numerous marketing plans and related business documents and communications in the record which outline messages, targets, and tactics for reaching selected target markets, e.g., Christopher Hepp 11/1/2010 email, ALLERGAN_MDL_01116174; Field Contact Form, 10/26/10, ALLERGAN_MDL_01116175; 2003 Actiq Marketing Plan, TEVA_CHI_00042882; Xcenda Statement of Work, Fentora, Payer Segmentation, TEVA_MDL_A_00500232; Duragesic Institutional Opportunity, December 2004, JAN-MS-03070303.

[43] Other stakeholders who can impact prescribing may include, for example: drug utilization review boards and pharmacy and therapeutics committee members, insurers and third-party payers, formulary managers, or pharmacy benefit managers.

[44] The goal of DTC marketing is to generate awareness on the part of patients (and prescribers, other stakeholders, and influencers, because they are also consumers and exposed to DTC efforts) and create dialogue between patients and prescribers with the expectation of generating a prescription. Pharmaceutical marketing also targets consumers and caregivers indirectly through its support of patient and disease advocacy groups. DTC marketing efforts can take the form of disease education, self-help messages, unbranded advertising, and public service or public relations efforts. See also e.g., related to direct-to-consumer marketing, Beckhardt (Teva) Deposition; Condodina (Teva) Deposition p.152; Day (Teva) Deposition, pp.223-224, 281-282; Bearer (Teva) Deposition, p.33.

[45] JAN-MS-00330384, Advocacy and Policy Key Launch Initiatives, Nucynta.



41. Yet, for most drugs, pharmaceutical marketers target those who make decisions about which treatments will be used by patients, namely, the prescribers, pharmacists, insurers, TTPs, PBMs, and formulary decision-makers.[46] The record in this case supports the proposition that Defendants, and other opioid manufacturers, planned and worked

[46] Insurance companies and PBMs are involved in creating mechanisms in the pharmaceutical supply chain to provide insurance coverage and payment to pharmacies for insured patients. If drugs are not listed on formularies, or have barriers to use, they will be used less. This gives insurers, third party payers, pharmacy benefit managers, and formulary decision-maker's significant market power. This is discussed later in this Report. See also e.g., Spokane (Teva) Deposition, p.240 and Exhibit 38.

diligently with multiple target audiences, including TPPs and PBMs, to ensure and maintain formulary coverage for the opioids they marketed.[47] [48] [49] [50]

42. Every target Customer requires accurate information to appropriately evaluate treatment alternatives. Much of the information available to stakeholders is either provided by, or influenced by, pharmaceutical marketers who seek to control the information in the marketplace that will create the desired position for their drug(s) in Customers minds.[51] [52] However, if the information provided by pharmaceutical marketers is flawed (e.g., incomplete, biased, not fair balanced, or based on poor

[47] E.g., TEVA_MDL_A_01132030; 035_ALLERGAN_MDL_01283526, Kadian Co-Pay Assistance Program; ALLERGAN_MDL_01338506; TEVA_CHI_00008900, pp.25-28; ENDO Pharmaceuticals 2008-2012 Opana Brand Tactical Plan, EPI000560276.

[48] Formulary decision-makers do not select a drug for the patient, but they decide which drugs will be available, and therefore more accessible to patients, through its formulary. Drugs that are not covered, or that have barriers to use (e.g., prior authorization) will be used less. This gives formulary decision-makers the ability to move market share, and drive or limit demand in a market.

[49] The number of advertisements submitted to the FDA on Form 2253 specifically aimed at formulary decision making increased from 71 in 2001 to 1647 in 2014, indicating growth in marketers' interest and outreach to formulary decision makers during this period. Internet promotion grew dramatically from a total of 1909 Form 2253 submissions in 2001 to 30,295 Form 2253 submissions in 2014. (Sullivan HW, Aikin KJ, Chung-Davis E, and Wade M. Prescription Drug Promotion from 2001-2014: Data from the U.S. Food and Drug Administration. PLoS One | DOI:10.1371/journal.pone.0155035, May 5, 2016.)

[50] E.g., Achieving Pull Through Excellence: Driving Demand By Leveraging Access, SCG/IM Collaboration, JAN-MS-00858249; Nucynta ER $25 Savings Card, JAN-MS-00228916; Nucynta Savings Card ROI Evaluation, June 2010, JAN-MS-00259847; $50 Off, Duragesic, JAN-MS-00291469; Duragesic Coupon ROI Analysis, March 2002, JAN-MS-00311391; Launch Readiness Review Market Access, July 30, 2010, JAN-MS-00815827.

[51] E.g., Barrett (Allergan) Deposition, p.257.

[52] Pharmaceutical marketers seek to carefully control the messages that are created and disseminated about their products. However, as noted in the adapted prescribing information processing model (Figure 2) non-marketer-controlled information, such as a patient advocacy group or a media article, is present in the marketplace and can also impact information processing by physicians. Marketers seek to ensure that the information emanating from sources such as these is consistent with their own carefully developed and internally approved messages. The marketer's desire to exert control over this non-marketer-dominated information explains, in part, why Defendant's support patient or disease advocacy groups.

science), false, untrue, deceptive, or misleading, patients are put at risk because drugs may not be used appropriately. Prescribers cannot make educated decisions without accurate information. Flawed information impacts the prescribing process and generates sales, but it violates the basic standards in pharmaceutical marketing set forth above.

Prescribers

43. Pharmaceutical marketers utilize the principles of segmentation, targeting and positioning to reach Customers. A common strategy for reaching Customers with marketing messages is to target prescribers who are most likely to generate prescriptions for the marketed drug.[53] Marketers identify prescribers using commercially available data, which groups prescribers, for example, into deciles (1-10) reflecting lower versus higher levels of prescribing. Marketers use this information to select prescribers, or groups of prescribers, as target Customers.[54] [55]Targeting high decile (more frequent prescribing) prescribers is consistent with marketing principles because it effectively targets Customers with potential to generate sales.[56]

44. For example, Watson recognized the value of targeting high prescribers. The Norco sales training manual instructed Professional Sales Representatives (PSRs)[57] to tell "trade" (e.g., retail pharmacies) customers who ask, "Am I going to move this stock?" to respond: "Absolutely. Norco™ has a high-powered promotional campaign under way to

[53] Boothe (Allergan) Deposition, pp.164-167. See also e.g., marketing plans such as the 2012 Fentora Brand Plan, p.58, TEVA_MDL_A_00763740.

[54] E.g., ACTIQ Physician Segmentation Guide, TEVA_MDL_A_01327080.

[55] E.g., Opana ER Tactical Plan, September 2012, ENDO-OPIOID_MDL-00508844.

[56] Fugh-Berman A, Ahari S. Following the Script: how drug reps make friends and influence doctors. PLoS Medicine 2007; 4(4):621-625.

[57] The "P" in the abbreviation PSR is understood to mean either "Professional" or "Pharmaceutical." There is no difference in the activities of PSRs that are dependent on the name used. In some cases, the term Medical Representative (MR) is used. MR is synonymous with the term PSR.

insure (sic) that the [product] message gets out. Plus, the promotion is being directed specifically at high prescribers of these products, where the message can have the greatest impact on prescriptions."[58]

45. Defendants used "deciles" to identify the best physicians for their PSRs to use in opioid sales-call planning[59] [60] and provided lists of Customers to PSRs.[61] These "call lists" identified prescribers to be targeted and those to be avoided ("do-not-call" or DNC list) due to concerns over abuse and diversion, or other restrictions on access to Customers.[62] Even though these DNC lists existed, it was not clear what impact they had on limiting PSR interactions with physicians who were placed on these lists.[63]

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[58] Norco Sales Training Manual, Frequently Asked Questions and Answers, ALLERGAN_MDL_03352627.

[59] The call lists, or lists of Customers to be seen by PSRs, are provided by the company. The Defendants' use of decile marketing was extensive as seen in numerous marketing planning, and other documents. A few examples are provided here, e.g., Actavis and Kadian, Pilot ABM Training October, 2011, ALLERGAN_MDL_00419788; Boothe (Allergan) Deposition, p.166; Kaisen (Teva) Deposition, p.81; Opana® ER Q4 2011 Quarterly Business Review, p.17, ENDO00002135; Bingol (Endo) Deposition, p.265; Bingol (Endo) Deposition, p.157; Boothe (Allergan) Deposition, p.166; Cramer (Purdue) Deposition, p.20; Jackson (Endo) Deposition, pp.215-220; Kaisen (Teva) Deposition, p.81; Lortie (Endo) Deposition, pp.152-153.

[60] PSRs are provided call lists by their respective company. Defendants' use of decile marketing was extensive and seen in numerous marketing planning and other documents. E.g., JAN-MS-00669512, Nucynta ER Segmentation Final Results; JAN-MS-00756523, Nucynta ER Target Optimization.

[61] E.g., Altier (Allergan) Deposition, pp.238-243; Morreale (Teva) Deposition, p.146; Day (Teva) Deposition, pp.104-106; Spokane (Teva) Deposition, p.90; Barto (Endo) Deposition, pp.301-303; Morreale (Teva) Deposition, p.146; Day (Teva) Deposition, p.106; Lortie (Endo) Deposition, pp.168-169,179-181.

[62] One Opana ER strategy for reaching Customers who may not be appropriate for sales calls was to focus on communicating with the Quality Assurance / Quality Improvement departments within hospitals, bypassing medical directors and relying on the influence of Quality Assurance / Quality Improvement professionals and their influence on decision makers such as the Medical Director. (Richard Welch 9/12/2012 email, ENDO-OR-CID-01315820)

[63] E.g., Kaisen (Teva) Deposition, pp.266-270; Sippial (Teva) Deposition, pp.326-328; Day (Teva) Deposition, pp.105-106; Spokane (Teva) Deposition, pp.89, 234-235; Leitch (Allergan) Deposition, pp.277-279; Lortie (Endo) Deposition, pp.181-185. I noted that Mr. Day was not aware of "pill mills" in his call area. Mr. Spokane indicated his instruction to the field [sales team]

46. At Endo, part of the planning to identify high prescribers involved identification of prescribers who were experienced with prescribing long-acting opioids. To qualify for this status, a prescriber was required to have written at least 48 prescriptions over the last 12 months.[64]

47. At Teva, Mr. Spokane, who was an area sales manager, seemed to be more concerned with sales and bonuses than ensuring that prescribers who were placed on DNC lists were properly vetted.[65] According to his testimony, Teva compliance used two criteria to determine who should appear on a DNC list: those who have had their licenses taken away or those who were in legal trouble.[66] Therefore, Customers who were only being investigated for suspicious prescribing activity were still candidates for sales calls.

48. Targeting high prescribers proved to be an effective strategy for Defendants given that during the first decade of opioid marketing, after the introduction of OxyContin, opioid prescribing in the U.S. increased four-fold.[67] One impact of Defendants targeting high prescribers was the creation of a core of heavy opioid prescribers with the top 1% of prescribers currently responsible for 49% of all opioid doses and 27% of all opioid prescriptions in the U.S.[68]

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was to stop calling on prescribers who were "sketchy or shady." Yet, two Teva speakers (MDs) were convicted of running an opioid pill mill in Alabama. (Spokane (Teva) Deposition, pp.89, 234-235) See also the Chris Meyer 5/26/2015 email chain with subject "Debarred/DNP meeting notes" and the attached presentation, Better Together, Debarred Reporting Process, May 2015, TEVA_MDL_A_11525303.

[64] Jackson (Endo) Deposition, pp.36-37.

[65] Spokane (Teva) Deposition, pp.213-217.

[66] Spokane (Teva) Deposition, p.218.

[67] Centers for Disease Control and Prevention. Vital Signs: Overdoses of Prescription Opioid Pain Relievers United States, 1999-2008. MMWR Morb Mortal Wkly Rep 2011; 60:1487-92.

[68] Kiang M, Humphreys K, Cullen M and Basu, S. Opioid prescribing patterns among medical providers in the Unites States, 2003-2017: retrospective, observational study. BMJ 2020; 368:16968 |DOI:10.1136/bmj.16968.

49. In addition to the use of deciles, Defendants also marketed to physicians in geographic areas where opioid prescribing was already high (and abuse was greater).[69] [70] Targeting high prescribers was key to Defendants' ability to expand the opioid market. Defendants extended this thinking (targeting high use potential) to physicians who care for patients with high need for pain medications, for example, workers compensation physicians or pain clinics.[71]

50. Mr. Barto, in Regulatory Affairs at Endo, noted with respect to the use of deciles in targeting prescribers, "the goal was not to grow the market but to take market share."[72] His characterization of Endo's goal is incomplete. From a marketing perspective, market expansion and capturing share are not mutually exclusive goals. Marketing, including Endo's marketing of opioids, did both.

51. Capturing market share is done by selling more of a product (or service) to existing customers, usually by stealing these customers from another business. A market expansion strategy is one that seeks to increase sales of a product (or service) to new customers, in addition to existing customers. This will grow or expand total sales in the market.

52. For example, seeking additional sales through expanded indications for opioids would represent a market expansion strategy. Defendants' marketing messages described in Section III (and Table 2) of this Report include these kinds of strategies aimed at

[69] E.g., Kadian LAO Decision-Making Process, Altier (Allergan) Deposition Exhibits 17 &18; Boothe (Allergan) Deposition, pp.164-167; Pyfer (Teva) Deposition, pp.220-227 and Pyfer Deposition Exhibit 12, 2002 Actiq Marketing Plan; Chapman (Endo) Deposition, pp.493-500; Schedule 6: Defendants' Marketing Plans.

[70] E.g., JAN-MS-00660589 & JAN-MS-00660588, Email and Nucynta Extended Team Meeting; Schedule 6: Defendants' Marketing Plans, where specific strategies, tactics and plans for targeting Customers are enumerated.

[71] Barto (Endo) Deposition, pp.301-303.

[72] Barto (Endo) Deposition, pp.296-298.

increasing the use of opioids in new types of patients and increasing the number of opioids used by existing patients. When a marketer expands the use of a product in this manner, as was done by Defendants, market share can also increase. However, market share and the total market are interrelated. For example, market share for a company can remain constant at 6%, but if the total market for opioids grows, that 6% market share will represent increased sales – 6% of a larger market. From a marketing perspective, *maintaining* market share in an expanding market is a common goal.[73]

53. From a marketing perspective, targeting high prescribers was key to opioid manufacturers', including Defendants', ability to expand the opioid market. As described in Section III of this Report, certain marketing messages used by Defendants were designed to increase the use of opioids in new patients (e.g., to treat new types of pain, i.e., market expansion) and to increase the number of opioids used by existing patients (e.g., market penetration).[74] Maintaining market share in an expanding market represents growth opportunity and was a common goal of Defendants' and other opioid manufacturers.[75]

54. Sometimes, market expansion goals were specifically stated. For example, a Fentora 2012 plan identifies the key issue that the "current prescriber base is not large enough to sustain market share or growth," and sets out the strategy to "expand target market base." (See insert below)[76]

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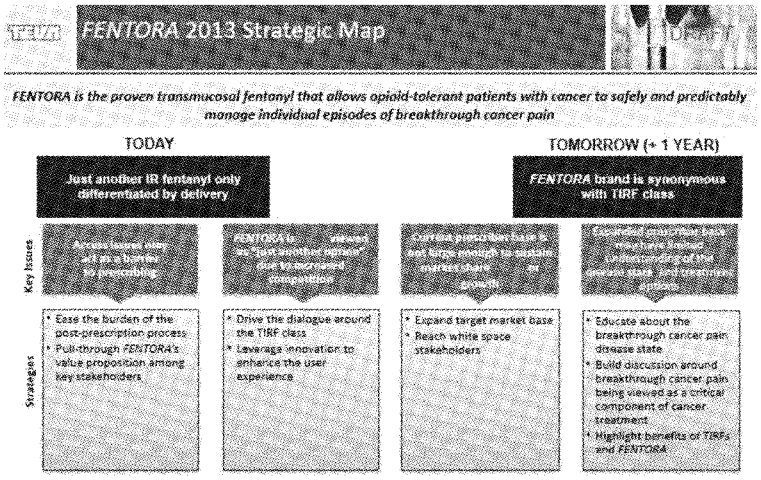
[73] See, e.g., Schedule 6: Defendants' Marketing Plans; Kotler, *supra.*

[74] A market development (expansion) strategy is defined as one that seeks to sell an existing product to "new" customers. (Kotler, P and Armstrong, G. *Principles of Marketing*. 17th Ed. 2018, Pearson, pp.48-50.) For opioids, market development goals were associated with messaging designed to, for example, increase sales of opioids through Customer messaging aimed at using these drugs to treat more types of pain (e.g., break-through-pain not associated with cancer, chronic back pain), patients, or conditions.

[75] Schedule 6: Defendants' Marketing Plans; Kotler, *supra.*

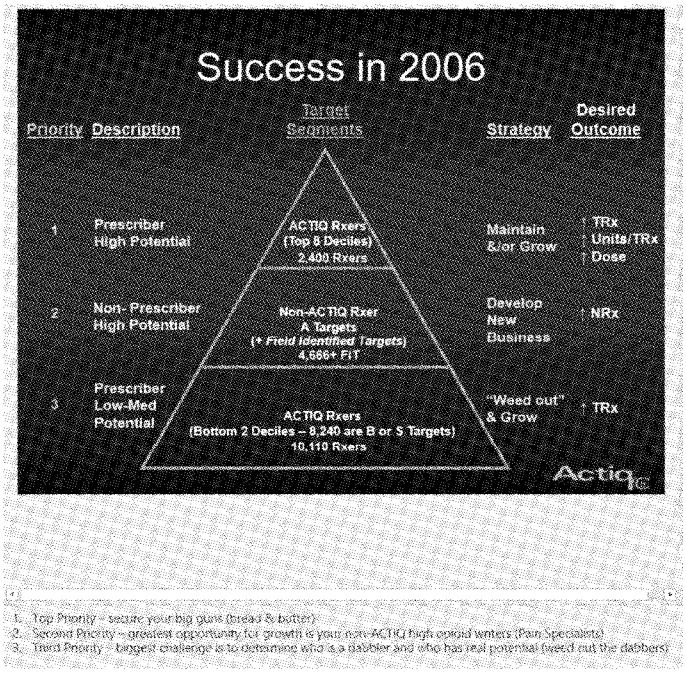
[76] Fentora Q4 Brand Team Meeting, TEVA_MDL_A_00881567.



55. In Cephalon's 2006 Actiq marketing plan, growth strategies were also specified. However, in this presentation and speaker's notes, it is clear that market growth and market penetration goals are both being emphasized. (See insert below)[77] Cephalon noted in this presentation the underlying conditions being treated with Actiq: 48% of patients being treated for back pain, 38% for neuropathic pain, 25% for headache, 17% for arthritis, and 6% for cancer, for which Actiq is indicated. The marketing implications of this information can be viewed from the perspective of off-label marketing, but the focus in this report is the overall impact of the marketing on opioid use. With this in mind, at the very least, Cephalon's efforts were expanding the market for Actiq (as set forth in its goals) and expanding opioid use.

[77] 2006 Actiq Marketing Plan, TEVA_MDL_02047670, pp.7, 27.

Note: On p.27 of this marketing plan, Cephalon describes the underlying conditions treated with Actiq, with 48% of patients being treated for back pain, 38% for neuropathic pain, 25% for headache, 17% for arthritis, and 6% for cancer (for which Actiq is indicated).



56. In addition to targeting high-volume prescribers, pharmaceutical marketers, including Defendants, can target prescribers who are utilizing competitive products.[78] This strategy is consistent with capturing market share, and because the opioid market was growing, this meant expanded sales when strategies worked.

57. Additional factors in targeting prescribers may include prescriber specialty, accessibility, or prescribing patterns such as previous use of a company's drug(s), or even individual prescriber characteristics.[79] The specific "targets" that a marketer chooses are significant when a drug has limited indications, such as Actiq that is indicated for opioid

[78] Kadian LAO Decision-Making Process, Altier (Allergan) Deposition Exhibits 17 &18; Boothe (Allergan) Deposition, pp.342-345 and Boothe Deposition Exhibit 20, Objection Handling Workshop.

[79] Targeting customers based on individual characteristics can include focusing on a thought leader, or key opinion leader (KOL) to gain increased prescriptions from this thought leader, and potentially other physicians when others rely on these KOLs as a source of influence on their own prescribing. See, e.g., Lubloy A. Factors affecting the uptake of new medicines a systematic literature review. Health Services Research 2014; 14:469-94.

experienced patients with breakthrough cancer pain. Marketing Actiq to prescribers who do not treat cancer would effectively circumvent the drugs limited indication and encourage off-label use.[80]

58. For example, Teva provided its PSRs with targeting reports and other data regarding prescribers of Actiq and Fentora, including provider type and specialty, practice location, license number, NPI and the number of prescriptions written.[81] However, even though Actiq and Fentora were only approved for the treatment of breakthrough cancer pain in opioid tolerant patients, many of the prescriber specialties on the target lists, such as sports medicine and general/family practice, did not generally treat these kinds of patients.[82] Further, Teva instructed its PSRs to apply a low threshold ("potential" to treat cancer patients) when choosing targets for sales calls.[83] Consequently, PSRs made sales calls on prescribers who did not routinely treat cancer patients.[84]

59. In addition to scientifically targeting prescribers to maximize product use (i.e., sales), effective pharmaceutical marketers take advantage of prescribers' need for information

[80] Targeting non-cancer patients and the impact that these activities had on the safe use of Actiq is addressed later in this Report and was seen in call logs where PSRs called on physicians within specialty areas that would not be expected to treat cancer. E.g., Dana Luscombe 5/5/2008 email TEVA_MDL_A_02894057; Core Visual Aid, TEVA_MDL_A_00551447. See also e.g., Nancy Shanflet 9/13/2004 email with subject "Actiq Marketing Targets," TEVA_MDL_A_00024290.

[81] Fentora Target Report, TEVA_MDL_A_01097268; Nikolaus 5/18/email, Actiq Targets, TEVA_MDL_A_01225652.

[82] Meeting Minutes, 8/30/2004 between Cephalon and DDMAC, "Cephalon's sales representatives are calling on physicians who are not treating BTCP and who are not prescribing Actiq already. This is especially concerning as many of the targeted specialty areas, such as physical medicine specialists, do not routinely treat cancer patients." TEVA_MDL_A_01584978. See also TEVA_MDL_A_11436747, Cephalon $425 Million Off-Label Marketing Agreement.

[83] E.g., TEVA_MDL_A_06384299, Condodina 11/28/06 email chain discussing Actiq promotions, including reference to a November 21, 2006 WSJ article "Cephalon Used Improper Tactics to Sell Drugs, Probe Finds," and an attached sales visit "Decision Tree" for use in screening prescriber specialties to determine if they possess the "potential" to treat cancer patients.

[84] Teva sales call logs, TEVA_MDL_A_02416207 and TEVA_MDL_A_00763717.

about drugs. Marketers choose to fill this need because many Customers rely on the pharmaceutical industry to provide them with technical, science-based information that is generally considered reliable.[85] Educational marketing efforts tap into prescribers' desire to make good decisions for patients that are based on reliable, valid, and unbiased information.

60. Pharmaceutical marketers take advantage of prescribers' scientific orientation[86] and need for information by, for example, sponsoring research, and distributing research results through peer-reviewed publications.[87] For example, Teva planned to initiate studies for off-label uses of Actiq for non-cancer pain, presumably to provide information that Customers might rely on in making the decision to use Actiq in non-cancer pain.[88] Studies supported by grants from Cephalon (Teva) were eventually published, including studies by Dr. Portenoy (non-cancer BTP, and chronic low back pain), and Dr. Fine (BTP in opioid tolerant patients with chronic pain).[89]

61. Peer-reviewed publications are generally perceived as unbiased, good science, which is valued by prescribers because it gives them confidence in the information they are receiving. This confidence is diminished when prescribers learn that literature is not

[85] Fugh-Berman A and Ahari S. Following the Script: How Drug Reps Make Friends and Influence Doctors. PLoS Medicine 2007; 4(4):621-625.

[86] Lubloy, 2014, *supra.*

[87] E.g., Kadian 2005 Publication Plan, ALLERGAN_MDL_00815516; Jerri Thatcher 10/31/2006 email, TEVA_MDL_A_01512147; Medical Affairs Internal Medicine Project Plan, JAN-MS-02289011; Bruce Moskovitz 10/17/2007 email to Ron Kuntz and Gary Vorsanger with subject "RE: Tapentadol Joint Publication Plan Team Meeting, JAN-MS-02305423; Janssen Pharmaceutica Inc., 2002-2003 Janssen Divisional Objectives, JAN-MS-02314614; AP-48 Global Publication Team Kick-off Meeting, November 6, 2003, JAN-MS-02474680.

[88] Actiq Marketing Plan 2003, TEVA_CHI_00042882, pp.26, 53.

[89] TEVA_MDL_A_13744430 (Portenoy); TEVA_MDL_A_00025990 (Portenoy); TEVA_MDL_A_13755704 (Fine). See also the Weinstein et al. paper "Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Cancer Pain, TEVA_FL_00013491; TEVA_FL_00013500 (Portenoy study of BTP in cancer patients).

based on reliable and valid research or contains commercial bias. Literature that is not based on good science puts prescribers and their patients at risk.

Third Party Payers

62. Third Party Payers (TPPs) cover, or pay for, the cost of drugs that are listed in their formulary or preferred drug list (PDL) for beneficiaries.[90] Formularies and PDLs are usually developed and maintained by pharmacy benefit managers (PBMs) who may work independently or in conjunction with pharmacy and therapeutics committees or drug utilization review committees or boards.[91] Formulary development involves deciding which drugs will be covered, which will be covered with certain limits to access, and which will not. Generally, if a drug is not covered, its utilization will be low or non-existent to individuals whose insurance is subject to that formulary.

63. Formularies and PDLs limit access to certain drugs with tools like prior authorization, step therapy, various hard and soft utilization edits, and preferred formulary status to purposefully drive utilization to desired levels within a prescription benefit plan.[92] These additional tools are under the control of the TPP or PBM, giving these decision-makers ways to direct demand toward or away from a manufacturer's drug. Through the formulary development process, TPPs and PBMs have a significant ability to drive market share by supporting the use of or creating barriers to utilization of a

[90] A formulary is a listing of the drugs approved for plan member reimbursement under the TPP's plan. Open formularies include all drugs. Closed formularies include only the drugs approved by the TPP. A preferred drug list includes all drugs but provides preferential treatment to drugs selected by the TPP.

[91] Influential physicians, thought leaders, and KOLs may also be members of pharmacy and therapeutics or other formulary development committees.

[92] For example, a drug may be covered, but the PBM can restrict utilization by placing the drug on "prior authorization" (PA) requiring prescribers or pharmacies to obtain permission to use the drug. PA is seen by industry as a potent barrier to sales and, therefore, industry representatives will work through marketing activities to avoid PA restrictions being placed on their drugs.

manufacturer's drug(s). For example, Cephalon strategized around potential formulary barriers in its 2006 Actiq Marketing Plan.[93] Defendants, including those at Janssen, recognize the importance of working with formulary decision makers to ensure coverage for their products, including building Key Opinion Leader (KOL) and consulting relationships with these clinical decision makers.[94]

64. Formulary decisions are also important in the institutional (e.g., hospital) environment and pharmaceutical sales teams can include PSRs or others with a focus on institutional selling. These teams may provide drug information to prescribers but also work to ensure hospital formulary coverage or inventory access for their products when patients are cared for in the institutional setting.[95]

65. Working within the formulary (reimbursement) landscape, pharmaceutical marketers, including Defendants, analyze and target TPP and PBM formulary decision makers.[96] As Customers, formulary decision makers require accurate clinical and economic evidence to inform appropriate formulary decisions. This evidence may include drug labeling and other relevant clinical or economic research that manufacturers believe will support the use of their drugs. Formulary developers (e.g., TPPs, PBMs, hospital formulary decision

[93] 2006 Actiq Marketing, TEVA_MDL_A_02047670 pp.4, 29, 36. See also the "Fentora COVERS Program Reimbursement, TEVA_MDL_A_00008283.

[94] E.g., JAN-MS-00361477 and JAN-MS-00361478, Wil Rivera 5/1/2009 email to Linda Blair-Cusumano with subject "Updated KOL Spreadsheet" and attachment "New England Region Pain KOLs 2009.xls"; 2006 Actiq Marketing, TEVA_MDL_A_02047670 pp.4, 29, 36.

[95] The issue of access is important when patients taking a specific medication in the community setting are admitted to a hospital where they may not have access to a drug due to formulary issues. A similar problem exists when a patient who is started on a drug in the hospital is discharged to the community where access to the drug prescribed in the hospital may be limited due to formulary issues.

[96] E.g., TEVA_MDL_A_02397625, Bill Cunningham 8/5/2004 email; Cephalon Sales Bulletin #17, June 14, 2004, TEVA_MDL_A_05445644; Actiq Reimbursement Hotline brochure, TEVA_MDL_A_08857270; Employee Self Appraisal, October 15, 2007, TEVA_MDL_A_00873333.

makers) may also seek other clinical information[97] to make decisions about drug coverage.

66. Pharmaceutical marketers rely on the fact that TPPs and PBMs need drug information to develop their formularies. Prescribers then rely on formularies, created in part with the pharmaceutical manufacturer's information and any associated commercial influence, when selecting a drug for a patient. Pharmaceutical companies who target TPPs and PBMs, therefore, have a strong influence on prescribing and a significant ability to drive a drug's market share.

67. Pharmaceutical marketers also rely on relationship building[98] and other indirect ways to influence a drugs inclusion on a formulary. For example, a manufacturer can indirectly exert marketing pressure on formulary decisions by using key opinion leaders as advocates for a drug and by supporting advocacy groups who want to ensure access to a specific drug.[99] This can impact formulary decision-makers because these stakeholders also have customers (i.e., employers, state Medicaid programs, insurers) and must make

[97] Other clinical information might include, for example, relevant clinical experience possessed by members of the pharmacy and therapeutics committee, published clinical research, and past utilization in the plan.

[98] Relationship marketing seeks to foster relationships with current or future customers by creating two-way dialogue to meet the customer's needs, build customer loyalty and create an advocate (e.g., KOL or Thought Leader) for a brand. This can be person-to-person or through technology. Relationship marketing helps ensure a positive experience with the brand and seeks to affect customer behavior. Relationship building also works on the personal level, PSRs frequently create dialogue regarding personal interests which are intended to create rapport and make people feel good about the interaction.

[99] E.g., Schedule 12: Amounts Paid to KOLs by Defendants; Schedule 11: Amounts Paid to Pain Advocacy Organizations & Professional Societies; Schedule 9: Defendants' Use of Advocacy. See also e.g., Teva Pharmaceuticals/Medical Affairs/U.S. Medical Advocacy membership and Sponsorship Descriptions Pain 2012, TEAV_MDL_A_00500208.

decisions consistent with their customers' desires. Public relations, lobbying efforts, or company-sponsored research can also indirectly influence formulary decisions.[100]

68. When TPPs or PBMs do not provide preferential status on a formulary or PDL for a drug, patients will have to pay more to access that drug through higher copays or even bearing the full cost of the drug out-of-pocket. This creates a barrier to the use of medications that pharmaceutical marketers recognize.[101] Therefore, a common goal of the pharmaceutical marketer is to obtain preferential formulary position, without restrictions that would limit utilization.[102]

69. When economic barriers exist, pharmaceutical marketers, including Defendants, have responded with "coupons" and other marketing strategies to reduce out-of-pocket costs

[100] Peay M and Peay E. The Role of Commercial Sources in the Adoption of a New Drug. Soc Sci Med 1988; 26(12):1183-89; Sah S and Fugh-Berman A. Physicians under the Influence: Social Psychology and Industry Marketing Strategies. Journal of Law, Medicine and Ethics 2013; 41(3):665-672.

[101] E.g., Message Recall Tracking Study, Q1 '12 Brand Presentation, May 23rd, 2012, Fentora, TEVA_MDL_A_00501903; Nucynta Contracting Update, JAN-MS-00020777.

See also literature such as e.g., Puig-Junoy J and Moreno-Torres I. Impact of Pharmaceutical Prior Authorisation Policies: A Systematic Review of the Literature. Pharmacoeconomics, 2007; 25(8):637-648; Roughead E, Zhang F, Ross-Degnan D, and Soumerai S. Differential Effect of Early or Late Implementation of Prior Authorization Policies on the Use of Cox II Inhibitors 2006 Apr; 44(4):378-82, doi: 10.1097/01.mlr.0000204056.31664.36; Clark R, Baxter J, Barton B, Aweh G, O'Connell E, and Fisher W. The Impact of Prior Authorization on Buprenorphine Dose, Relapse Rates, and Cost for Massachusetts Medicaid Beneficiaries with Opioid Dependence. Health Services Research, 2014; 49(6):1964-1979; Yu C, Soumerai S, Ross-Dengan D, Zhang F, and Adams A. Unintended Impacts of a Medicaid Prior Authorization Policy on Access to Medications for Bipolar Illness. Medical Care, 2010; 48(10):4-9; Kotzan JA, Perri M III, Martin BC. Assessment of Medicaid prior-approval policies on prescription expenditures: market share analysis of Medicaid and cash prescriptions. J Managed Care Pharm 1996; 2(6): 651-6.

[102] E.g., November 2010, Strategic Customer Group, JAN-MS-00466015_Confidential, p.19; Nucynta Contracting Update, JAN-MS-00020777.

to patients, thereby reducing or removing that barrier to utilization.[103] [104] These coupons are important in all patient care settings, including hospitals where patients may be prescribed a medication while in the hospital but may face barriers to access when discharged into the community.

Others

70. In addition to prescribers and third-party payers, other important targets of pharmaceutical marketers include, for example, patients and caregivers, policy makers, academic and clinical researchers, sites of care (e.g., institutions, long term care, retail, or surgery centers), and influencers (e.g., professional and patient advocacy groups, employers, thought leaders, or policy makers, caregivers/families), and lobbying efforts.[105]

71. Pharmacists play a critical role in the delivery of medications by selecting which products they stock, and their influence on patients' decisions about whether to fill a given prescription. Because of this, pharmacists are targeted by pharmaceutical companies to ensure their products are stocked for dispensing, and to create favorable opinions towards the use of opioids by pharmacists.[106]

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[103] E.g., Fentora Marketing Mix Analysis Refresh, TEVA_MDL_A_01205575; Snyder (Allergan) California PMK Deposition, p.293; Grillone (Teva) California Deposition, p.65; Killion (Allergan) California Deposition, pp.158-159; April 2010 REP DOC Market Research Cost Specific Findings, JAN-MS-00259847_2010; $50 off Duragesic, JAN-MS-00291469; Duragesic Coupon ROI Analysis, MarketRx, July 2002, JAN-MS-00311391; Opana ER Brand Plan 2009, p.15, ENDO_NMAG-00233037; PPLPC008000005359, p.45.

[104] E.g., Nucynta $25 Savings Card, JAN-MS-00228916; $0 co-pay on first Rx., Pay no more than $25 Savings Card, JAN-MS-00229864; April 2010 REP DOC Market Research Cost Specific Findings, JAN-MS-00259847_2010; $50 off Duragesic, JAN-MS-00291469; Duragesic Coupon ROI Analysis, MarketRx, July 2002, JAN-MS-00311391.

[105] Schedule 6, Defendants' Marketing Plans, provides a listing of Defendants' marketing plans which specifically identify the various market segments targeted (using deciles and other metrics).

[106] E.g., Fitch (Allergan) California Deposition, pp.80-81; Knobloch (Allergan) California Deposition, pp.55, 108-109, 128, 178-184.

Common Marketing Techniques Used to Influence Prescribing

72. Pharmaceutical marketing encompasses a wide range of methods that are effective in generating demand for prescription drugs.[107] With a focus on prescribers who appreciate science,[108] pharmaceutical marketing techniques work best when the marketing messages appear to be based on scientific evidence. Science is appealing to prescribers because it provides a seemingly unbiased, non-commercial basis for the use of medication. The desire to integrate marketing messages with science, and communicate this with Customers, is the foundation of many of the marketing strategies Defendants used.

73. As noted in this report, personal (or direct) selling, also referred to as product detailing, is a common, and potent form of promotion. To understand the impact of detailing, research has shown that physicians may not recognize the impact that personal selling has on their own prescribing practices.[109] Other work has shown that physicians may not be able to discriminate between promotional information, e.g., information provided by a sales representative, and scientific evidence,[110] and further believe that their

[107] E.g., Schedule 6: Defendants' Marketing Plans; Teva | Global Compliance US Sales Compliance Policy Playbook, TEVA_MDL_A_04242715; Nucynta Contracting Update, JAN-MS-00020777.

[108] Whether science based or not, Janssen planned to use materials that had an "academic look and feel" to ensure success with its promotions. Taitel (Janssen) New Hampshire Deposition (JAN-FL-00167663) Exhibit 20, pp.4, 48. (JAN-MS-00476219)

[109] Chimonas S, Brennan TA, Rothman DJ. Physicians and drug representatives: exploring the dynamics of the relationship. J Gen Intern Medicine 2007; 22:184-190; Spurling GK, Mansfield PR, Montgomery BD, Lexchin J, Douse J, Othman N et al. Information from pharmaceutical companies and the quality, quantity, and cost of physicians' prescribing: A systematic review. PLoS Med. 2010; 7(10): e1000352. DOI:10.1371/journal.pmed.1000352; Steinman MA, Shlipak MG, McPhee SJ. Of principles and pens: Attitudes and practices of medicine housestaff toward pharmaceutical industry promotions. Am J Med. 2001; 110:551-557.

[110] Fickweiler F, Fickweiler W, Urbach E. Interactions between physicians and the pharmaceutical industry generally and sales representatives specifically and their association with physicians' attitudes and prescribing habits: a systematic review. BMJ Open 2017; 7:e016408.

colleagues are more susceptible to industry influences than they themselves are.[111] Other research has shown that physicians may not be aware of the impact that commercial sources (versus e.g., scientific evidence) of information can have on their prescribing,[112] including the receipt of gifts or payments[113] from industry sources. Some research has demonstrated a correlation between financial relationships among doctors and drug companies with greater payments associated with higher volumes of prescribing.[114] All of this research has informed the practices pharmaceutical marketers employ to grow their influence on prescriber decision-making with respect to drug

[111] Patwardhan A. Physicians-Pharmaceutical Sales Representative Interactions and Conflict of Interest. Inquiry 2016; 53:1-5.

[112] See, e.g., E. Clayton, "'Tis Always the Season for Giving," CALPIRG Report, September 2004, pp.1-9; Editorial Staff, "Pharmaceutical Marketing to Physicians: Free Gifts Carry a High Price," American Medical News, June 10, 2002; A. Wazana, "Physicians and the Pharmaceutical Industry," The Journal of the American Medical Association, January 19, 2000; 283(3):373-380; A. Fugh-Berman, "The Corporate Coauthor," Journal of General Internal Medicine, June 2005; 20(6):546-548. J. Avorn, M. Chen, and R. Hartley, "Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians," American Journal of Medicine, 73(1), July 1982, pp.4-8. P. Azoulay, "Do Pharmaceutical Sales Respond to Scientific Evidence?" Journal of Economics and Management Strategy, 2002; 11(4):551-94. It should be noted that because many scientific studies of prescription drugs are funded by the manufacturer the separation between promotion and scientific evidence that Azoulay assumes may not truly exist.

[113] A. Wazana, *supra.* See also J. Dana and G. Loewenstein, "A Social Science Perspective on Gifts to Physicians from Industry," The Journal of the American Medical Association, 290(2), July 9, 2003, pp.252-55. Physician denial of the influence of industry communication, samples, and gifts (including free medical education) may be understood in the context of extensive findings from behavioral psychology regarding unintentional and subconscious biases. W. Sandberg et al., "The Effect of Educational Gifts from Pharmaceutical Firms on Medical Students' Recall of Company Names or Products," Academic Medicine, 72(10), October 1997, pp.916-18; B. Hodges, "Interactions with the Pharmaceutical Industry: Experiences and Attitudes of Psychiatry Residents, Interns and Clerks," Canadian Medical Association Journal, 153(5), September 1, 1995, pp.553-59.

[114] Charles Ornstein, Mike Tigas and Ryann Grochowski Jones. Dollars for Doctors, Now There's Proof: Docs Who Get Company Cash Tend to Prescribe More Brand-Name Meds. ProPublica, March 17, 2016. https://www.propublica.org/article/doctors-who-take-company-cash-tend-to-prescribe-more-brand-name-drugs (last accessed March 2, 2019). See working paper methodology: https://static.propublica.org/projects/d4d/20160317-matching-industry-payments.pdf?22 (last accessed March 9, 2019).

choices. The Endo Pain Library program, where prescribers could select a medical reference free of charge, is a good example of how pharmaceutical companies leverage relationships with prescribers.[115]

74. Specifically related to opioids, Hadland et al. (2018) analyzed the extent to which pharmaceutical industry payments to physicians related to opioids during 2014 was associated with opioid prescribing behavior during 2015. The results indicated that: "receipt of any opioid-related payments from industry in 2014 was associated with 9.3% (95% CI, 8.7%-9.9%) more opioid claims in 2015 compared with physicians who received no such payments" (p.862). Hadland also investigated the impact of industry meals provided to physicians finding that "each additional meal was associated with an increase of 0.7% (95% CI, 0.6%-0.8%) in opioid claims."[116]

75. Other research has supported the growing concerns over payments from drug makers to prescribers.[117] [118] This body of literature suggests that regardless of what prescribers

[115] E.g., Kathleen Cronshaw 2/11/2013 email to Endo Pain Reps with subject 2013 Opana ER with INTAC Library Program. See also the Endo KOL Executive Engagement Program, that had the goal to "increase customer intimacy to show that Endo is a trusted partner in pain management through a series of executive level dinner programs," ENDO-OPIOID_MDL-00468149 and cover email ENDO-OPIOID_MDL-00468149.

[116] Hadland S, Yu L, Krieger M, Marshall B and Cerda M. Association of Pharmaceutical Industry Marketing of Opioid Products to Physicians with Subsequent Opioid Prescribing. JAMA Internal Medicine, June 2018; 178(6):861-863.

[117] Zezza M and Bachhuber M. Payments from drug companies to physicians are associated with higher volume and more expensive opioid analgesic prescribing. PLOS|ONE December 19, 2018. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0209383 (last accessed February 20, 2019).

[118] Mitchell A, Winn A, Lund J, and Dusetzina S. Evaluating the Strength of the Association Between Industry Payments and Prescribing Practices in Oncology. The Oncologist. Online: February 6, 2019. http://theoncologist.alphamedpress.org/content/early/2019/01/31/theoncologist.2018-0423 (last accessed February 9, 2019); Grande D. Limiting the influence of pharmaceutical industry gifts on physicians: self-regulation or government intervention? J Gen Intern Med. 2010; 25(1):79-83; Greenland P. Time for the medical profession to act: new policies needed now on interactions between pharmaceutical companies and physicians. Arch Intern Med. 2009;

may think about their decision-making, and the inputs to the decision-making process, the role of the pharmaceutical marketer significantly impacts their prescribing.[119]

Personal Selling

76. Prescribers need accurate drug information to take good care of their patients.[120] [121] When there is an information need, a virtual army of PSRs[122] stands ready to step in and provide the information and messages created for dissemination by their companies. This information can, for example, be focused on pharmaceutical products, diseases

169(9):829-831; Yeh JS, Franklin JM, Avorn J, Landon J, Kesselheim AS. Association of industry payments to physicians with the prescribing of brand-name statins in Massachusetts. JAMA Intern Med. 2016; 176(6):763-768.

[119] See, e.g., Grande D. Limiting the influence of pharmaceutical industry gifts on physicians: self-regulation or government intervention? J Gen Intern Med. 2010; 25(1):79-83; Greenland P. Time for the medical profession to act: new policies needed now on interactions between pharmaceutical companies and physicians. Arch Intern Med. 2009; 169(9):829-831; Hadland S, Yu L, Krieger M, Marshall B, and Cerda M. Association of Pharmaceutical Industry Marketing of Opioid Products to Physicians with Subsequent Opioid Prescribing. JAMA Internal Medicine, June 2018; 178(6):861-863; Zezza M and Bachhuber M. Payments from drug companies to physicians are associated with higher volume and more expensive opioid analgesic prescribing. PLOS|ONE December 19, 2018, https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0209383 (last accessed February 20, 2019); Orlowski JP and Wateska L. The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns. CHEST 1992; 102(1):270-273; Mitchell A, Winn A, Lund J, and Dusetzina S. Evaluating the Strength of the Association Between Industry Payments and Prescribing Practices in Oncology. The Oncologist. Published online before print February 6, 2019. http://theoncologist.alphamedpress.org/content/early/2019/01/31/theoncologist.2018-0423 (last accessed February 9, 2019).

[120] The Pharmaceutical Research and Manufacturers Association published a brochure in 2008 entitled, "Pharmaceutical Marketing in Perspective." In this brochure, they highlight the role of the PSR noting that PSRs help support effective patient care by disseminating information to prescribers. PHRMA, Pharmaceutical Marketing in Perspective, brochure. http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_brochure_influences_on_prescribing_final.pdf (last accessed February 9, 2020).

[121] E.g., Condodina (Teva) Deposition, pp.257-258.

[122] A 1999-2000 era document, attributed to Scott Levin, showed there were 3,412 PSRs promoting "pain." (JAN-MS-00785795)

being treated, or even treatment guidelines. While this information can educate, it also impacts Customers' decision-making, and therefore, product sales.

77. Medical Science Liaisons (MSLs), while not classified as sales personnel, contribute to sales effectiveness through their contributions to marketing intelligence as well as Customer education, for example, medical information requests regarding off-label use of marketed drugs.

78. Pharmaceutical companies use PSRs to provide information to prescribers and to generate prescriptions.[123] In fact, personal selling, through PSRs (and indirectly through MSLs), is effective and has traditionally accounted for more than half of all pharmaceutical marketing expenditures industry-wide.[124] [125]

[123] See, e.g., Ali Murshid M, Mohaidin Z. Models and theories of prescribing decisions: A review and suggested new model. Pharmacy Practice 2017 Apr-Jun; 15(2):990; Datta A and Dave D. Effects of Physician-directed Pharmaceutical Promotion on Prescription Behaviors: Longitudinal Evidence. Health Economics. April 2017; 26(4):450-469; Stros M and Lee N. Marketing dimensions in the prescription pharmaceutical industry: a systematic literature review. J of Strategic Marketing 2015; 23(4):318-336.

[124] See, e.g., Creyer E and Hrsistodoulakis I. Marketing pharmaceutical products to physicians: sales reps influence physicians' impressions of the industry. Marketing Health Services. 1998; 18(2): 34-38; Huston P. Doctors want more industry-sponsored meetings. Medical Marketing & Media. 1993; 28(3):48-53; John Mack, Pharma Marketing News. Pharma Promotional Spending in 2013. http://www.pharma-mkting.com/articles/pm1305-article01/ (last accessed June 18, 2020); Anon. Persuading the Prescribers: Pharmaceutical Marketing and its Influence on Physicians and Patients, at http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients (last accessed June 18, 2020); Gonul, F., Carter, F., Petrova, E., & Srinivasan, K. Promotion of prescription drugs and its impact on physicians' choice behavior. Journal of Marketing, 2001; 65:79–90.

[125] The impact of the sales force on sales is described in numerous documents. Generally, the larger the sales force, the greater the top-line sales expectations. E.g., Impact of Withdrawal of Field-Based Promotion for Kadian, March 13, 2009, ALLERGAN_MDL_00448421; Actiq 2002 Marketing Plan, TEVA_MDL_A_00454816; Fentora Marketing and Sales January 9, 2012, p.6; ALLERGAN_MDL_01692522; Promotional Response of Fentora, Findings, TEVA_MDL_A_01543547.

79. PSRs are the primary tool that a pharmaceutical marketer can rely on to communicate and implement the full scope of messages and activities in the marketing plans. The PSR is central to the coordination of marketing activities in the field and they serve as the link between marketing planning and its implementation with Customers.[126] Because of the critical nature of their roles, PSRs are extensively trained, closely monitored and evaluated, coached and given feedback, rewarded for performance (sales) and sometimes terminated when performance does not meet company goals or standards.[127]

80. Defendants' PSRs were relentless in their pursuit of sales calls, visiting some Customers multiple times per month. In some cases, PSRs went to great lengths to consummate a sale. For example, Cephalon PSR Mr. Lou Ciampi once took it upon himself to counsel an anesthesiologist's patient "Michael" about the proper use of his new Actiq prescription. Mr. Ciampi then drove to the pharmacy, picked up the patient's Actiq, and returned to

[126] This Report documents numerous activities which are planned at the national level and carried out by PSRs, including in the state of Florida., such as the identification, cultivation, analysis, organization and implementation of activities with KOLs. See also e.g., Spokane (Teva) Deposition, pp.39-40.

[127] E.g., Leitch (Allergan) Deposition, pp.206-211; Kaisen (Teva) Deposition, p.40; Sippial (Teva) Deposition, p.78; Snyder (Allergan) Deposition, pp.159-160; Spokane (Teva) Deposition, pp.285-286; Morreale (Teva) Deposition, pp.48-62 and Morreale Deposition Exhibits 5, 6, and 7; Sippial (Teva) Deposition, pp.345-348; Altier (Allergan) Deposition, pp.315- 319; Chris Hepp 2/16/2012 email, Acquired_Actavis_00181335; Sherperd 2/28/2012 email, ALLERGAN_NY_00039119; ENDO_FLAG_-00106823, Foley 1/3/2011 email with subject "PIP report;" ENDO_FLAG-00106824, PIP Report Naples; ENDO_FLAG-00106825, PIP Report Fort Myers; ENDOSell Coaching Report, Oscar Farach, 7-11-2007, ENDO_FLAG-00128800; Brad Strode, ENDOSell Coaching Report, 11-17-2007, ENDO_FLAG-00166371; ENDOSell Coaching Report, ENDO_FLAG-00166390.

Dr. Shurman's office to deliver the medication to the patient.[128] While I did not see this behavior repeated, this example demonstrates aggressive PSR behavior.[129] [130]

81. PSRs generally create notes related to their sales calls, referred to as "call notes," or "call logs" to partially document a PSRs interaction with Customers and the general messages, or materials discussed with the Customer. A sampling of Defendants' call notes in this matter are presented in Table 1.

82. At some point, Defendants' documentation of sales calls no longer contained free-form commentary entered by the PSR describing the nature of what was communicated to the prescriber.[131] Instead, call logs reflected choices from drop-down menus with predefined options that PSRs could select. This change in the call note format limited the kind of information that could be gleaned from the commentary formerly provided by PSRs.

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[128] Ciampi (Teva) California Deposition, p.129 and Ciampi Deposition Exhibit 16 (an excerpt from a call log).

[129] This incident was not the only time that Mr. Ciampi was relentless in his pursuit of increasing TRx. In a note to the file on April 24, 2003, Joe Duarte wrote, "Discussion concerning Joe's discussion with Lou Ciampi. Joe overheard conversation Lou was conducting with a patient. Lou spent 40 minutes or so guiding the patient through reimbursement process. Lou suggested that since the patient was having problems getting reimbursed for Actiq that he/she visit the ER 2 or 3 times a week to drive up healthcare costs for PacifiCare and then documenting this with PA through the physicians to force plan to pay for Actiq. Certainly (sic) stepped over the line in this situation. Received call from Joe the day after and it was decided that Joe will talk with Andrea Braun the following day to inform her of Lou's activities." (Ciampi (Teva) California Deposition, pp.158-159 and Ciampi Deposition Exhibit 22) In this situation, perhaps Mr. Ciampi was influenced by Teva sales training promoting the use of Actiq in migraine and even referring to Actiq as "ER on a stick," Etiology of Migraine presentation, undated, 17 pages, TEVA_MDL_A_00505311.

[130] E.g., 2007.05.23 Kasik ENDOSell Coaching Report, ENDO-OPIOID MDL-00684008.

[131] E.g., Sippial (Teva) Deposition, pp.45-51. Compare, Actiq sales call database (TEVA_MDL_A_02416207) and Fentora sales call database (TEVA_MDL_A_00763717).

83. Defendants' marketing reflected the value of personal selling and a reliance on sales personnel to increase sales.[132] For example, Ken Peterson, a PriCara Big 12 North Pain District Manager, wrote to his team in 2010 regarding the relationship between sales calls and prescriptions, "I realize the idea of more sales calls equaling more scripts is not a revelation." He also provided the team with some "top-line analytics" of this relationship, specifically:[133]

- "Customers with an average of 1.5 to 3 calls per month ***have double!*** [emphasis in original] the average monthly Rx vs. customers with 1 to 1.5 calls per month
- When you compare those same call average above, the total 7 month Rx volume per customer jumps up ***104%!*** [emphasis in original]
- Rx persistency also increases significantly as you increase average calls per month
- Something else that stands out is the almost perfect shading from yellow to green as you increase average calls per month on each customer."

84. Given the importance of the sales force, it is apparent why Janssen contracted with Quintiles to market its Nucynta IR and ER.[134] Additional outside sales personnel would work to maintain or grow Nucynta sales.

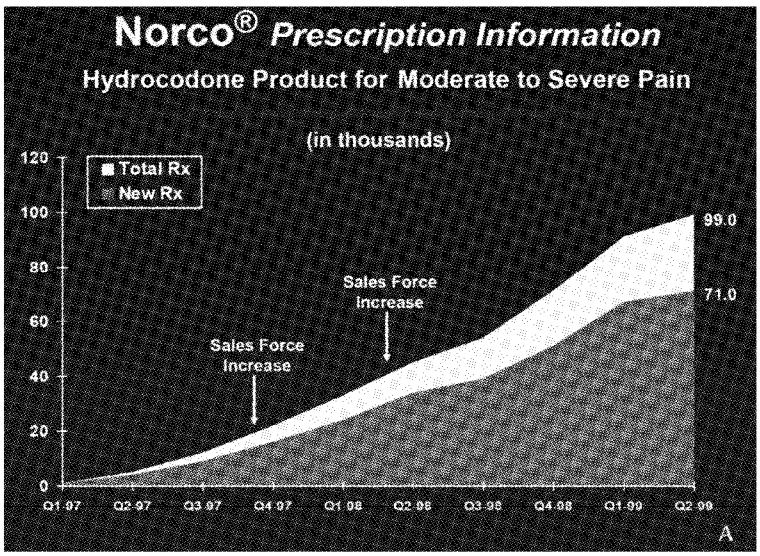
85. As noted above, the expectation was more sales calls would result in more prescriptions. This was reflected in a Watson investor report where the graphics (see

[132] E.g., Schedule 6: Defendants' Marketing Plans.

[133] Ken Peterson 5/27/2010 email to his team with subject "Call Frequency Converter," JAN-MS-02470285.

[134] JAN-MS-01049919; David Lin presentation from about 2012 where he describes the role of Quintiles as a "trusted partner." Mr. Lin refers to Janssen's "PainForce," the partnership between Janssen and Quintiles, as an elite team with clinical expertise in pain, marketplace savvy, and ability to "thrive in ambiguity." (JAN-MS-00020005, p.16)

insert below) support the correlation between sales force increases and increased new and total prescriptions.[135]



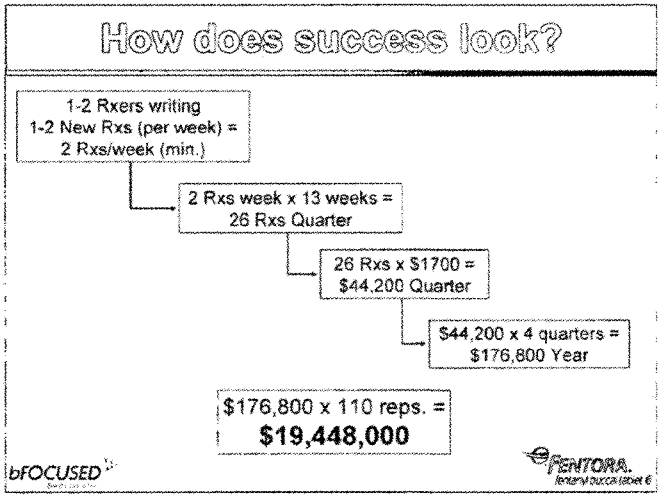
86. A 2009 study by Health Products Research conducted for Actavis quantified the expected impact of reductions in the Kadian sales force on the product's sales. Based on this analysis, Actavis was able to anticipate "a reduction of 34-47% of Kadian TRx (and $'s) in 2009 as a result of withdrawing detailing."[136] A decline in sales, resulting in the removal of detailing efforts would support the proposition that detailing results in increased sales.

87. In a Teva sales training program entitled, "Creating Synergy: Pain Talk with Oncology," the ultimate goal of successful sales calls was noted in the slide "How does success

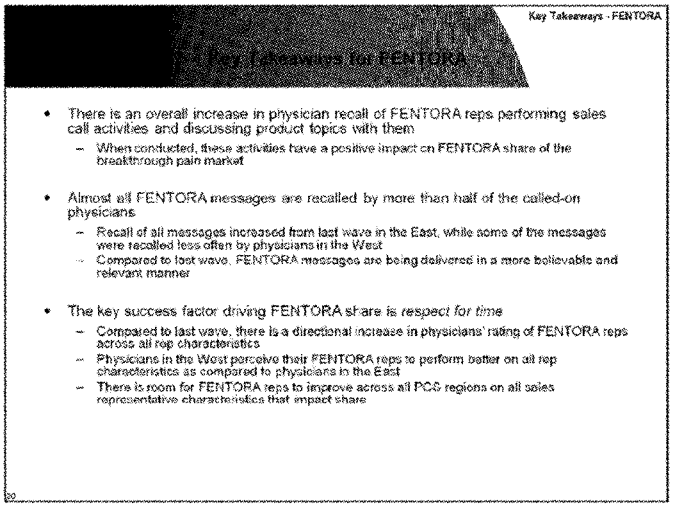
[135] Watson Pharmaceuticals, Inc. NYSE: WPI, TEVA_MDL_A_02414300, p.14.

[136] ALLERGAN_MDL_00448421, Impact of Withdrawal of Field-Based Promotion for Kadian, March 13, 2009. With respect to Kadian and the short period of time remaining on its patent, after the product acquisition in 2008, Actavis had to decide how much to invest in the direct marketing of this drug. This document assessed options for the size of the sales force.

look?" Here, we see the relationship between prescription generation and profits. (See insert below)[137]



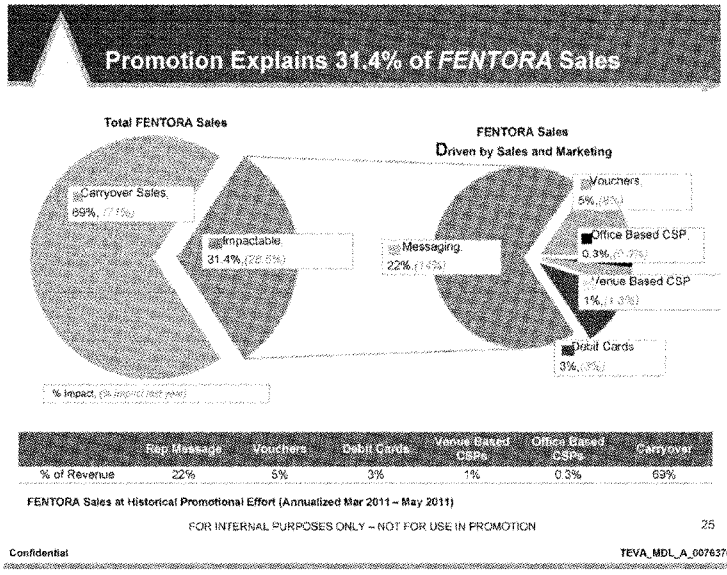
88. Similarly, ZS Associates conducted a sales force effectiveness study for Cephalon in 2010. The "Key Takeaways" for Fentora are presented in the insert below.[138]



[137] Creating Synergy: Pain Talk with Oncology, p.5, TEVA_MDL_A_00002281.

[138] TEVA_MDL_A_00766455, ZS Associates May 4, 2010 Sales Force Effectiveness Study.

89. In a different type of analysis, Teva examined the impact of its promotional tactics on sales performance of Fentora.[139] This evaluation demonstrated that promotional tactics jointly explained 31.4% of annual Fentora sales. (See insert below) The balance of sales, stemming from prior product use were termed "carryover sales" and represented 69% of Teva's revenue from the Fentora product. This implies that once trial and adoption have occurred, prescribing is durable to a large extent and Customers will remain loyal to the brand and continue to prescribe the product. It is important to note that the *original trial* of the medication was likely influenced by pharmaceutical marketing efforts.



90. Data points such as these, and others noted in this Report, support the proposition that there is a positive correlation between marketing, including detailing, and sales. In fact,

[139] TEVA_MDL_A_00763740, 2012 Fentora Brand Plan. See also Fentora 2014 Annual Operating Plan (August 2013), p.11, TEVA_MDL_A_00763899.

industry wide, personal selling is one of the most powerful and widely used pharmaceutical marketing techniques.[140] Defendants' marketing documents and the marketing literature both support this proposition.[141] Personal selling is effective because it utilizes effective communication techniques, education (information) and

[140] The extensive literature on pharmaceutical marketing provides substantial support for the proposition that personal selling (detailing using PSRs) is a cost-effective means of promotion for drugs. While a complex issue, the evidence indicates that pharmaceutical manufacturers obtain a positive return on investment for detailing. See, e.g., "Return on Investment Implications for Pharmaceutical Promotional Expenditures: The Role of Marketing Mix Interactions." (Narayanan S, Desiraju, R and Chintahunta P. Return on Investment Implications for Pharmaceutical Promotional Expenditures: The Role of Marketing Mix Interactions Journal of Marketing. October 2004; 68:90-105.) See also other literature describing the relationship between detailing and sales, including, e.g., Liu Q, Gupta S, Venkataraman S, and Lie H. An Empirical Model of Drug Detailing: Dynamic Competition and Policy Implications. Management Science. August 2016; 62(8):2149-2455; Wood SF, Podrasky J, McMonagle MA, Raveendran J, Bysshe T, Hogenmiller A, et al. (2017) Influence of pharmaceutical marketing [gifts] on Medicare prescriptions in the District of Columbia. PLoS ONE 12(10):e0186060; Fickweiler F, Fickweiler W, Urbach E. Interactions between physicians and the pharmaceutical industry generally and sales representatives specifically and their association with physicians' attitudes and prescribing habits: a systematic review. BMJ Open 2017; 7:e016408. Brax H, Fadlallah R, Al-Khaled L, Kahale LA, Nas H, El-Jardali F, et al. (2017) Association between physicians' interaction with pharmaceutical companies and their clinical practices: A systematic review and meta-analysis. PLoS ONE 12(4) e0175493; Spurling G, Mansfield PR, Montgomery BD, Lexchin J, Doust J, Othman N, Vitry AI. Information from Pharmaceutical Companies and the Quality, Quantity and Cost of Physicians' Prescribing: A Systematic Review. PLoS Med 2010; 7(10):e1000352; Ahmed, R.R., Vveinhardt, J., Streimikiene, D., and Awais, M. Amfiteatru Economic, 2016; 18(41):153-167; Gonul, F., Carter, F., Petrova, E., & Srinivasan, K. (2001). Promotion of prescription drugs and its impact on physicians' choice behavior. Journal of Marketing, 65, 79-90; Chintagunta P, Gottler R and Kim,M. New Drug Diffusion When Forward-Looking Physicians Learn from patient Feedback and Detailing. Journal of Marketing Research. December 2012; 49:807-821; other relevant papers cited *infra*.

[141] Campo K, Staebel OD, Gijsbrechts E, and Waterschoot W. Physicians' Decision Process for Drug Prescription and the Impact of Pharmaceutical Marketing Mix Instruments. Health Marketing Quarterly 2005; 22(4):73-107; Orlowski JP and Wateska L. The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns. CHEST 1992; 102(1):270-273.

relationship building to communicate with, educate, and influence prescribers.[142] Further, sales personnel can directly provide promotional materials (referred to as "leave behinds") that reinforce and remind prescribers about sales messages even after a sales call.[143] [144]

91. However, recipients of marketing materials provided by pharmaceutical companies should use this information for medical decision-making carefully because it may not always be accurate,[145] [146] and PSRs, through their salary and bonus incentive programs discussed below, also have a commercial bias potential that impacts their communication with Customers.[147]

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[142] Manchanda P, Honka E. The effects and role of direct-to-physician marketing in the pharmaceutical industry: an integrative review. Yale J. Health Policy Law & Ethics 2005; 5:785-812.

[143] M.Y. Peay and E.R. Peay. The Role of Commercial Sources in the Adoption of a New Drug. Social Science and Medicine 1998; 26:1183–1189.

[144] PSRs generally like leave behind materials because they serve as a lasting reminder to the prescriber for both the product advertised and the company. For example, approved reprints are utilized as leave behinds because when presented to prescribers they provide a springboard for discussion and serve as a reminder for Customers after the sales call. E.g., ALLERGAN_MDL_01540065, Allergan Sales Call Log circa 2005-2008; Courtney Tholen 2/2/2017 email, TEVA_MDL_A_08741610; Lisa Peletsky 8/18/2010 email, TEVA_MDL_A_11440517; Valerie Kaisen 3/15/2010 email, TEVA_MDL_A_01868375; ENDO_FLAG_DATA_00000008, material drop log.

[145] Cardarelli R, Licciardone JC, Taylor LG. A cross-sectional evidence-based review of pharmaceutical promotional marketing brochures and their underlying studies: is what they tell us important and true? BMC Family Practice 2006; 7:13; Cooper RJ, Schriger DL, Wallace RC, Mikulich VJ, Wilkes MS. The Quantity and Quality of Scientific Graphs in Pharmaceutical Advertisements. Journal of General Internal Medicine, 2003; 18:294-297; Villanueva P, Peiro S, Librero J, Pereiro I. Accuracy of Pharmaceutical Advertisements in Medical Journals. Lancet 2003; 361:27-32.

[146] Pfyer (Teva) Deposition Exhibit 18 (2002 Actiq Marketing Plan); Beckhardt (Teva) Deposition, pp.230-232, 250-256, and Exhibit 14, RMP vs. Actiq Marketing Plans.

[147] For example, the Nucynta Contest Blast Off Flyer informs PSRs that they can earn $40 per Nucynta prescription and be considered for a trip to the Virgin Islands. (JAN-MS-00362270 & JAN-MS-00362272) See also other examples, such as JAN-MS-00362273.

92. Further, with respect to the "education" provided by PSRs, marketing has the core goal of increasing product awareness and knowledge by providing information to Customers. PSR information educates customers, but is marketing, nevertheless. Defendants compensation of PSRs with salary, bonus, and incentives confirms the marketing-education synergy by attaching financial rewards to the education PSRs provide and the outcomes of that education: prescription sales.[148]

93. Combining incentives for PSRs to achieve sales goals with aggressive sales expectations (and metrics) would work to increase sales and to expand the total market for opioids.[149] [150] This could mean captured market share or expansion of the total market for opioids. While I have seen numerous incentive programs, many of which are cited in

[148] E.g., 2012 Bonus Roll-Out Presentation, "A BRAND NEW DAY," TEVA_MDL_A_02351662; Boothe (Allergan) Deposition, pp.36-40; Condodina (Teva) Deposition, p.162; Day (Teva) Deposition, pp.117-118; Gillenkirk (Teva) Deposition, pp.27-28, 254; Snyder (Allergan) Deposition, pp.159-160 and Exhibit 5; ALLERGAN_MDL_00397811, 2011 Kadian Area Business Manager Incentive Compensation Program; Pain Care Specialist 4th Quarter 2006 Incentive Compensation Plan (TEVA_CHI_00041421); Michael Perfetto 11/7/2011 email, ALLERGAN_MDL_00186509; Acquired_Actavis_02283431 p.16; Pain Care Specialist, 4th Quarter 2006 Incentive Compensation Plan, TEVA_CHI_00039257 (there are two versions, this version is purported to be without errors); Hassler (Teva) 30(b)(6) Deposition, pp.247-248; 2012 Bonus Plan Overview to Pain Specialists, February 27, 2012, TEVA)MDL_A_07093742, TEVA_FL_00019167, Gillenkirk (Teva) Deposition Exhibit 13.

[149] Mintzes B and Lexchin J. The "Nuts and Bolts" of Opioid Marketing: Promotional Messages to Family Doctors in Sacramento, Vancouver, Montreal, and Toulouse. J Gen Intern Med. DOI:10.1007/211606-019-05584-5; Hadland SE, Cerda M, Li Y, Krieger MS, Marshall BDL. Association of Pharmaceutical Industry Marketing of Opioid Products to Physicians with Subsequent Opioid Prescribing. JAMA Internal Med. 2018; 178(6):861-3; Van Zee A. The promotion and marketing of oxycontin: commercial triumph, public health tragedy. Am J Public Health. 2009; 99(2):221-7.

[150] It is important to consider incentivizing PSRs in the context of two issues: 1) marketing messages aimed at more broadly defining who should be treated with opioids, for how long, and at what doses (see marketing plans and Section III of this Report); and, 2) Defendants' expectation that the pain market was growing. These two issues imply an expanding market for opioids. There are numerous data points identified in this Report that support the proposition that the marketing of opioids was designed to expand which patients or types of pain should be treated with opioids in the pain product category.

this Report, I have not seen efforts by Defendants to cap or limit the market for opioids, for example in their marketing plans, marketing goals, or sales quotas set for PSRs. What I have seen is ever increasing sales targets and evidence that the market for opioids expanded significantly.[151]

94. The act of incentivizing PSRs must be considered in the context of how incentives and marketing messages were linked: opioid marketing sought to define more broadly who should be treated with opioids (e.g., which patients, what type of pain), for how long, and at what doses,[152] and attaining these goals was rewarded by incentive compensation plans.

95. As noted in this Report, capturing market share, and expanding the market for opioids are not mutually exclusive sales goals. I agree that Defendants, and other opioid manufacturers sought to grow market share. However, the marketing messages in Table 2 reveal corollary goals that are focused on growing the size of the overall opioid market (market development).[153] Trends in opioid use nationally,[154] and the marketing metrics gathered by opioid manufacturers, including Defendants, confirm this.

96. These data points support the proposition that both market share and market expansion occurred because of opioid manufacturers, including Defendants', marketing of opioids. Based on the examples provided here, and many other examples I have seen,

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[151] See the marketing plans and sales metrics cited in this Report; Schedule 6: Defendants' Marketing Plans; Schedule 13: DEA Production Quotas and Requests; JAN-MS-02320363, Duragesic 2003 Business Plan, July 30, 2002; JAN-MS-02320366, Duragesic 2004 Business Plan August 6, 2003.

[152] Schedule 6: Defendants' Marketing Plans; Section III of this Report.

[153] See Schedule 6: Defendants' Marketing Plans; Table 2: Defendants' Marketing Messages.

[154] See, e.g., Pezalla et al. Secular trends in opioid prescribing in the USA. Journal of Pain Research 2017; 10:383-387; Jayawardhana J, Abraham A, and Perri M. Opioid Analgesics in Georgia Medicaid: Trends in Potential Inappropriate Prescribing Practices by Demographic Characteristics, 2009-2014. Journal of Managed Care and Specialty Pharmacy 2018 Sep; 24(9):886-894; Schedule 10 Evaluation of Marketing Impact by Defendants.

these data also uniformly support the proposition that increased use of PSRs to contact Customers with market penetration and market development sales messages resulted in increased sales of opioids. This directly links Defendants' marketing to the increased prescribing of opioids.

Research, Publications & Medical Journal Advertising

97. Marketing aims to create favorable perceptions in customers' minds about an advertised product. For pharmaceutical marketers, this includes using science (e.g., by supporting research, writing, or commissioning publications, or medical journal advertising) to the best advantage to create the desired product position. In marketing, there is an expectation that marketing messages are truthful and accurate. PSRs agreed that this expectation existed with their Customers.[155]

98. Medical journals are useful to the pharmaceutical marketer because they allow advertising to be inserted along with published research. Peer-reviewed publications are generally considered to be unbiased and reliable sources of information, and physicians rely on the conclusions of research studies to make decisions for their patients. Opioid manufacturers, including Defendants', took advantage of Customer preference for science-based information to market opioids.

99. However, the growing body of medication research and publications may contain commercial bias.[156] [157] Even peer-reviewed research, with appropriate disclosures of

[155] E.g., Fitch (Allergan) California Deposition, pp.60-61, 109-110; Hagy (Allergan) California Deposition, p.44; Knobloch (Allergan) California Deposition, p.117; Killion (Allergan) California Deposition, p.202.

[156] Company-sponsored research can include financial or other support provided in the conduct of research or in the publication process. This would include, for example, research funding, study protocol development (research design, selection of clinical endpoints, study period, etc.), writing assistance, or payments to investigators who may also be KOLs or provide other paid consulting services (e.g., CME talks) to companies.

[157] See, e.g., Tasi A. Conflicts Between Commercial and Scientific Interests in Pharmaceutical Advertising for Medical Journals. International Journal of Health Services Research, 2003;

funding sources and investigators' potential conflicts of interest, may still be perceived by prescribers as less objective. When commercial interests are not disclosed or are disguised, and conflicts are perceived or are discovered, the credibility of the information in the publication is further diminished.[158]

100. Pharmaceutical marketers also advertise in medical journals, alongside peer-reviewed research.[159] This advertising works because when prescribers are reading medical journals and the research contained therein, they also see promotional, company-sponsored advertisements. The presence of advertisements, alongside credible research, lends credibility to the advertisements, making them more effective.[160]

101. Defendants' marketing and other business plans, including "publication" plans, included goals to support research and publications, and to provide grants for research aimed at supporting marketing claims.[161]

Peer-to-Peer Marketing

102. A core marketing principle (and tactic) is "opinion leadership" because people listen to others whom they believe have greater knowledge and experience about a subject. A

33(4):751-768; L. Friedman and E. Richter, "Relationship Between Conflicts of Interest and Research Results," Journal of General Internal Medicine, 2004; 19(1):51-56.

[158] See, e.g., Cooper R and Schriger D. The availability of references and the sponsorship of original research cited in pharmaceutical advertisements. Canadian Medical Association Journal, 2005; 172(4):487-491; Friedman L and Richter E. Relationship Between Conflicts of Interest and Research Results. Journal General Internal Medicine 2004; 19(1):51-56.

[159] E.g., TEVA_MDL_A_01140792.

[160] Fugh-Berman A, Alladin K and Chow J. Advertising in Medical Journals: Should Current Practices Change? PLoS Medicine, 2006; 3(6):e130. https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.0030130&type=printable (last accessed June 18, 2020).

[161] E.g., Kadian 2005 Publication Plan, ALLERGAN_MDL_00815516; Schedule 6: Defendants' Marketing Plans; Table 2: Defendants' Marketing Messages (includes citations of research); Schedules 10, 12 and 13 related to advocacy and KOLs; FEBT [Fentanyl Effervescent Buccal Tablet] Strategic Publication Plan 2005-2006, July 2005, TEVA_MDL_A_00556886.

significant driver of a physician's view of a drug is how the drug is perceived by peer-physicians, making "opinion leadership" or "peer-to-peer" marketing an effective sales technique. Peer-to-peer marketing uses key opinion leaders (KOLs) or "influencers" and word-of-mouth to create an expanding awareness and more rapid adoption of new pharmaceuticals by prescribers and other stakeholders.[162]

103. The use of KOLs works because it legitimizes marketing messages, increases Customer awareness of a company's product(s), and conveys favorable impressions and experience with a drug, when the information comes from a respected peer.[163] KOLs are also valuable because they can engage in discussion with the medical community that is outside the scope of what would be appropriate for a manufacturer to say about its product.[164] To this point, Ms. Beckhardt described in her deposition, with respect to Actiq and Fentora, Cephalon's support (payment) of KOLs to speak at medical meetings about the results of studies using these two drugs in non-cancer pain.[165]

104. Ms. Bearer, Associate Director of the East Region Account Management Team at Cephalon, noted that one of her goals for the Fentora product was to collaborate and

[162] Peer-to-peer marketing frequently involves dinners or other programming where Customers are brought together for education and discussion with KOLs. E.g., the Kadian Advocacy Development presentation from 2006 that develops the role and utility of KOLs, as well as Actavis (Alpharma) plans for developing advocacy with respect to Kadian. (ALLERGAN_MDL_02513100) See also the Paula Castagno 12/5/2003 email, TEVA_MDL_A_07182275; JAN_MS_00312510.

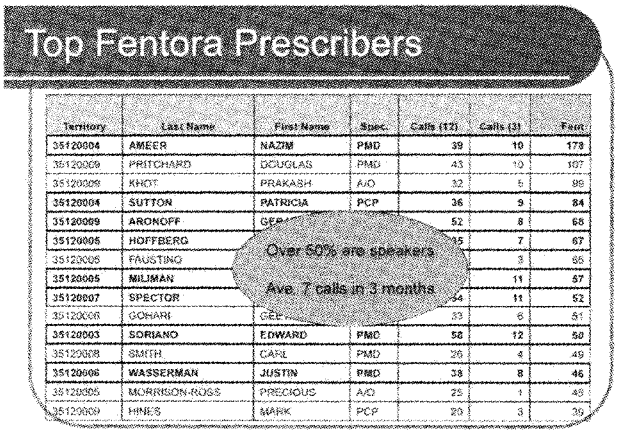
[163] See generally, Leveraging Peer-to-Peer Networks in Pharmaceutical Marketing. Innovation & Marketing in the Pharmaceutical Industry, Emerging Practices, Research, and Policies. Ding, Eliashberg and Stremersch Eds., Springer, 2014, Chapter 15, pp.457-475; David Rear, Show Me the Money, Medical Marketing & Media, May 2012, mmm-online.com, Med Ed Report 2012 pp.52-54; J.S. Coleman, E. Katz, and H. Menzel. Social Processes in Physicians' Adoption of a New Drug. J of Chronic Diseases, 1959; 9(1):1-19; E.R. Berndt, R.S. Pindyck and P. Azoulay, "Consumption Externalities and Diffusion in Pharmaceutical Markets: Antiulcer Drugs," The Journal of Industrial Economics, 2003; 51(2):243-270.

[164] Bearer (Teva) Deposition, pp.192-193; Barrett (Allergan) Deposition, pp.193-194, and Deposition Exhibit 11.

[165] Beckhardt (Teva/Cephalon) Deposition, pp.302-305.

communicate with sales teams to identify KOLs .[166] This was the norm for Cephalon's sales and marketing professionals as engagement with KOLs was noted by numerous employees.[167]

105. In some cases, KOLs who were paid speakers, were also among the top Fentora prescribers.[168] (See insert below) Further, for at least some speakers who did not agree with Cephalon's philosophy regarding the use of short acting opioids for the treatment of non-cancer pain, these speakers were "cancelled" and no longer used by Cephalon.[169] This is a subtle form of control of the message (content) of these kinds of non-promotional educational programs.



Top Fentora Prescribers

Territory	Last Name	First Name	Spec	Calls (12)	Calls (3)	Fent
35120004	AMEER	NAZIM	PMD	39	10	178
35120009	PRITCHARD	DOUGLAS	PMD	43	10	107
35120009	KHOT	PRAKASH	A/O	32	5	96
35120004	SUTTON	PATRICIA	PCP	36	9	84
35120009	ARONOFF	GEF		52	8	68
35120005	HOFFBERG			35	7	67
35120005	FAUSTINO				3	65
35120005	MILMAN				11	57
35120007	SPECTOR			54	11	52
35120006	GOHARI	GEF		33	6	51
35120003	SORIANO	EDWARD	PMD	58	12	50
35120008	SMITH	CARL	PMD	26	4	49
35120006	WASSERMAN	JUSTIN	PMD	38	8	46
35120005	MORRISON-ROSS	PRECIOUS	A/O	25	1	45
35120009	HINES	MARK	PCP	20	3	39

Over 50% are speakers

Ave. 7 calls in 3 months

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HIGHLY CONFIDENTIAL TEVA_AAMD_00726908

[166] TEVA_MDL_A_00873333, Employee Self Appraisal, Deborah Bearer, October 15, 2007.

[167] E.g., Bearer (Teva/Cephalon) Deposition, pp.48-53; Beckhardt (Teva/Cephalon) Deposition, pp.42-47, 275-278, 304-308, 338-339, 347-348; Condodina (Teva) Deposition, pp.369, 372-373; Day (Teva) Deposition, pp.55-60, 172; Barrett (Allergan) Deposition, pp.160-161, 193 and Deposition Exhibit 11 (BARRETT_MDL_00000114); Spokane (Teva) Deposition, pp.34-40, 174-175.

[168] 2008 National Sales Meeting, TEVA_MDL_A_09601937.

[169] TEVA_MDL_A_01401012, Castagno 5/3/2004 email; TEVA_MDL_A_02588793, Dittbenner 5/15/2004 email.

106. However, Ms. Altier noted that Actavis did not hire KOLs to promote Kadian. She explained that "[w]e were at the end of our product lifecycle. Generic competition was imminent. Our goal was to maintain product share."[170] In fact, according to Ms. Altier, the Kadian sales force was "let go" after the merger with Watson in 2012, based on a decision by Watson management.[171] Mr. Boothe also confirmed that KOLs were not used for Kadian while he was employed by Alpharma.[172]

107. Mr. Bingol at Endo characterized the use of KOLS as "[u]sing KOLs as thought leaders -- they had a broad network and a broad following, and if they were -- as they work with you, it brings more credibility to the message.[173]

108. The selection of KOLs sometimes involved detailed analysis of their qualifications.[174] For example, at Teva, KOLs were recruited through a "cross-functional" team composed of marketing, legal, compliance and medical that worked to develop the speaker's bureau composed of key opinion leader speakers.[175]

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[170] Altier (Allergan) Deposition, pp.369-370.

[171] According to Ms. Altier, the Kadian sales force was a contracted sales force that numbered about 20 (InVentiv) through about 2009 and up to as many as 48 between about 2010 and 2012. In 2012, in-person marketing ceased, and all Kadian marketing was withdrawn in late 2013. From this point on, Kadian was marketed as a generic product. (Altier (Allergan) Deposition, pp.39-79, 138-148)

[172] Boothe (Allergan) Deposition, pp.357-373. Mr. Booth does note that KOL strategy was considered with respect to the planning for the MoxDuo product, which was never launched.

[173] Bingol (Endo) Deposition, p.95.

[174] E.g., Beckhardt (Teva/Cephalon) Deposition, p.308; Cephalon Speaker Bureau Policy, TEVA_MDL_A_03206965; Dana Luscombe 5/24/2004 email with attachment, Sales Bulletin #16, May 24, 2002 Cephalon Speaker Bureau Changes, TEVA_MDL_A_08873054; TEVA_MDL_A_03458944, Teva Call Log; KOL ranking spreadsheet, JAN-MS-01498613; Email chain from Haya Taitel to Gregory Imber with subject FW: Master KOL listing (including rankings of KOLs), JAN-MS-02533808; Duragesic KOL Mapping Analysis, JAN-MS-02533811; JAN-MS-0253813, National KOL Valuation Index Spreadsheet.

[175] Day (Teva) Deposition, pp.59-60.

109. While most of the documents identifying KOL selection criteria included the requirement that a thought leader actually be a current prescriber of a company's product,[176] in one instance, the ability to deliver credible messages was linked directly to how much of a company's product was being prescribed by the potential KOL. According to Mr. Ciampi's notes, Anesthesiologist Joseph Shurman was an aspiring KOL. Mr. Ciampi wrote about his interaction with Dr. Shurman regarding becoming a speaker for Cephalon, "He wants to become a speaker for Actiq. I told him that one of the speaker requirements is to have at least 20 patients. He is striving to meet that number. Currently he has 3 patients on Actiq."[177] This example demonstrates a type of control that opioid marketers like Cephalon can exert over educational program content.

110. Janssen's program planners noticed when KOL speakers did not convey favorable impressions about their product. For example, at a June 2009 Janssen speaker program in Dallas, Texas, Dr. Jeffrey Loomer, a Janssen speaker at a Nucynta program, told the audience that Nucynta should not be prescribed for more than 90 days. This caught the attention of Haya Taitel, Group Product Director for Tapentadol. She commented:

> I received a disturbing feedback about a speaker program in which the speaker indicated to the audience that Nucynta should not be prescribed for more than 90 days. Rob – who was the speaker? Can we educate the speaker that we studied Nucynta for 90 days in our safety study but the FDA via our label did not put time restriction on this medication.[sic] While it is an acute pain indication, acute exacerbation of pain can be of longer use need.[178]

[176] E.g., Spokane (Teva) Deposition, pp.35-36.

[177] Ciampi (Teva) California Deposition Exhibit 16.

[178] Haya Taitel 6/25/2009 email with subject "Got Feedback about a speaker program." (JAN-MS-00254146)

111. Another benefit of peer-to-peer marketing is the expansion of the marketer's "reach." Peer-to-peer marketing enables manufacturers to pass messages along to these physicians who may not be reachable via personal selling. Further, peer-to-peer networks can increase efficiency and return on investment (ROI) when used synergistically with the sales call, as targeted prescribers are reached via both the sales encounter and through social and professional networks.[179] [180] [181] By engaging KOLs, manufacturers tap into a critical antecedent of prescribing prescription drugs: the experience of peers and the confidence this brings to the prescriber's decision process. However, because KOLs are carefully cultivated,[182] and usually paid by pharmaceutical companies interested in advancing their drugs, the objectivity of KOLs should be questioned.[183] [184] [185] [186]

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[179] Leveraging Peer-to-Peer Networks in Pharmaceutical Marketing. Innovation & Marketing in the Pharmaceutical Industry, Emerging Practices, Research, and Policies. Ding, Eliashberg and Stremersch Eds., Springer, 2014, Chapter 15, pp.457-475.

[180] The depositions of PSRs in this matter underscore the important role that PSRs play in the development of KOLs and Defendants' relationships with KOLs, including in speaker programs. The content of speaker programs can be seen in Schedule 7C: Teva Speaker Program Slides. See also e.g., a 2008 Fentora promotional program, TEVA_MDL_A_11320672, and cover email, TEVA_MDL_A_11320671.

[181] Speaker programs also presented marketing opportunities for Defendants, such as was seen in the Jim Reilly 9/4/2012 email chain with subject "Dr. Gatz." Dr. Gatz expressed reservations regarding Fentora and there was discussion of how speaker training would be a way to "refocus" his prescribing to Fentora exclusively. (TEVA_MDL_A_00399758)

[182] E.g., Fallon Medica LLC, Securing the Future of Fentora: The Launch of the Secure REMS Program in Support of Fentora and Actiq (Cephalon), TEVA_MDL_A_00679308, p.4.

[183] See, e.g., D'Arcy E. Presence, alignments and shared authenticity: Considering the new era of engagement between experts and the pharmaceutical industry. Journal of Medical Marketing 2009; 9(2):175-183; Elliott C. The Secret Lives of Big Pharma's 'Thought Leaders.' Chronicle of Higher Education 2010; 57(4); Moynihan R. Key Opinion Leaders Independent Experts or drug representatives in disguise? British Medical Journal 2008; 336(June):1402-1403; Iskozitz M. MD Twitter-base may help ID KOLs. Med Ed Report, mmm-online.com December 2012, Medical Marketing and Media, p.23; Mack J, Developing Win-Win Key Opinion Leader Relationships. Pharma Marketing News 2003; 2(10):3-5. Available at: http://www.news.pharma-mkting.com/pmn210-article01.pdf (last accessed January 3, 2019).

112. KOLs and other prominent Customers also participate in company-sponsored industry advisory boards. An advisory board brings together multiple opinion leaders[187] where topics related to the drug, disease, indications, side effects, or other issues are openly discussed. Through this process, a pharmaceutical manufacturer can glean, and impart, significant market information, learn how its drug is perceived in the medical community, and identify new strengths, weaknesses, opportunities, or threats that should be considered in marketing planning. Advisory boards also educate participants about a manufacturer's product and provide an opportunity for KOLs to exchange information that could impact their own (the KOL) prescribing practices while the sponsoring company gathers information from Customers.[188] In sum, KOLs are used to "infect" other prescribers with favorable opinions regarding a company's drug.[189]

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[184] Steinbrook R. Commercial support and continuing medical education N Engl J Med. 2005; 352(6):534-5.

[185] See also the Senate investigation of opioid manufacturers' relationships with advocacy groups. (December 16, 2020 letter to Members of the Senate Finance Committee from Senators Chuck Grassley and Ron Wyden, Re: Findings from the Investigation of Opioid Manufacturers' Financial Relationships with Patient Advocacy Groups and other Tax-Exempt Entities.)

[186] E.g., Kati Chupa 12/9/2002 email to Russell Portenoy regarding a grant request from Dr. Portenoy, JAN-MS-00784576; Molly McDonald 10/9/2003 email to Russell Portenoy with subject "RE: AP=48 Steering Committee" where Ms. McDonald refers to Dr. Portenoy' s involvement as "Critical to our commercialization process," JAN-MS-00725920; Winifred Schein 2010 email exchange with Robyn Kohn, copied to Dr. Portenoy, regarding a grant and the development of a pain clinic in the Emergency Department at Beth Israel Medical Center, JAN-MS-00392809 & JAN-MS-00392825.

[187] E.g., The Kadian Advocacy Development Brainstorming Meeting, ALLERGAN_MDL_02513100, p.5; TEVA_MDL_A_00498707; Cephalon Pain Franchise, Health Care Professional Advisory Board, March 30 – April 1, 2007, TEVA_MDL_A_02030686 and cover email, TEVA_MDL_A_02030685.

[188] E.g., JAN-MS-00304927; Taitel (Janssen) New Hampshire Deposition (JAN-FL-00167663), pp.94-95, and Deposition Exhibits 3, 4, 14 & 15, Tapentadol Advisory Board Meetings in Philadelphia and Chicago; Opana ER National Advisory Board, ENDO-CHI_LIT-00034272; ENDO-CHI_LIT-00210619; PPLP003400564, National Pain Advisory Meeting, Purdue Pharma; MNK-T1_0000206953; MNK-T1_0000108564; MNK-T1_0000117600.

[189] Altier (Allergan) Deposition, p.183 and Exhibit 6.

113. Another extension of peer-to-peer marketing is the use of health advocacy groups, which often provide national level thought and policy leadership related to disease and treatments. Janssen analyzed the influence advocacy groups had on prescribers and patients and studied these advocacy groups to better understand this influence.[190] By supporting and influencing such advocacy groups, Defendants were able to support wider dissemination of their marketing messages, through advocacy groups that appeared to be unbiased.[191] [192] [193] [194]

114. Advocacy groups such as, for example, the American Academy of Pain Medicine (AAPM), American Geriatrics Society (AGS), and the American Pain Foundation (APF) all worked

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[190] JAN-MS-00358806, Cassie Hallberg 5/12/2009 email with subject Canceled: Advocacy / key stakeholders in New England, with attachment "Pain Stakeholders Strategy sv.ppt, and the attachment, JAN-MS-00358807, Influence Map by Functional Responsibility/Pain Policy Scores from Pain & Policy Studies Group.

[191] E.g., Beckhardt (Teva/Cephalon) Deposition, pp.346-361 and Deposition Exhibits 23, 24 and 25; Stacey Beckhardt 12/21/2007 email, TEVA_MDL_A_09544530, and attachments TEVA_MDL_A_09544532 and TEVA_MDL_A_09544534; ALLERGAN_MDL_01010175; Teva 2012-2016 Grant Support (Payments), TEVA_MDL_A_00565051; Day (Teva) Deposition Exhibit 27, TEVA_FL_00013555, AAPM /TEVA Pre-Con Deck.

[192] In JAN-MS-00383085, Janssen answers the question of how advocacy can have an impact for chronic pain and diabetic peripheral neuropathy: creating awareness of the disease, latest treatments and barriers to access, and improving and maintaining access by shaping policy, public and private outreach (e.g., letters of support from partner organizations) and impacting legislation.

[193] Update & 2013 National Advocacy Business Planning, JAN-MS-00393085. This document touts Purdue, Janssen, Pfizer, and Endo as providing the highest total advocacy support in four categories: programmatic support, capacity building, access and reimbursement, and general support. The "Imagine the Possibilities Pain Coalition" included here maps out advocacy projects, objectives, and timelines for dissemination. This coalition is "a working group of recognized experts in the field of pain aiming to fill unmet needs and gaps in patient care." This definition is remarkably like the goal of marketing. On slide 16 is a compilation of representative organizations Janssen was committed to regarding pain advocacy.

[194] E.g., JAN-MS-00406874, Pain Programs, educational grant records funded by Janssen, by year; JAN-MS-00919438, American Pain Society Corporate Membership Brochure; JAN-MS-00000001, 1997-2011 List of Janssen payments made to various advocacy groups such as AAPM, AGS, APF, APS, JCAHO, Center for Bioethics, and honorarium fees to KOLs such as Drs. Portenoy, Fishman, and Fine.

to increase the awareness of and access to pain treatment,[195] and were supported by opioid manufacturers, including Defendants.[196]

115. In 2001, AAPM disseminated a press release regarding diversion and abuse of controlled substances, which included the statement:[197]

> Experience and investigation have shown that when opioids are prescribed and used appropriately in the treatment of pain there is minimal danger of creating an addictive disorder. Evidence to date indicates that substance abuse problems have not increased as a result of the increased availability of therapeutic opioids. The public health problem represented by misuse of prescription opioids is miniscule in comparison with that of untreated and unrelenting pain.

This press release expresses opinions that effectively minimized concerns over diversion, and abuse, as well as increased availability of opioids. Advocacy groups regularly made such statements to further the marketing interests of the Defendants who funded them. Consistency of the advocacy and marketing messages, along with the financial support of these groups by Defendants, supports the proposition that Defendants' use of advocacy had marketing purpose.

116. Teva supported advocacy groups like the Joint Commission on Accreditation of Hospitals (JCAHO) and the Federation of State Medical Boards (FSMB), both of which distributed guidelines or standards for opioid use.[198] In some instances, Defendants' support went beyond financial support aimed at influencing messages and included directly contributing to or editing advocacy messages. For example, Susan Larijani, Senior

[195] See, e.g., TEVA_MDL_A_01089593; TEVA_MDL_A_01171101; TEVA_MDL_A_01171351; TEVA_MDL_A_01174115; TEVA_MDL_A_01174116.

[196] Senate investigation of opioid manufacturers' relationships with advocacy groups, December 16, 2020 letter to Members of the Senate Finance Committee from Senators Chuck Grassley and Ron Wyden, Re: Findings from the Investigation of Opioid Manufacturers' Financial Relationships with Patient Advocacy Groups and other Tax-Exempt Entities.

[197] February 16, 2001 AAPM Press Release, PPLPC039000033400.

[198] Schedule 11: Amounts Paid to Psin Advocacy Organizations & Professional Societies.

Manager of Professional Services and Medical Information at Teva, suggested edits to the American Chronic Pain Association Medication and Chronic Pain Supplement for 2005.[199]

117. In addition to supporting influential groups like JCAHO, Janssen also created strategy aimed at its institutional Customers that included the distribution of JCAHO materials.[200] Janssen's "Let's Talk Pain" coalition was another well planned and executed strategy that had as its goal "to bring together advocates for people in pain from the nursing, medical / allied medical, and nursing [sic] communities to enhance provider and patient communication about pain and to improve quality of care, and raise awareness of the issue around side effects from pain medicines and how they can hamper appropriate care."[201] Created prior to the launch of Nucynta, this coalition included the APF, AAPM, and a pain nursing group, the American Society of Pain Management Nursing. The coalition was launched in September of 2008. Dr. Fishman, a prominent industry KOL and then Chair of the APF, did press interviews about the coalition, demonstrating how the use of KOLs could be integrated across advocacy, KOLs, patients and health care professionals.

118. Defendants', and other opioid manufacturers, use of KOLs, peer-to-peer marketing, and advocacy groups to reach marketing goals was epitomized by their interactions with Dr. Portenoy who helped them reach marketing goals. Dr. Portenoy, a top national KOL, was an important component of Defendants' influence with advocacy groups, along with

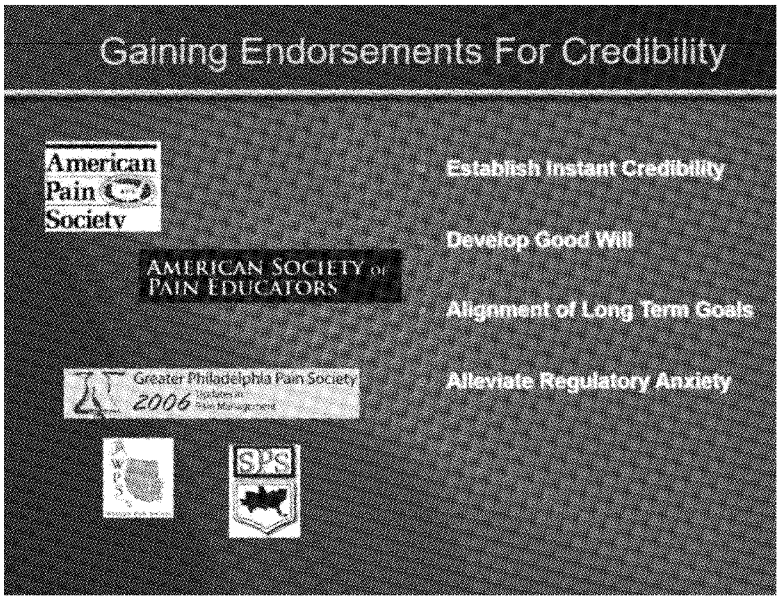
[199] Stacey Beckhardt 1/20/2005 email, TEVA_MDL_A_10070432.

[200] Paul Lowman 1/6/2012 email to Patricia Yap with subject Institutional Quality Initiative – Improving Pain Management in the Hospital, JAN-MS-00289213; Keith Hofbeck 1/27/2102 email to Patricia Yap with subject RE: Institutional Quality Campaign Initiative, JAN-MS-00664671; Institutional Quality Campaign Initiative, decile.ten communications, Work Order, JAN-MS-00664673.

[201] Greg Panico 8/27/2008 email to Lori Lonczak and others with subject "Let's Talk Pain" coalition – launch press release, JAN-MS-00324259.

others such as Dr. Perry Fine, Dr. Scott Fishman, and Dr. Charles Argoff.[202] Dr. Portenoy's (and other KOLs) work with industry and advocacy groups supported by industry, helped disseminate the marketing messages Defendants wanted communicated to Customers. These messages were consistent with opioid manufacturers' promotional marketing messages and created more favorable perceptions about opioids by minimizing the known risks, which removed barriers to opioid use, and stimulated sales.[203]

119. In a Janssen presentation, the company notes the benefit of gaining endorsements from advocacy groups such as the APS: instant credibility.[204] (See insert below) This credibility was essential to the successful deployment of Defendants' marketing messages.



[202] TEVA_MDL_A_00500316; ENDO_OPIOID_DEPMAT-000034526.

[203] See Section III of this Report.

[204] Lynn Leonard 6/29/2007 email to colleagues at Ortho and Janssen with subject "Unbranded Tactical v1. ppt (JAN-MS-00442057), and the presentation "Non-Branded Promotion," JAN-MS-00442058, p.20.

120. The use of opinion leadership by Defendants is marketing.[205] Further, funding of advocacy groups was an integral part of Defendants marketing.[206] Even with limited ability to impact the content of specific programs or communication materials, Defendants invested in advocacy groups that were consistent with Defendants' own messaging goals. This monetary support, as with KOLs, created an unavoidable commercial conflict of interest, calling into question the independence of advocacy organizations.

121. I have reviewed numerous documents with respect to KOLs and the value they bring to pharmaceutical marketers. These examples, and others like them, support the proposition that Defendants leveraged the value of KOLs, including the use of advocacy groups, to increase sales.

Continuing Medical Education (CME)

122. CME is a promotional tool used by the pharmaceutical industry.[207] [208] Pharmaceutical companies support educational efforts through accredited CME and non-certified

[205] E.g., Beckhardt (Teva) Deposition, pp.335-345, Ms. Beckhardt worked closely with advocacy organizations, including public relations activities.

[206] Schedule 12: Amounts Paid to KOLs by Defendants and Schedule 11: Amounts Paid to Pain Advocacy Organizations & Professional Societies.

[207] See, e.g., Is continuing medical education a drug-promotion tool? Steinman MA and Baron RB. Canadian Family Physician (October 2007) 53; 10:1650-51; Continuing Medical Education, Physicians and Pavlov. Can we change what happens when industry rings the bell? Lichter PR. Arch Ophthalmol, Nov 2008; 126(11):1593-1597; Separating Continuing Medical Education from Pharmaceutical Marketing. Relman AS. JAMA, April 18, 2001, 285; 15:2007-2012; Industry Strongly Supports Continuing Medical Education. Holmer AF. JAMA, April 18, 2001; 285(15):2012; Commercial Support and Continuing Medical Education. Steinbrook R. N Engl J Med February 10, 2005, 352; 6:534-35.

[208] See, e.g., 2001 Duragesic Tactical Plan Review, a plan developed for Janssen by Discovery International, the recommendation is made to "Generate awareness and call to action among patient/caregivers." One supporting tactic for this strategy was a "National CME initiative." This tactic was also recommended for other strategies. (JAN-MS-00306713)

education.[209] This *marketing* education is delivered in a number of ways, including for example, face-to-face dinner meetings or other meals, webinars, symposia, pre-recorded messages, etc. While these programs educate Customers, they may also serve business goals such as priming a market for a new product entry, shifting market share, or expanding product use.[210]

123. Accredited CME and non-certified education have distinct differences. Accredited CME activities include those supported by drug companies but intended by the Accreditation Council for Continuing Medical Education (ACCME) to be independent of promotional influence.[211] Accredited CME activities are attractive to physicians because they must earn a certain number of hours of CME each year to continue licensure, which attracts prescribers to industry-sponsored, free, CME. KOLs may also be used to deliver CME programs, adding value to the sponsorship by the drug company.[212] However, this added value comes at the expense of potential bias that may stem from the use of a KOL who may have financial ties to the pharmaceutical company.

124. Medical education can also take the form of promotional-education activities. However, non-certified, promotional education that is controlled by a manufacturer must present information that is consistent with the FDA-approved label.[213] Pharmaceutical

[209] Defendants' marketing plans cited throughout this Report detail CME efforts in Schedule 6: Defendants' Marketing Plans.

[210] E.g., the Emerging Solutions in Pain (ESP), Assessing and Managing Low Back Pain: The Option for Opioids (Summer 2003) continuing education program sponsored by Cephalon and delivered by Medicom Worldwide, Inc. (TEVA_MDL_A_01165648. See also e.g., TEVA_MDL_A_00827353, The Emerging Solutions in Pain: The Interface of Pain and Addiction, 2007)

[211] Accreditation Council for Continuing Medical Education, http://www.accme.org.

[212] Schedule 12: Amounts Paid to KOLs by Defendants.

[213] There are other benefits to promotional education, such as the ability for a marketer to reach prescribers whom they have not been able to reach (e.g., prescribers who refuse to see PSRs, or practice settings with rules against seeing PSRs). In addition, the content of these programs is not always limited to on-label discussions, such as in TEVA_MDL_A_02030368.

companies seem to prefer accredited CME, possibly due to the expectation of return on investment that is estimated to be $3.56 in increased sales for each dollar spent on accredited CME.[214] One explanation for the popularity of industry-sponsored CME (both accredited and non-certified) is that it is almost always free of charge and prescribers can fulfill license requirements for annual continuing education.

125. In general, CME activities take multiple forms:[215]

- Educational Materials (e.g., publications, clinical practice guidelines)
- Medical Education Conferences (e.g., symposia, lectures, workshops)
- Peer-to-Peer Education (e.g., meetings with providers at their practice site, thought or opinion leaders)

126. Pharmaceutical companies continue to invest in CME because of its impact on brand performance.[216] A basic method for assessing return on CME is to assess the numbers of participants attending a CME program. [217] However, the value of CME as a marketing tool goes beyond these metrics and can include assessment of learning that occurred, the effectiveness of the presenters, changes in prescribing, or how the CME may impact practice and patient care. These evaluations provide useful information to marketers that can help shape future marketing activities. Finally, CME is also a way to further

[214] Brody H. Pharmaceutical industry financial support for medical education: benefit, or undue influence? Journal of Law, Medicine, & Ethics 2009; 37(3):451-460.

[215] Mazmanian P and Davis D. Continuing Medical Education and the Physician as a Learner: Guide to the Evidence. JAMA 2002; 288(9):1057-1060.

[216] M. Chren and C. Landefeld, "Physicians' Behavior and Their Interactions with Drug Companies: A Controlled Study of Physicians Who Requested Additions to a Hospital Drug Formulary," *The Journal of the American Medical Association*, 1994; 271(19):684-689.

[217] E.g., JAN-MS-02564213; JAN-MS-02564214; JAN-MS-00312510; JAN-MS-00312512; JAN-MS-00312513.

peer-to-peer education when participants interact and influencers (i.e., KOLs) are employed to provide educational programs.[218]

127. Teva and Endo utilized KOLs at dinner meetings as a part of their marketing of opioids, including in the state of Florida.[219] [220] For example, in March of 2007, Endo sales manager Greg Pyszczymuka supervised sales rep Elizabeth Bagi-Pabst in sponsoring a dinner in Jacksonville, at Ruth's Chris steakhouse, at which KOL Dr. Charles Argoff spoke. The same month, Dr. Argoff spoke at a Runyon's in Ft. Lauderdale. Endo sponsored more than 1,100 meetings, using a variety of KOLs, in Florida between 2008 and 2012.[221]

128. With respect to Dr. Argoff, he was the author of the Endo supported "From the Bench to the Bedside: Case Challenges in Pain Management: Opioid Therapy for Chronic Pain." Endo used this article in its promotions and trained its PSRs to use the case studies to "engender" thinking about opioid choices when communicating with prescribers.[222]

129. Defendants avoid calling dinner meetings, and related activities (e.g., lunches, in-service trainings), marketing, but these activities are part of their comprehensive marketing

[218] E.g., Beckhardt (Teva) Deposition, pp.234-236; Condodina (Teva) Deposition, pp.378-387. See also the Dr. Portenoy program entitled "Managing Pain: Improving Patient Outcomes and Minimizing Risk in Opioid Therapy of Chronic Pain," TEVA_FL_00017230 (TEVA_MDL_A_00835509, Condodina (Teva) Deposition Exhibit 23).

[219] E.g., Cephalon Status Report, April 27, 2004, TEVA_MDL_A_02588709; Pain Medicine Independent Medical Education 2006 Year-End Report, TEVA_MDL_A_00564864; 2015 Medical Education Programs, "Pain Matters," TEVA_MDL_A_08657807; TEVA_MDL_A_00008174; TEVA_MDL_A_00553218; TEVA_MDL_A_03413816; Schedule 12: Amounts Paid to KOLs by Defendants; Speaker Analysis Summary, JAN-MS-00309771 and JAN-MS-00314799; Speaker rating and payment spreadsheet, JAN-MS-00458370; Speaker Analysis Summary, JAN-MS-00588903.

[220] See, e.g., Opana Speaker's Bureau Frequently Asked Questions, ENDO-OPIOID_MDL-00673642; Opana Dinner Meeting Master List, ENDO-OPIOID_MDL-00380720; Opana ER Speaker Bureau Programs, spreadsheet, ENDO-Opioid_MDL-00381938.

[221] SpeakerNet Data File, Florida, ENDO_FLAG_DATA_00000007.

[222] ENDO-OPIOID_MDL-02885147.

plans.[223] The purpose of planning, sponsoring, controlling the content and presentation of information, and conducting and assessing the impact of these "educational" activities is absolutely marketing.[224] [225]

130. From a marketing perspective trying to differentiate between educating customers and marketing to customers is just semantics, and a distinction Defendants did not make in their planning documents. Pharmaceutical marketers who educate Customers through product or disease state promotions, through e.g., continuing education, lunch or dinner meetings, add value to enhance exchange; this *is* marketing.

Clinical Practice Guidelines

131. Clinical practice guidelines (CPGs), sometimes referred to as clinical protocols or clinical pathways, are documents that contain structured recommendations designed to assist health care professionals in providing patient care. These guidelines seek to improve the process of care and patient outcomes and include decision aids in the selection of drug therapy.[226] Guidelines may be developed by institutions, researchers, advocacy groups, clinicians and others to provide evidence-based protocols for treatment. CPGs have become a cornerstone of prescribers' and other health care professionals' medical decision-making. As noted above, Defendants, and other opioid manufacturers, taught sales personnel about CPGs, and used CPGs developed by KOLs and advocacy groups to support their products.[227]

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[223] E.g., Beckhardt (Teva) Deposition, p.221 and Exhibit 12, CME in the 2002 Actiq marketing plan.

[224] In relation to Figure 2, CME and related activities are part of the external, marketer-controlled stimuli that impact prescribers' awareness of medication choices and the cognitive processes involved in memory and decision-making.

[225] E.g., Pain Pulse, a "peer-to-peer videoconference." (JAN-MS-00236779)

[226] Graham R. Clinical Practice Guidelines We Can Trust. Washington D.C., National Academies Press, 2011.

[227] Altier (Allergan) Deposition, pp.123-130, 268-275 and Deposition Exhibits, 2, 14; Kadian Value Proposition, Medical Affairs, July 2012, Barrett Deposition Exhibit 18 and Barrett (Allergan) Deposition, pp.257-262, 280; Bearer (Teva) Deposition, pp.79-83 and Deposition Exhibit 4

132. Pharmaceutical marketers have utilized the strategy of influencing the development of clinical guidelines, and ensuring the dissemination of favorable guidelines, to favorably impact which drugs prescribers select, and therefore sales of these drugs.[228] Pharmaceutical marketers also focus on medical school campuses because medical students practice the CPGs they learn there.

133. Ideally, unbiased, evidence-based CPGs lay out a clinical pathway to the selection of medications determined to be most effective for patients and provide evidenced-based options. However, CPGs also impact prescribing through medication formularies. Formulary decision makers seek and use evidence-based protocols, and the consensus of medication experts in their decision-making. This gives their decisions credibility and when a formulary positions a drug as a first-line therapy in a guideline, prescribers are more likely to prescribe the drug.[229]

134. Teva/Cephalon worked with KOLs and advocacy organizations who were involved in the development of CPGs. While these activities were a part of Defendants' marketing and effective for generating sales, the use of KOLs and advocacy organizations that are financially tied to Defendants creates commercial bias that cannot be separated from

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(TEVA_MDL_A_04838673, Managed Care and Reimbursement Objectives); Bearer (Teva) Deposition, pp.148-167 and ACTIQ Managed Care Dossier, Bearer Deposition Exhibit 12 (TEVA_CHI_00036931); see also ACTIQ Managed Care Dossier in Bearer (Teva) Deposition Exhibit 11; Spokane (Teva) Deposition, pp.159-160 and Deposition Exhibit 20, p.14; Diabetic Peripheral Neuropathy Pain Discussion and Concepts, August 24, 2011 JAN-MS-02562468.

[228] See, e.g., Lugtenberg M, Burgers JS, Westert GP. Effects of evidence-based clinical practice guidelines on quality of care: a systematic review. Qual Saf Health Care. 2009; 18: 385–392. doi: 10.1136/qshc.2008.028043, 19812102; Choudhry N, Stekfox H and Detsky A. Relationships between Authors and Clinical Practice Guidelines and the Pharmaceutical Industry. JAMA, 2002; 287(5):612-617; Detsky, Editorial, Sources of bias for authors of clinical practice guidelines, Canadian Medical Association Journal, 2006; 175(9):1033; Shaneyfelt T and Centor R. Reassessment of Clinical Practice Guidelines. JAMA 2009; 301(8):868-869. See also e.g., Taitel (Janssen) New Hampshire Deposition (JAN-FL-00167663) Exhibit 20, p.19.

[229] Increased confidence in formulary decisions is important, but it is also worth noting that formulary drugs are easier to prescribe and lack barriers to the drug's use.

the CPGs developed.[230] At the very least, based on pharmaceutical marketing standards, all financial relationships should be disclosed for Customers to have the information needed to evaluate potential conflicts of interest.

Influence on Formularies

135. Prescribing choices are influenced by which drugs are included on prescription formularies for insurance coverage.[231] When formulary drugs differ from prescribers' habits, prescribers must adapt their medication choices to match a patient's formulary, or the patient may have higher out-of-pocket costs or be denied coverage. This ties formulary decisions by the TPP or PBM to the success of a branded drug[232] and creates opportunities for pharmaceutical marketers who can effectively impact formulary decision-making. The record in this case supports the proposition that Defendants worked to monitor, obtain, and maintain a desirable formulary status for their drugs.[233]

Direct-to-Consumer Marketing

136. In the 1980s, pharmaceutical companies discovered the powerful impact that consumers could exert on prescribing decisions when they learn about drugs via media coverage, public relations efforts, news stories, and even advertisements for prescription medications. A distinction should be made between DTC marketing and DTC advertising, the former of which encompasses all aspects of DTC consumer activities including DTC advertising. DTC advertising is a term of art that has come to

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[230] Schedule 11: Amounts Paid to Pain Advocacy Organizations & Professional Societies and Schedule 12: Amounts Paid to KOLs by Defendants.

[231] See, e.g., *Pharmaceutical Marketing*, Ch. 4 & 12, Rollins, B.L. & Perri, M. (eds.) (2013); Virabhak S., Shinogle JA. Physicians' prescribing responses to a restricted formulary: the impact of Medicaid preferred drug lists in Illinois and Louisiana. Am J of Managed Care 2005; 11:SP14-20. https://europepmc.org/abstract/med/15700905.

[232] In certain cases, generic products receive automatic, preferred-tier, formulary (or PDL) status.

[233] E.g.,Altier (Allergan) Deposition Exhibit 19, Hepp Field Coaching Report, ACTAVIS0965746; Managed Markets Formulary Mechanisms to Contain Costs, TEVA_CHI-00004939.

represent media advertisements for prescription medication that are commonly seen on TV and in magazines. From its inception, marketers learned that DTC marketing and advertising could move a drug quickly through the early stages of its life cycle and rapidly increase adoption and expand sales by increasing patient and prescriber awareness of treatment alternatives.[234] [235]

137. However, DTC marketing may also trivialize drug use by making drug consumption a part of everyday life, mislead or confuse consumers, and increase costs by promoting more expensive brand name medications.[236] DTC marketing and advertising increase patient requests for a medication and these requests have been shown to substantially affect prescribing decisions, even when the requested medications are dangerous, and even when the drug itself was not directly advertised to consumers.[237] [238] An example of this

[234] Regarding the pros and cons of DTC marketing, see, e.g., Donohue J. A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection. The Milbank Quarterly 2006; 84(24):659-699; Perri M and Nelson A. An Exploratory Analysis of Consumer Recognition of Direct-to-Consumer Advertising of Prescription Medications. J of Heath Care Marketing 1987; 7:9-17; Perri M and Dickson WM. Consumer Reaction to a Direct-to-Consumer Prescription Drug Advertising Campaign. Journal of Health Care Marketing 1988; 8:66-69; Perri M. The Past, Present and Future of Direct-to-Consumer Advertising in the Pharmaceutical Industry. Clinical Therapeutics 1999; 21:1798-1811.

[235] https://us.kantar.com/business/health/2017/drug-advertising-booms/ (last accessed February 28, 2019) Jon Swallen, Drug Advertising Booms to $6.4 Billion, May 8, 2017.

[236] Shimp T and Dyer R. The Pain-Pill-Pleasure Model and Illicit Drug Consumption. J of Consumer Research, 1979 June;6(1):36-46.

[237] See, e.g., McKinlay J, Trachtenberg F, Marceau L, Katz J, and Fischer M. Effects of Patient Medication Requests on Physician Prescribing Behavior: Results of a Factorial Experiment. Med Care. 2014 April; 52(4):294-299.

[238] Koch-Laking A and Park M. Q/Does DTC advertising affect physician prescribing habits? Journal of Family Practice 2010; 59(11):649-50; Arney J, Street R and Naik A. Factors Shaping Physicians' Willingness to Accommodate Medication Requests. Evaluation & the Health Professions. 2014; 37(3):349-365; Huh J and Langteau R. Presumed Influence of Direct-to-Consumer (DTC) Prescription Drug Advertising on Patients, The Physician's Perspective. Journal of Advertising, 2007; 36(3):151-172; Kravitz R, Epstein R et. Al., Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants, A Randomized Controlled Trial. JAMA 2007; 293(16):1995-2002; Mintzes B, Barer ML, Kravitz RL, et al. How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without

was seen in the 2011 marketing plan for Fentora where Cephalon (Teva) noted (see insert below) target marketing efforts aimed at patients as part of its "Target Audience Strategy:"[239]

- *Patient*
  Cancer patient outreach has been limited in prior years. An opportunity exists to engage BTP cancer patients to support a more proactive and productive dialogue with their physicians and allied health practitioners. 2011 tactics will concentrate on in office initiatives designed to increase patient awareness of BTCP and how *FENTORA* uniquely matches the onset, intensity and duration of BTCP. The objective of the 2011 Patient Activation initiative will be educational based and will also highlight real *FENTORA* success stories to compliment the professional campaign in an effort to improve HCP and patient dialogue and in the end, elevate the patient experience.

138. The influence of some DTC marketing on consumers is indirect. Patients learn about drugs from other sources such as friends or family who take medications, advocacy groups who seek to increase awareness of diseases or treatments, and internet[240]

legal DTCA. Canadian Medical Journal (CMAJ) 2003; 169(5):405–412. Campbell EG, Pham-Kanter G, Vogeli C, et al. Physician acquiescence to patient demands for brand-name drugs: Results of a national survey of physicians. JAMA. 2013; 173(3):1–3. Becker S and Midoun M. Effects of Direct-to-Consumer Advertising on Patient Prescription Requests and Physician Prescribing: A Systematic Review of Psychiatry-Relevant Studies. J Clin Psychiatry. 2016 October; 77(10):e1293-99; Weissman J, Blumenthal D, Silk A, Newman M, Zaper K, Leitman R and Feibelman S. Physicians Report On Patient Encounters Involving Direct-to-Consumer Advertising. Health Affairs, 2004 (Jan-Jun); Vol Suppl Web Exclusive. W4-219-33; Aikin K, Swasy J, and Braman A. Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results. Final Report, November 19, 2004. https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM600276.pdf (last accessed June 18, 2020).

[239] Fentora 2011 Marketing Plan, TEVA_MDL_A_01184456, p.12.

[240] According to a study published by FDA staff, Internet promotion grew dramatically from a total of 1909 Form 2253 submissions in 2001 to 30,295 Form 2253 submissions in 2014. Sullivan HW, Aikin KJ Chung-Davis E, and Wade M. Prescription Drug Promotion from 2001-2014: Data from the U.S. Food and Drug Administration. PLoS One | DOI:10.1371/journal.pone.0155035, May 5, 2016.

searches. Advocacy groups, like the U.S. Pain Foundation, American Academy of Pain Medicine, or the American Pain Society, are an effective way for a pharmaceutical marketer to reach consumers without disclosing their commercial interests.

139. Patients see and hear messages from advocacy groups, which increases awareness and stimulates discussion with prescribers in the same fashion as advertisements. Further, advocacy groups are generally perceived to be unbiased and trustworthy, increasing the credibility of this source of drug information. However, there are concerns regarding this route of persuasion because manufacturers' financial support of advocacy groups appears to be linked to "opioid friendly," "amplified and reinforced messages favoring increased opioid use" by these groups.[241]

140. DTC marketing also includes targeted patient education, such as community-based talks designed for patients and caregivers and other ways (e.g., patient brochures) of reaching patients with marketing messages.[242] Patient education provides a direct means for pharmaceutical marketers to educate patients about a drug or disease and is also effective in increasing awareness and stimulating patients to have discussions with prescribers. Indirect methods, such as the use of advocacy groups or direct patient

[241] Fueling an Epidemic (Report Two), Exposing the Financial Ties Between Opioid Manufacturers and Third-Party Advocacy Groups. U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members Office; https://www.hsdl.org/?abstract&did=808171 (last accessed June 18, 2020); Fueling an Epidemic, Supplement to the February 2018 Report, https://www.hsgac.senate.gov/imo/media/doc/SUPPLEMENT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf (last accessed June 18, 2020). Rothman S, Raveis V, Friedman B and Rothman D. Health Advocacy Organizations and the Pharmaceutical Industry. Am J of Public Health. 2011; 101(4):602-609.

[242] E.g., TEVA_MDL_A_11575927 (Fentora, patient as customer); Understanding Your Treatment, An educational brochure for patients from the makers of Fentora, TEVA_MDL_A_01149871.

contact via brochures and self-help aids, are additional ways for pharmaceutical marketers to reach prescribers vis-a-vis patients with messages about drugs.

Branded and Unbranded Marketing

141. Branded pharmaceutical marketing is the promotion of a specific drug, by the drug's name and its indication.[243] The FDA regulates branded marketing.[244] Manufacturers submit advertising materials to the FDA's Office of Prescription Drug Promotion (OPDP), but FDA approval before dissemination is not required. Thus, inaccurate, or unbalanced advertisements may be in circulation until the FDA identifies them.[245] The FDA can intervene in many ways, including by way of a warning letter for advertising materials that it finds do not accurately convey a drug's labeling. FDA's oversight of advertising can be delayed, allowing improper advertising materials to reach a large audience before being pulled back.[246]

142. Pharmaceutical marketing is also done through unbranded channels. Unbranded marketing is not regulated and includes activities that create awareness of a disease or condition, advocate for patient care or prepare a favorable environment in the

[243] Examples of Actavis and Teva Branded marketing materials are provided in Schedule 7A: Actavis Promotional Materials & Schedule 7B: Teva Promotional Materials.

[244] All advertisements and promotional labeling for an FDA approved medication are required to be submitted when they are first used or disseminated on a form FDA-2253. https://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/AdvertisingLabelingPromotionalMaterials/ucm118171.htm; Instructions for Completing Form 2253, https://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm375154.pdf (last accessed June 18, 2020). This does not mean, however, that all advertisements and promotional labeling are reviewed by the FDA. See, e.g., TEVA_MDL_A_00025238 (2253 submission); TEVA_MDL_A_00025378 (2253 Submission).

[245] It is my understanding that the OPDP does not review each of the tens of thousands of pieces of advertising materials that are submitted each year.

[246] A Government Accountability Office report from 2008 detailed that it takes the FDA about 7 months to organize a warning letter and another 4 months on average for manufacturers to respond to it by removing or adjusting their advertising materials. https://www.gao.gov/new.items/d08835.pdf (last accessed February 28, 2019).

marketplace for sales,[247] without mentioning a drug's name or making any representations about the drug. Because there is no mention of a product, or representations about the product, in an unbranded ad, this form of advertising does not require FDA approval prior to dissemination.[248]

143. Unbranded advertisements increase awareness of a drug or disease. In other words, unbranded advertisements get patients thinking and talking about their disease with the goal of seeking treatment, which might include a prescription medication. [249] This increases the size of the overall market for the products that are relevant to this treatment. For example, Cephalon utilized (among other things) posters, table cards, and the patient brochure entitled "Breakthrough Pain: Do you still have pain?" to increase awareness of breakthrough pain (BTP).[250] Cephalon also supported the American Pain Foundation "Target Chronic Pain Notebook," which was an educational

[247] Taitel (Janssen) New Hampshire Deposition (JAN-FL-00167663), pp.114-117.

[248] Guidance for Industry, Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms. January 2004 (Draft). https://www.hlregulation.com/files/2015/05/2004-draft-guidance-on-disease-awareness-activities.pdf (last accessed March 14, 2021).

[249] See, e.g., Alves T, Mantel-Teeuwisse A, Paschke A, Leufkens H, Puil L, Poplavska E, and Mintzes B. Unbranded advertising of prescription medicines to the public by pharmaceutical companies. Cochrane Database of Systematic Reviews, 2017, Issue 7. Art. No. CD012699. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD012699/epdf/full (last accessed July 8, 2021); Beth Snyder Bulik, Unbranded pharma ads - what are they good for? Actually, quite a bit, marketing panelists say. FiercePharma, March 11, 2018. https://www.fiercepharma.com/marketing/unbranded-pharma-ad-what-are-they-good-for-actually-quite-a-bit-marketer-panelists-say (last accessed June 18, 2020); Aimee Picchi, The rise of the "unbranded" pharmaceutical ad. CBS News, MoneyWatch, August 30, 2016. https://www.cbsnews.com/news/the-rise-of-the-unbranded-pharmaceutical-ad/ (last accessed June 18, 2020).

[250] Beckhardt (Teva/Cephalon) Deposition, pp.344-361 and Deposition Exhibits 23, 24, and 25; Breakthrough Pain, Do you still have pain? (Brochure), TEVA_MDL_A_01575976. See also e.g., Andy Pyfer 4/9/2004 email, TEVA_MDL_A02030687; Patient Brochure, TEVA_MDL_A_02030696.

program for patients aimed at helping patients increase their involvement in their care.[251]

144. Research has shown that subjects who have viewed non-branded advertisements develop positive behavioral intentions which makes them more likely to act on information from the ads, for example, by seeking treatment (or more information) from a healthcare provider.[252] Therefore, unbranded advertising provides a pathway for pharmaceutical marketers to impact the prescribing process.

145. From a marketing impact perspective, unbranded advertising makes the most sense for a pharmaceutical marketer when the marketer is trying to expand the overall size of a market. While there will likely be spillover effects from the unbranded advertising which could impact market share, unbranded advertisements are limited in that they do not mention a product by name. Therefore, patients exposed to unbranded advertising would not be able to, based on the unbranded marketing, request a specific manufacturer's product (and increase market share for that product). When a marketer is competing for market share, marketing principles dictate that repeated exposures to product information are most effective; not omitting product information (i.e., name) entirely.

146. Increasing awareness of a disease or its treatment will expand the numbers of patients seeking care, or treatment. Sophisticated marketers, like Defendants and other opioid manufacturers, realize that when used in combination as part of an integrated marketing program, branded and unbranded marketing can create powerful synergies.

147. Marketers disseminate unbranded marketing messages directly to Customers, but a subtler form of unbranded marketing is when pharmaceutical marketers work with

[251] TEVA_MDL_A_02291004, Target Chronic Pain Notebook.

[252] Rollins B, King K, Zinkhan G, and Perri M. Nonbranded or Branded Direct-to-consumer Prescription Drug Advertising – Which is More Effective? Health Marketing Quarterly, 2011; 28(1):86-98.

external organizations, such as the advocacy groups discussed above, with an interest in a specific disease, condition or even symptoms.[253] Part of the appeal of unbranded marketing is that this form of marketing is generally perceived as neutral, "grassroots," unbiased or scientific, but this can be misleading for two reasons. First, unbranded marketing is not required to inform the patient of the risks of a medication, thus conferring the concept of greater safety of use. Second, the marketing may be disseminated through a third-party organization that is funded by the marketer, thereby creating concerns for commercial bias in the information disseminated.[254]

148. Defendants utilized unbranded marketing, including partnering with advocacy organizations such as the American Pain Foundation, American Pain Society, American Academy of Pain Medicine, and many other regional and national organizations, to deliver unbranded marketing messages related to the use of opioids.[255] [256] While unbranded marketing is perceived in a generally positive way by patients and it is not

[253] E.g., Finding Relief, Pain Management in Older Adults, featuring Kathy Baker, sponsored by PriCara. (JAN-MS- 02522610)

[254] Fueling an Epidemic (Report Two), Exposing the Financial Ties Between Opioid Manufacturers and Third-Party Advocacy Groups. U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members Office; https://www.hsdl.org/?abstract&did=808171 (last accessed March 7, 2021); Fueling an Epidemic, Supplement to the February 2018 Report, https://www.hsgac.senate.gov/imo/media/doc/SUPPLEMENT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf (last accessed June 18, 2020). Rothman S, Raveis V, Friedman B and Rothman D. Health Advocacy Organizations and the Pharmaceutical Industry. Am J of Public Health. 2011; 101(4):602-609.

[255] E.g., American Pain Foundation, Treatment Options: A guide for People Living with Pain, sponsored by Ligand Pharmaceuticals, Cephalon, Medtronic, and Purdue, TEVA_MDL_A_01090496; American Pain Association Guide for People Living with Pain, publicly available; Spokane (Teva) Deposition, pp.40-41; Altier (Allergan) Deposition, pp.125-129; Barrett (Allergan) Deposition, pp.114-118, 279-281; Teva support for the American Pain Society 24th Annual Scientific Meeting Proceedings, TEVA_MDL_A_05510585.

[256] Janssen documents related to planning and execution of work with advocacy groups can be seen in, e.g., JAN-MS-00000205; JAN-MS-00264703; JAN-MS-02508517; JAN-MS-00932379; JAN-MS-00922821.

scrutinized by regulatory agencies in the same manner as branded marketing, unbranded marketing by companies should follow the same pharmaceutical marketing standards identified above.

Summary

149. Defendants utilized a battery of integrated, coordinated, sophisticated, and aggressive marketing techniques to sell increasing quantities of opioids, nationally, and in Florida.[257] These methods, including, but not limited to, personal selling, the use of research, publications and medical journal advertising, peer-to-peer marketing, continuing medical education, clinical practice guidelines, working to influence formularies and formulary decision makers, direct to consumer marketing, and unbranded marketing are time tested and based in marketing science. Research has shown that adoption of new drugs is impacted by these activities, which possess degrees of commercial bias.[258] These methods represent the most effective ways for pharmaceutical manufacturers, including Defendants in the state of Florida, to create their desired product "position" in Customers' minds.[259]

[257] Schedule 6: Defendants' Marketing Plans; Altier Deposition, p.356; Snyder (Allergan) Deposition, p.271.

[258] See, e.g., Peay M and Peay E. The Role of Commercial Sources in the Adoption of a New Drug. Soc Sci Med 1988; 26(12):1183-89; Sah S and Fugh-Berman A. Physicians under the Influence: Social Psychology and Industry Marketing Strategies. Journal of Law, Medicine and Ethics 2013; 41(3):665-672; December 16, 2020 letter to Members of the Senate Finance Committee from Senators Chuck Grassley and Ron Wyden, Re: Findings from the Investigation of Opioid Manufacturers' Financial Relationships with Patient Advocacy Groups and other Tax-Exempt Entities.

[259] This assertion is supported by the numerous research articles cited in this report and the larger body of literature on pharmaceutical marketing. My own work experience, research and publications further support this conclusion.

Marketing Messages Are Different from the Package Insert

150. When a drug is approved for use by the FDA the 'package insert' (PI) establishes the boundaries for what information or messages a pharmaceutical company can legitimately discuss in its marketing. While the (PI) is a part of a company's marketing, a drug's marketing is far more comprehensive than the PI and includes all materials, techniques, communications, and messages used to promote the drug. The PI includes a large amount of information that could not be covered entirely during the typical sales encounter. In fact, one goal of drug marketing is to distill and communicate the technical information, or "drug features," in the PI into a few, brief talking points, which marketers seek to communicate as "drug benefits."[260]

151. However, the FDA requires a balance of benefits and risks in promotional materials and communications. This means that the net impression of the materials or communication provides a fair balance of benefit and risk information; the treatment of benefit and risk information is comparably thorough and complete.[261] When fair balance is not present,

[260] Drug features are the notable characteristics of the drug. For example, features might include a once-a-day dosage form, a smaller tablet size, or improved efficacy. Marketers seek to turn drug features such as these into customer benefits; in this example, better medication adherence, an easier to swallow tablet, or better pain relief, respectively.

[261] According to the Office of Prescription Drug Promotion (OPDP), drug advertising must be accurate, balance the benefit and risk information, be consistent with prescribing information (the PI) and only include information that is supported by strong evidence. OPDP regulates TV and radio advertisements, written and printed prescription drug promotional materials, speaker program presentations and sales representative presentations. See https://www.fda.gov/drugs/office-prescription-drug-promotion/truthful-prescription-drug-advertising-and-promotion (last accessed February 23, 2020). This expectation is also consistent with my training as a PSR. The FDA prescription drug advertising glossary of terms defines fair balance in written materials as: "The law requires that product claim ads give a "fair balance" of information about drug risks as compared with information about drug benefits. This means that the content and presentation of a drug's most important risks must be reasonably similar to the content and presentation of its benefits. This does not mean that equal space must be given to risks and benefits in print ads, or equal time to risks and benefits in broadcast ads. The amount of time or space needed to present risk information will depend on the drug's risks and the way

from a pharmaceutical marketing perspective, product messages are misleading or deceptive because they do not convey all the important information needed for a Customer to make a decision about a drug's use. Discussed in Section III, multiple data points from this analysis inform the assessment of the degree of balance of benefits and harms in Defendants' marketing materials.

152. In a sales situation, product benefits, or the "talking points" used by a PSR are limited by the amount of time available to communicate with a prescriber. For most prescribers this will be only a few minutes, placing time pressure on the sales encounter, and limiting the information that can be presented or discussed.[262] This means marketers must be selective in what they choose to talk about in a sales encounter, while keeping in mind that the information selected must be consistent with the PI. For example, sales encounter talking points might focus on statements about drug benefits that are designed to reduce concerns about the medication and stimulate prescribing with minimal attention to potential harms.[263]

153. When providing fair balance, PSRs must provide both benefit and risk information. However, consistent with research in this area, even when negative information was the subject of PSR communications, the information was framed in a positive manner. [264]

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that both the benefits and risks are presented." https://www.fda.gov/drugs/prescription-drug-advertising/drug-advertising-glossary-terms#F (last accessed February 23, 2020).

[262] See, e.g., Gordon D. November 15, 2002, Dealing with Drug Reps. Physicians Practice e-newsletter. http://www.physicianspractice.com/operations/dealing-drug-reps (last accessed June 18, 2020); Matthew Arnold, Shadowing the Reps. Medical Marketing and Media Online, November 2012:39-42. https://biopharmaalliance.com/uploads/Shadowing_the_reps_MM_M.pdf (last accessed June 18, 2020).

[263] E.g., Fentora Objections and Company Approved Responses, TEVA_MDL_A_00021120; and other "objection handler" documents in sales training materials cited in this Report.

[264] Handling objections and reducing concerns prescribers may have about a medication is a staple of sales training and development. E.g., Taking Aim at Objections, Combunox, ALLERGAN_MDL_03502668; Managers Meeting 2007, Sales Training, TEVA_MDL_A_00358559

Turning a negative into a positive and reducing concerns prescribers may have about a medication was a staple of Defendants' sales training and development documents I reviewed.

154. The PI, however, is different than these carefully crafted promotional messages focused on turning drug features into benefits. The PI is technical and scientific information. It is FDA approved before launch and *not intended* to be promotional.[265] Because time is limited in the sales encounter, and because drug benefits rather than technical descriptions of drug features are what persuade a prescriber, marketers do not use the PI itself as their primary tool, even though it must generally be referenced. Marketing messages (i.e., the information-flow that turns a drug feature into a drug benefit) are created with information the marketer wants the Customer to see and hear, not just a summary of the PI.

155. Beyond the limited use of the PI, pharmaceutical marketers, including Defendants, use many channels to communicate their messages, or "talking points," to prescribers

(focus on managed care); Fentora Training, TEVA_MDL_A_00359511; Handling Objections Workshop, Leader Guide, TEVA_MDL_A_00390736.

[265] While the PI is intended to be non-promotional, this was not always the case. The development of the OxyContin PI was described as: "The evolution of the package insert from its original draft over four years ago was a particularly interesting and informative process. Dr. Curtis Wright, the FDA medical reviewer, upon first reviewing it, stated that he had never seen a package insert with as much promotional and marketing material in it as ours. (Clearly our package insert team, representing Medical, Scientific Communications, Pharmacokinetics and Drug Metabolism, and Marketing, did its job skillfully.) Dr. Wright even told us that all of this promotional material would disappear. It did not. In fact, the package insert contains all of the major elements of our long-range marketing platform for this drug and proved most valuable when it came time to negotiate promotional copy with the Division of Drug Marketing, Advertising and Compliance, DDMAC. We argued extensively with DDMAC in January through March of this year. The result of these, "discussions" was a tremendous set of promotional claim rich copy. And the consequence? About 50 million in sales in the first year, more than 37,000 prescriptions per month, and a market share approaching 13 percent. That is quite a beginning." (RS030719 Sackler, Richard, pp.202-203 and Exhibit 30). Purdue's success with the OxyContin PI could also have had "spillover" effects, in this instance, related to regulatory affairs.

including, but not limited to: personal selling (detailing), use of medical literature, continuing medical education (CME), development of clinical guidelines, sponsored meals, and opportunities for interactions with other prescribers (opinion leadership, peer-influence).[266] [267] [268] [269] [270] However, PSRs are pivotal to pharmaceutical manufacturers ability to educate prescribers and shape prescribing behavior.[271] [272]

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[266] See, e.g., Adair RF and Holmgren LR. Do drug samples influence resident prescribing behavior? A randomized trial. Am J of Medicine 2005; 118(8):881-884; Avorn J, Chen M, and Hartley R. Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians. Am J of Medicine 1982; 73:1-7.

[267] See, e.g., Spiller L, and Wymer W. Physicians' Perception and Uses of Commercial Drug Information Sources: An Examination of Pharmaceutical Marketing to Physicians. Health Marketing Quarterly, 2001; 19(1):91-106; Ndosi M, and Newell R. Medicine information sources used by nurses at the point of care. Journal of Clinical Nursing, 19, 2695-2661; McGettigan P, Golden J, Fryer R and Feely J. Prescribers prefer people: The sources of information used by doctors for prescribing suggest that the medium is more important than the message. J of Clin Pharmacol 2001; 51:184-189; Pines A. Patient information leaflets: friend or foe? Climacteric 2015; 18:664-665.

[268] E.g., TEVA_MDL_A_02301119; TEVA_MDL_A_04313917; ENDO-CA-00164784 & ENDO-CA-00164785.

[269] E.g., 2003 Duragesic Key Tactics Review, JAN-MS-00306778; 2009 Tapentadol Unbranded Acute Pain Message Platform, JAN-MS-00339425 and email JAN-MS-00339422; Primary Care Medical Education Plans 2007, JAN-MS-00410975; Tapentadol Publication Client Status Report, JAN-MS-00437356.

[270] See, e.g., Lubloy A. Factors affecting the uptake of new medicines a systematic literature review. Health Services Research 2014; 14:469-94; Fugh-Berman A, Alladin K and Chow J. Advertising in Medical Journal: Should Current Practices Change? PLoS Medicine, 2006; 3(6):e130, https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.0030130&type=printable (last accessed June 18, 2020).

[271] Direct sales through pharmaceutical representatives is the single largest marketing expense for most pharmaceutical companies. See, e.g., Share of promotional spending of top 20 pharmaceutical companies in the U.S. by allocation in 2013. (68%) https://www.statista.com/statistics/388002/promotional-spending-allocation-from-top-20-pharma-companies-in-the-us/ (last accessed June 18, 2020); Pharma Promotional Spending in 2013: Professional eDetailing, DTC Advertising, Professional Meetings, Journal Advertising. Pharma Guy, http://www.pharma-mkting.com/articles/pmn1305-article01/ (last accessed March 9, 2019).

[272] See, e.g., Spurling G, Mansfield PR, Montgomery BD, Lexchin J, Doust J, Othman N, Vitry AI. Information from Pharmaceutical Companies and the Quality, Quantity and Cost of

156. PSRs expose prescribers to the full spectrum of the marketer's carefully crafted information,[273] which is designed to generate prescription sales,[274] including information that goes beyond the scope of the package insert. Marketing principles and my experience suggest, and the record supports, the proposition that prescribers consider all the information, from all sources, that is communicated to them by pharmaceutical companies, including Defendants, and rarely rely on the PI alone. Moreover, once information is communicated to prescribers *and processed into memory* it will have lasting effects on prescribing decisions (see Figure 2, Physician Prescribing Information Processing Model, above).

Physicians' Prescribing: A Systematic Review. PLoS Med 2010; 7(10):e1000352; Brody, H. The Company We Keep: Why Physicians Should Refuse to See Pharmaceutical Representatives, (Reflection). Annals of Family Medicine 2005; 3(1):82-85. Findings include higher prescribing, higher cost of drugs and less appropriate (quality) prescribing.

[273] While product labeling must conform to FDA requirements, when a sales representative discusses a drug with a prescriber, the sales representative decides what information is covered and where emphasis is placed.

[274] See, e.g., Wood SF, Podrasky J, McMonagle MA, Raveendran J, Bysshe T, Hogenmiller A, et al. (2017) Influence of pharmaceutical marketing on Medicare prescriptions in the District of Columbia. PLoS ONE 12(10): e0186060; Brax H, Fadlallah R, Al-Khaled L, Kahale LA, Nas H, El-Jardali F, et al. (2017) Association between physicians' interaction with pharmaceutical companies and their clinical practices: A systematic review and meta-analysis. PLoS ONE 12(4): e0175493; Spurling G, Mansfield PR, Montgomery BD, Lexchin J, Doust J, Othman N, Vitry AI. Information from Pharmaceutical Companies and the Quality, Quantity and Cost of Physicians' Prescribing: A Systematic Review. PLoS Med 2010; 7(10):e1000352; Steinman MA, Bero LA, Chren MM, Landefeld CS. Narrative Review: The Promotion of Gabapentin: An Analysis of Internal Industry Documents. Ann Intern Med. 2006; 145:284-293; Ahmed, R.R., Vveinhardt, J., Streimikiene, D., and Awais, M., 2016. Mediating and Marketing Factors Influence the Prescription Behavior of Physicians: An Empirical Investigation. Amfiteatru Economic, 18(41), pp.153-167; Katz D, Caplan A, Merz JF. All Gifts Large and Small: Toward an Understanding of the Ethics of Pharmaceutical Industry Gift-Giving. Am J Bioethics 2010; 10(10):11-17; Gonul, F., Carter, F., Petrova, E., & Srinivasan, K. (2001). Promotion of prescription drugs and its impact on physicians' choice behavior. Journal of Marketing, 65, 79-90; DeJong C, Aguilar T, Tseng CW, Lin G, Boscardin W, and Dudley A. Pharmaceutical Industry-Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries. JAMA Internal Medicine. 2016; 176(8):1114-1122; King M and Bearman PS. Gifts and influence: Conflict of interest policies and prescribing of psychotropic medications in the United States. Social Science and Medicine 2017; 172:153-162.

II. MARKETING IN THE PHARMACEUTICAL SUPPLY CHAIN

157. Pharmaceutical marketing is implemented through an integrated supply chain (Figure 3) that is part of the "place" marketing mix variable. The stakeholders in this system work together to market, sell, and pay for pharmaceutical products. The U.S. pharmaceutical supply chain is composed of manufacturers, wholesale distributors, and pharmacies in the distribution of medicines and other stakeholders that coordinate revenue flows. Supply is ensured for prescription opioids by manufacturers, including Defendants in this matter. In addition to wholesale distributors (e.g., McKesson, Cardinal Health, or AmerisourceBergen), pharmacy chains, such as CVS and Walgreens, also engage in internal wholesale distribution of medicines, acting as their own distributors, either alone, or in cooperation with wholesale distributors.

158. The goal of the pharmaceutical supply system is to move products from manufacturers to the customer. Each stakeholder has the common goal of selling pharmaceuticals by working with and through others in the supply chain system.

159. The primary marketing messages from manufacturers to wholesale distributors are expected to be focused on price, quality, drug availability, and service. Pharmacists that dispense prescriptions may also receive these marketing messages, and additionally, promotional messages focused on drug features and benefits, similar to prescribers. For example, Endo supported continuing education for pharmacists related to the management of chronic pain that communicated messages consistent with their overall marketing of opioids (Section III of this report, and Table 2).[275]

[275] WAGMDL00766955, Navigating the Management of Chronic Pain: A Pharmacist's Guide. Power-Pak C.E.

160. With respect to pharmacies, large chain pharmacies like Walgreens recognized the issues associated with pain management, especially in Florida, where it noted that the top 30 opioid prescribers nationally were practicing in Florida.[276] [277] [278]

161. Ensuring the proper function of the supply chain is important to pharmaceutical companies who will lose sales if resistance to their drug is encountered at any point in the system, including at the pharmacy level. Revenue flows (Figure 3) between various parts of the supply chain system in a variety of forms, including payments, rebates, and chargebacks that ensure members of the supply chain system have data, such as utilization, supply, and distribution, showing exactly where each bottle of pills is going and at what price. [279] [280] This data is used in financial planning, manufacturing, and marketing of pharmaceuticals and provides critical metrics to pharmaceutical marketers for assessing past, and planning future, marketing efforts.

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[276] WAGFLDEA00000659, Joel Wright (Walgreens) 7/23/2010 email to Terry Gubbins (Walgreens) with subject "Re: Handling Pain Management RXs."

[277] See also documents related to managing the dispensing process related to opioids and other controlled substances, such as e.g., WAGGLDEA00000363. Raval 8/6/2010 email to District 109RX with subject "FW:RXM Meeting – Oxycodone."; WAG00000446; WAGFLDEA00000447; WAGFLDEA00000741; WAGFLDEA00000912; WAFLDEA00000925, Bryon Wheeldon 3/24/2011 email chain regarding Markets 3 and 28 Controlled Substances Meetings, in this communication Mr. Gubbins notes that "[n]o need to create additional best practices, or to create policies that are more restrictive than the state and federal laws."; WAGFLDEA00001288, oxy metrics (percent of prescriptions);

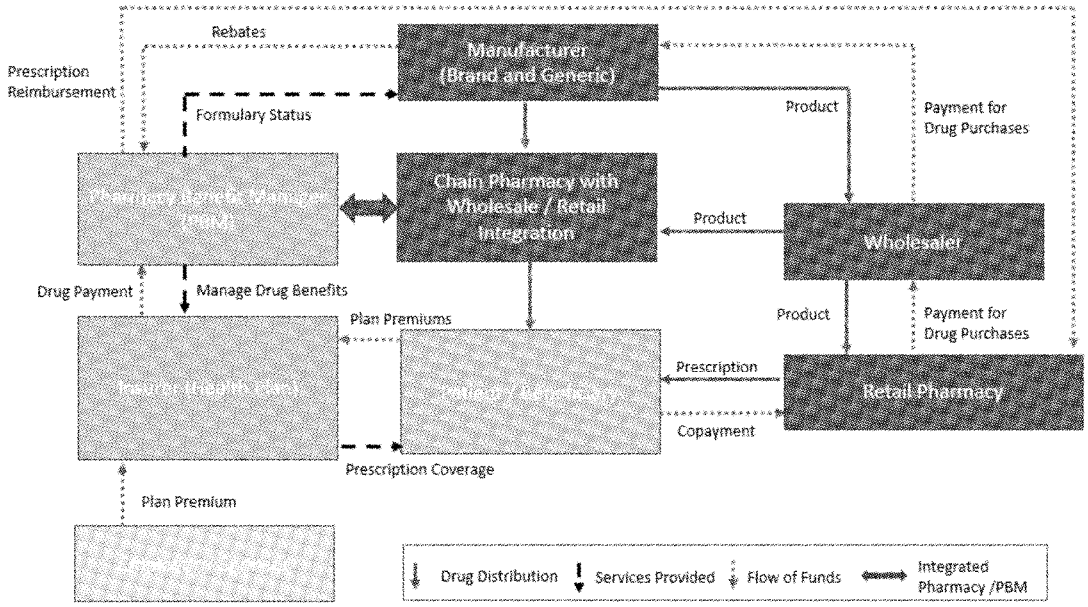
[278] CVS made the continuing education program "Pharmacists' Responsibility in Appropriate Controlled Substance Dispensing" available to all their pharmacists CVS 2/12/2013 group email announcing the free CE program "Pharmacists Responsibility in Appropriate Controlled Substance Dispensing," CVS_MDLT1B-000002484.

[279] Manufacturers routinely negotiate contract prices with customers such as retail pharmacy operations. Wholesalers ensure that each customer ultimately pays their contracted amount through a system of contracts, chargebacks, and rebates. See Figure 3: Flow of Services, Product and Funds in the Pharmaceutical Supply Chain System.

[280] E.g., 2010 Cardinal Health Presentation, CAH_MDL2804_02103500; Seid email, PPLPC008000041397.

162. Given the complexity of revenue flows, wholesalers, manufacturers, and pharmacies have a synergistic relationship, each relying on the other to sustain sales. The wholesale function is also important to retail pharmacy, as wholesalers offer attractive pricing in connection with their negotiation of volume discounts with manufacturers (e.g., source programs). This is especially important for generic medicines, where pharmaceutical wholesalers can give preferential treatment to a specific manufacturer's products by stocking only (or preferentially) selected manufacturer's products for distribution and/or generic purchasing programs.

Figure 3: Flow of Services, Product, and Funds in the Pharmaceutical Supply Chain System[281]



[281] This figure is adapted from "Prescription Drug Pricing in the Private Sector," January 2007. The Congress of the United States, Congressional Budget Office.

III. DEFENDANTS' MARKETING OF OPIOIDS

A. Background and Competitive Market for Opioids

163. According to the Kadian Learning System,[282] an Allergan sales training manual, the need to regulate controlled substances, including opioids, to prevent diversion and abuse (corollaries of addiction) has been on the legislative agenda since about the 1930s. Yet, opioid use has grown over time in response to both patients' need for analgesia and the marketing of drugs to fill that need.[283] The KLS, and many other of Defendants' documents and communications demonstrate awareness of the dangers of opioids.[284]

164. Morphine and meperidine have been available as commercial pharmaceutical drugs for many years. The stigma of morphine with healthcare professionals limited its use primarily to end-of-life care and cancer pain.[285] In the 1970s the pharmaceutical industry began to market codeine, hydrocodone, and oxycodone products in combination with aspirin or acetaminophen, under trade names such as Tylenol with Codeine (including multiple strengths of the codeine component) Vicodin and

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[282] Kadian Learning System, Chapter Six: Drug Abuse and Chronic Pain, ALLERGAN_MDL_00436784, p.00436786.

[283] Other sales training manuals and scripts are identified in Schedule 8: Sales Training Manuals and Scripts; Fentora Learning System, with cover email at TEVA_MDL_A_00890304; Fentora Learning System, Pre-Module, Introduction to Pain, Cephalon 2008, TEVA-MDL_A_00890305; "A change is coming…effervescent speed,"TEVA_FL_00001942; Fentanyl Effervescent Buccal Tablet (FEBT) Learning System, TEVA_MDL_A_00003586; Putting it All Together Workshop, Leader Guide, TEVA_MDL_A_00004012; 2008 Fentora World Cup Internal War Games Workshop, TEVA_MDA_A_00008543; Fentora Phase II Marketplace Workshop, Facilitators Guide, TEVA_MDL_A_00346497; Verilogue Sound Insight, Fentora Breakthrough Pain Conversation Study, October 8, 2009, TEVA_MDL_A_00500779.

[284] Awareness of the dangers of opioids was seen in Defendants' documents ranging from product labeling to the "backgrounder" documents cited in this report, to marketing planning documents. The need for REMS programs also supports the proposition of awareness of the dangers of opioids. See also, Stacey Beckhardt 11/25/2003 email TEVA_MDL_A_003316708; Andy Pyfer 4/28/2004 email chain, TEVA_MDL_A_04108856; Stacey Beckhardt 1/24/2005 email, TEVA_MDL_A_03272549.

[285] E.g., Duragesic Pain Specialist Overview, JAN-MS-00302787, p.29; Legal and Ethical Issues Affecting Pain Management, Family Practice.com, PKY180769094.

Percocet.[286] Over time, utilization of these drugs grew, but health professionals remained conservative in their prescription of opioids. These conservative views towards opioid use have been shared by pharmacists because they see firsthand the full scope of consequences that can result from opioid use, such as addiction and drug seeking behaviors.[287]

165. In July of 1982, Lortab (hydrocodone and acetaminophen) was approved for treating pain. Five years later, Purdue's MS Contin (extended-release morphine sulfate), which at the time did not have approval from the FDA as a new drug, was marketed as a "generic" morphine product before its formal approval under a new drug application by the FDA. Because of problems with orally administered morphine, Purdue was eager to introduce its MS Contin because of its new, extended-release formulation.[288]

166. In 1991, a unique product, Duragesic (fentanyl transdermal patch), was introduced to provide long-acting delivery of fentanyl for patients who needed sustained analgesia.[289] Duragesic was direct competition for MS Contin in the extended-release category of analgesia. Other competitors included hydromorphone and oxycodone combinations, but these did not provide for extended release, until the introduction of OxyContin.

167. A few years later, Chris Johnson and Michelle Sheridan at Janssen shared the "OxyContin Backgrounder Family Feud Questions" with others at the company. This

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[286] Percodan was an oxycodone/aspirin combination.

[287] E.g., JAN-MS-00659218, Yap (Janssen) New Hampshire Deposition Exhibit 20; JAN-MS-00662577, Yap (Janssen) New Hampshire Deposition Exhibit 21.

[288] The "Contin" delivery system uses a polymer matrix to create sustained delivery of the embedded drug. This system uses a water based and a non-water (hydrophobic) based polymer, blending the drug with the water-based polymer. When combined, the drug dissolves from the water-based component limited by the rate of the hydrophobic component. This delivery matrix provides the original drug at a slower rate over a longer period but does not alter the active ingredient.

[289] Duragesic 2003 Business Plan JAN-MS-02324033; 2001 Janssen Pain Franchise Review, JAN-MS-02118349.

competitive-intelligence document contained interesting insights for Janssen into how OxyContin marketers viewed the competitive situation between the two drugs.[290] Within Janssen, others worked to continue to develop a better understanding of the strengths, weaknesses, opportunities and threats related to the pain market. In a 2001 Pain Franchise Plan, Janssen carefully analyzed the market, including the potential for "evidence-based guidelines" to negatively impact the company's sales.[291]

168. Through about 1994, Purdue marketing research revealed that the Class II opioid market was growing at a rate more than 12% each year. However, oxycodone combination product sales had slowed, and according to Purdue, this was likely due to the introduction of long-acting opioid formulations that were capturing market share, and because Class III opioids (e.g., hydrocodone) were easier to prescribe. Further, marketing planners at Purdue realized its MS Contin would soon be subject to generic competition and worked to develop a strategy to replace its vulnerable MS Contin sales with sales of its newer, long-acting oxycodone product, OxyContin.

169. In 1995, Ultram (tramadol, Janssen) was approved by the FDA as a non-controlled analgesic.[292] While less potent on a milligram per milligram basis than morphine (about 1/10 or .1 MMEs) Ultram was not controlled and offered ease of prescribing as a product feature. However, its manufacturer was cautioned by the FDA not to use this feature as a marketing tool.[293]

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[290] Michelle Sheridan 1/17/2000 email JAN-MS-02727829; OxyContin Backgrounder Family Feud Questions, JAN-MS02727830.

[291] Janssen 2001 Pain Franchise Plan (8/3/2000), JAN-MS-00785752.

[292] The issue of a drug's schedule, or controlled status, has been a factor in prescribing for many years as prescribers are generally more reluctant to write prescriptions for CII than CIII, CIV, or CV substances.

[293] NDA 20-281, March 3, 1995 FDA letter to Jean O'Connor, Senior Director of Regulatory Affairs, where the FDA notes: "As Ultram may have an abuse potential of an unknown degree, you are not permitted to advertise, promote or market the drug product by calling attention to its unscheduled status under the U.S. Controlled Substance Act."

170. At about the same time, Purdue was also developing extensive marketing plans for the launch of OxyContin.[294] This planning proved effective for Purdue's OxyContin; sales increased to nearly $1 billion in 2000. During about the same time period, Purdue's sales force grew from 256 PSRs in 1995 to 674 PSRs in 2000.[295] These efforts on the part of Purdue would serve to ensure success with its launch of OxyContin and to prime the market for other manufacturers' future product introductions. Priming the market impacts others (usually competitors or customers) through a "spillover" effect.[296] For example, Purdue's marketing aimed at increasing awareness of its "new" long-acting opioid created Customer knowledge of this product category and had the potential to stimulate current or *future* sales for its competitors. The increase in the market for pain control initiated by Purdue attracted the attention of Customers, and competing manufacturers, through this spillover effect and the market expanded with the addition of other branded opioid products such as Kadian (morphine sulfate extended-release, Allergan, 1996),[297] Actiq (fentanyl oral lozenge, 1998),[298] and Avinza (morphine sulfate, 2002).

171. Kadian was approved by the FDA in July of 1996. The product was marketed by Alpharma prior to being acquired by Actavis Inc. In mid-2009, Allergan began marketing Kadian and continued promoting the product until about December of 2012 using a

[294] 1995 OxyContin Launch Plan, PURCHI-003286149, pp.1-5.

[295] OxyContin Market Events, PPLP012000371063.

[296] Note 1, *supra*.

[297] Kadian was introduced by Alpharma in 1996. Based on deposition testimony, Alpharma was acquired by Actavis in 2008. Actavis was acquired by Watson in 2012, but the resulting company retained the Actavis name. In 2015 Actavis acquired Allergan and the resulting company retained the Allergan name. A year later, Allergan divested Actavis to Teva. (Woods California Deposition, pp.14-15; Booth (Allergan) Deposition, p.33)

[298] Actiq was approved by the FDA in 1998 and launched by Abbott in April of 1999. Anesta acquired Actiq from Abbott in February of 2000 and began marketing Actiq in May of 2000. In October of 2000 Cephalon acquired Anesta. Cephalon relaunched Actiq in March of 2001. Actiq Marketing 2002, TEVA_MDL_A_05734046.

contract sales force (InVentiv) of between 18 and 46 sales professionals. Allergan also used telemarketing, conducted by TMS Health and Technekes, to reach prescribers.[299] Using lists of high prescribers (developed from Wolters Kluwer data) created by Tegra Analytics, the Kadian sales force provided direct education of prescribers. In addition, and in coordination with the sales force, Kadian has a website, copay cards, a patient assistance program, and a patient adherence program (direct-to-consumer) to promote the use of Kadian.

172. 1998 brought the introduction of Actiq that was developed by Anesta, a subsidiary of Cephalon. After being marketed briefly by Abbott Hospital Products, Anesta re-acquired the rights to the drug and re-launched the product.[300] Actiq was unique in its delivery system and approved for treating breakthrough cancer pain in patients who have previously used opioids. Actiq's indication required its marketing be limited to cancer patients with breakthrough pain.[301] [302] However, the 2002 marketing plan for Actiq revealed that the drug was being used mostly in non-cancer patients. Nevertheless, the

[299] Tegra's target lists identified the top Kadian prescribers in addition to other branded and generic morphine prescribers. Prescribers who were not within the geographic territory of a member of the contract sales team were referred to the telemarketing arm (TMS Health and Technekes) of Actavis/Allergan marketing for contact.

[300] Actiq Master Plan, November 16, 2000, TEVA_MDL_01159082; Actiq Sales Training, March 12, 2003, TEVA_MDL_A_05304106; TEVA_MDL_A_05304064.

[301] From its original approval in 1998 the FDA had made it clear that Actiq required restrictions on distribution and use to assure it was used safely. Actiq was approved subject to the Risk Management Plan (RMP) that the FDA referred to as an "integral part of the approved NDA for the product" and informed Anesta that any change to the RMP would need to be approved by the FDA. (Marchione Deposition Exhibit 5, FDA November 4, 1998 letter to Patricia Richards of the Anesta Corporation)

[302] Marchione (Teva) Deposition, pp.78-79, 86.

Actiq marketing plans continued to target non-cancer prescribers, evidenced in the rapid growth in Actiq sales.[303] [304]

173. In addition to its marketing plan data, other Cephalon (Teva) documents were focused on the issue of off-label use of Actiq. For example, in a Regulatory Telephone Contact Report, memorializing a discussion with Dr. Robert Rappaport, Director of Anesthetic, Critical Care and Addiction Drug Products at the FDA, Ms. Marchione noted, "Dr. Rappaport stated that (sic) FDA is very concerned about reports of diversion and misuse of Actiq. He said that there have been discussions at very high levels of the Agency regarding several issues involving the use of our product."[305] [306]

174. Mr. Brennan, a former Cephalon employee with responsibility for Quality Assurance audits, also had concerns and wrote to the FDA informing the agency of multiple violations related to Actiq's marketing and its Risk Management Plan (RMP), alleging

[303] ACTIQ 2002 Marketing Plan, Pyfer (Teva) Deposition Exhibit 18 (TEVA_MDL_A_00454816), Beckhardt (Teva) Deposition, pp.195-227 and Exhibit 12; Marchione (Teva) Deposition Exhibit 14, Tracie Parker 6/23/2004 email.

[304] Actiq, as a generic product by Teva, was included on the Teva Generics website as seen in e.g., TEVA_MDL_A_00764247. See also the Fentora website pages, e.g., TEVA_MDL_A_00764273; TEVA_MDL_A_00764285; TEVA_MDAL_A_00764996; TEVA_MDAL_A_00764940; TEVA_MDAL_A_00764831; TEVA_MDAL_A_00764721; TEVA_MDAL_A_00764694; TEVA_MDAL_A_00764674; TEVA_MDL_A_00764613; TEVA_MDL_A_00764540; TEVA_MDL_A_00764528; TEVA_MDL_A_00764368; TEVA_MDL_A_00764356.

[305] Marchione (Teva) Deposition Exhibit 18, Marchione 6/7/2004 email with subject FW:FDA Contact Report – FDA Raises Concerns about Actiq Off-Label Use and Diversion.

[306] Marchione (Teva) Deposition, pp.327, 332-341 (explanation of her letter to Dr. Rappaport, Table 8 and footnote), 512-526 and Marchione Deposition Exhibit 11, Cover letter to Dr. Rappaport and a collection of Teva documents.)

that the company was not taking actions to "reduce the ratio of prescriptions written by specialties representing inappropriate patient selection."[307] [308]

175. By 2007, Teva had agreed to recognize its improper off-label promotion of Actiq and to pay a $425 million fine and plead guilty for its actions.[309] There should be no question that by about this time period, Defendants were on notice that opioids were dangerous drugs and every effort should be taken to ensure their safe and effective use, including

[307] Dave Brennan letter to Kerry Woods at the FDA, dated February 23, 2004. (Marchione (Teva) Deposition Exhibits 10, 15, 17) See also the Marchione (Teva) Deposition and related Exhibits where the management of the RMP, an internal audit (Exhibit 12) and related standard operating procedures are discussed. The Actiq MP allowed for "targeted" medical specialties to prescribe Actiq without judgment. However, non-targeted physician specialties demonstrating high prescribing rates would be an indicator of off-label use of the drug. Limits were set at 15% market share for these non-targeted prescribers. Internal correspondence reveals how the company worked to reframe how compliance with the RMP was demonstrated, for example, breaking down prescriber specialties into very narrow specialties that were unlikely to result in utilization patterns greater than the 15% limit imposed by the RMP. Ms. Marchione discussed Teva's handling of a finding, in the 2005 Actiq marketing plan, that Primary Care prescribers (who are not "targeted" prescribers since they do not treat cancer) were accounting for 20% of the TRx for Actiq, when the RMP required actions to be taken when any prescriber specialty are exceeded 15%. (Marchione (Teva) Deposition, pp.257-266 and Marchione Deposition Exhibit 16, 2005 Actiq Marketing Plan) The internal audit referenced above is the Quality Assurance Memorandum to the QA File from Dave Brennan: Internal Audit of Actiq Risk Management Program, 2nd Qtr 2003. This audit concluded that Cephalon was not in compliance with the commitments communicated to the FDA in the RMP. (TEVA_MDL_A_01159577)

[308] Ms. Marchione also noted that Dr. Rappaport had expressed concerns that Actiq's RMPs were not working to limit Actiq use in her contact report.

[309] U.S. Department of Justice, Statement of United States Attorney Michael Mukasey and Acting United States Attorney Laurie Magid on the $425 million settlement for off-label drug marketing of Actiq, September 29, 2008. (TEVA_MDL_A_11436748 or https://www.justice.gov/sites/default/files/civil/legacy/2014/01/09/Cephalon%20Press%20Release.pdf (last accessed August 10, 2020).

with respect to diversion and abuse, and use in unintended populations.[310] [311] [312] Yet, even as late as 2006 Cephalon still developed plans for marketing Actiq that set forth the goal of maximizing TRx and Sales, pre and post its loss of exclusivity.[313]

176. When Actiq was replaced with the Fentora product, and the company began to market the fentanyl buccal tablet, Cephalon's own internal audit indicated there were still areas of concern, including the need to improve the monitoring of speaker programs, the distribution of "unsolicited" requests for off-label information by PSRs, and the appropriateness of Fentora call lists.[314]

177. Between 1999 and 2003, Endo launched variant strengths of Percocet (a combination oxycodone/APAP product), doubling the maximum strength from 5 mg of oxycodone to 10 mg to capture more of the oxycodone market.[315] In 2006, Endo launched Opana / Opana ER (oxymorphone) in the *"hostile"* regulatory and political environment surrounding new long-acting opioids.[316] Because Endo recognized, as evidenced in the Opana marketing plans, that there was little differentiation between Opana and other long acting opioids, the company sought to leverage its efficacy and safety data to

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[310] Marchione (Teva)Deposition, pp.87-88 and Marchione Deposition Exhibit 7, Actiq Risk Management Plan August 1. 2001, NDA Number 20-747.

[311] US-DEA-00001767, (MCKMDL00562501) U.S. Department of Justice Drug Enforcement Administration September 27, 2006 Joseph T Rannazzisi letter to commercial entities in the United States; US-DEA-00001767, U.S. Department of Justice Drug Enforcement Administration December 27. 2007 Joseph T Rannazzisi letter to commercial entities in the United States (focus on Manufacturers).

[312] On September 10, 2007 Cephalon distributed a "Dear Healthcare Professional" letter, TEVA_MDL_A_03400542.

[313] Actiq End of Lifecycle Plan, April 2006, TEVA_MDL_A_00010836. This slide deck also included detailed analysis of how the market was changing, especially with respect to generics.

[314] TEVA_MDL_A_00763720, February 2008 Cephalon Internal Audit of U.S. Sales & Marketing Compliance Programs.

[315] ENDO-OPIOID_MDL-04908522; ENDO-OPIOID_MDL-03388210; ENDO-OPIOID_MDL-04136658.

[316] 2006 Opana Business Plan 1, ENDO-CHI_LIT-00552969.

position Opana as the most "complete" opioid on the market. Endo utilized messages (discussed in detail below) such as, "Stay ahead of the Pain,"[317] which encourages the use of pain medication regardless of symptoms.

178. Patient Profiles, a teaching tool for sales representatives to help doctors identify patients for treatment with Opana, was introduced by Endo in 2007. Endo created fictitious patients, like a carpenter suffering from chronic low back pain, an osteoarthritis patient with knee problems, or a cancer patient to help sales representatives coach doctors into identifying potential patients in their practice. Each patient profile reflected different Opana features that Endo highlighted as advantages and suggests to prescribers the kinds of patients that might be candidates for Opana.[318]

179. In 2008, Janssen launched the NEO Pathways campaign that was designed to prime the pain market for the introduction of Nucynta.[319] The NEO Pathways modules were aimed at reshaping existing paradigms in pain management, teaching prescribers what they should consider when choosing a medication for their patients and diffusing concerns over prescribing controlled substances. By focusing on the undertreatment of pain Janssen could tap into prescribers' desire to take good care of patients while increasing opioid use, and the future sales of Nucynta.

180. Embeda (Alpharma) came to market in 2009 and was a combination of morphine and naltrexone. Naltrexone blocks the effects of opioids, including euphoria and feelings of well-being that can lead to opioid abuse.

[317] END00038091, "Help Your Patients Stay Ahead of Pain."

[318] END00018819, New Sales Tools: Patient Profiles.

[319] Tapentadol NEO-PATHWAYS, Heading in new directions in pain management, JAN-MS-0047660331.

181. Janssen launched Nucynta (Tapentadol) in 2009, and two years later the extended-release formulation of the drug, Nucynta ER (extended release) came to market.[320] Pharmacologically, [321] Nucynta was a new opioid molecule that Janssen hypothesized had a dual mechanism[322] of action: *mu*-receptor agonist and norepinephrine reuptake inhibition. The focus on this new dual mechanism of action also included avoidance of the word opioid. In a 2007 planning document on how to present the new molecule to J&J shareholders, Greg Panico (Senior Director, CNS/Internal Medicine Communications) agrees with a message from David Upmalis (Senior Director, CNS/Analgesia) that "we should take out opiate and say centrally-acting."[323] Janssen positioned this new molecule as an alternative that "offers the efficacy of oxycodone with better tolerability."[324]

182. Over the next few years, the use of opioid analgesics for both medical and non-medical uses grew in the U.S.[325] Dr. Sairam Atluri, Medical Director of the Tri-Sate Spine Care

[320] Janssen marketed Nucynta/Nucynta ER until about 2015 when it was divested.

[321] Tapentadol has an MME of 0.4 and the immediate release formulation that initially came to market was available in 50mg and 100mg tablets, with a morphine milligram equivalence (MME) of 20mg and 40mg. These MMEs represent relatively high doses of an immediate release formulation.

[322] Chronic Pain Management Message Platform, JAN-MS-00068759; Christine Rauschkolb 9/16/2008 email chain, JAN_MS_01124875.

[323] Haya Taitel 4/11/2007 email chain to Greg Panico, David Upmalis, Ron Kuntz, Rodrigo Moreno, Lynn Leonard, and Christine Rauschkolb with subject, "RE: TAPENTADOL mention at J&J Shareholders meeting April 26," JAN-MS-00268513.

[324] Tapentadol Business Plan 2008, attached to email from Haya Taitel to Ron Kuntz, dated 5/31/2007 with subject line, "RE: 2008 BP slide deck," JAN-MS-00442019.

[325] See, e.g., Guy G, Zhang K, Bohm M, Losby J, Lewis B, Young R, Murphy L, and Dowell D. Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015. US Department of Health and Human Services/Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, 2017; 66(26):697-704; Mosher, H, Krebs E, Carrel M, Kabloi P, Vander Weg M, and Lund B. Trends in Prevalent and Incident Opioid Receipt: an Observational Study in Veterans Health Administration 2004-2012. J of General Internal Medicine 2014; 30(5):597-604; Atluri S, Sudarshan G, and Manchikanti L. Assessment of the Trends in Medical Use and Misuse of Opioid Analgesics from 2004 to 2011. Pain Physician, 2014; 17:E119-E128.

Institute in Ohio, published an assessment of trends in medical use and misuse of opioid analgesics in 2014. Using data from the Automation of Reports and Consolidated Orders System (ARCOS) and Drug Abuse Warning Network (DAWN) it was estimated that overall opioid use increased by 1,448% from 1996 to 2011. Misuse increased at three times this rate (4,680% from 1996 to 2011). Further, the increase of opioids for medical uses appears to contribute to increased non-medical use (diversion and abuse).[326]

183. Over time, FDA scrutiny of opioid promotional messages resulted in several warning letters being issued to opioid marketers.[327] These letters focused on concerns that promotional materials used by drug makers contained false or misleading statements related to safety and efficacy (i.e., claims opioids were safer and more effective than the scientific evidence would support) and the promotion of opioids beyond their approved

[326] Atluri S, Sudarshan G, and Manchikanti L. Assessment of the Trends in Medical Use and Misuse of Opioid Analgesics from 2004 to 2011. Pain Physician, 2014; 17:E119-E128.

[327] November 20, 1996 FDA Warning Letter to Raymond Sackler, President, The Purdue Frederick Company (MS Contin); March 5, 1998 Warning Letter to Jacqueline Brown, Janssen Pharmaceutica (Duragesic); May 11, 2000, FDA Warning Letter to Beth Connelly, R.N., Purdue Pharma L.P. (OxyContin); January 17, 2003 Warning Letter to Michael Freidman, Purdue Pharma L.P., The Purdue Frederick Company (OxyContin); September 2, 2004, Warning Letter to Dr. Ajit Shetty (Duragesic) JAN-MS-00779345; March 10, 2005 Warning letter to James Burrus, Johnson & Johnson Pharmaceutical Research & Development LLC, (Duragesic), JAN-MS-00291349; March 24, 2008 Warning Letter to King Pharmaceuticals (Avinza); March 26, 2009 Warning Letter to Carole S. Marchione, Cephalon, Inc.; May 12, 2009 Warning Letter to Johnson and Johnson (Ultram); February 18, 2010 Warning Letter to Doug Boothe, Actavis US (Kadian); March 15, 2010 Warning Letter to Marci Schentzel, King Pharmaceuticals, Inc. (Embeda); August 26, 2011 Warning Letter to Roxanne McGregor-Beck, Ortho-McNeil-Janssen Pharmaceuticals, Inc. (Nucynta); November 12, 2010 Warning letter to Roxanne McGregor-Beck, Johnson & Johnson Pharmaceutical Research & Development, LLC, JAN-MS-00230364.

indications.[328] These concerns were echoed in settlement and plea agreements with opioid manufacturers, including some Defendants in this matter.[329]

184. After about 2007, as awareness of growing problems with opioids continued to increase,[330] opioid manufacturers sought new ways to expand sales.[331] This included reformulations of existing drugs and focusing on claims of abuse deterrent formulations.[332] [333] Leading what could be described as the second wave of product modifications (the first being controlled release), Allergan, and other opioid manufacturers, conducted research that supported development of abuse

[328] Related to the off-label promotion of Actiq, see, e.g., the "Etiology of Migraine" presentation that Mr. Spokane attributed to the marketing team, where Actiq was referred to as an "ER on a stick." Spokane (Teva) Deposition pp.124-129 and Exhibit 13, TEVA_FL_00001424.

[329] May 8, 2007 Purdue Pharma settles multi-state marketing claim. John Obrien, Legal Newsline, https://legalnewsline.com/stories/510518258-purdue-pharma-settles-multi-state-marketing-claim (last accessed July 29, 2020). The states taking part in this settlement include: Arizona, Arkansas, California, Connecticut, Idaho, Illinois, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Montana, Nebraska, Nevada, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington and Wisconsin. The District of Columbia was also participating in this settlement; Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing, https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html (last accessed February 10, 2020).

[330] E.g., ACTIQ 2002 Marketing Plan, Pyfer (Teva) Deposition Exhibit 18 (TEVA_MDL_A_00454816) p.2; Actiq 2004 Marketing Plan, TEVA_CHI_00042951; JAN-MS-00011705, Nucynta / Nucynta ER Situation Assessment, p.10.

[331] E.g., 2012 10 Year Plan, PPLP004149692; PPLPC016000255303, BDC meeting – Project Tango.

[332] E.g., TEVA_CHI_00042951 pp.41-42; 2015 Coplan email, PPLPC019001155586; 2014 Performance Management Report, Day Matthew M., TEVA_MDL_A_08802273.

[333] New formulations also had value to opioid manufacturers related to the product lifecycle and patent protection. New formulations may provide additional years of patent exclusivity for products at the end of the patent life, a practice in marketing known as "evergreening."

deterrent/tamper resistant formulations.[334] [335] This focus on tamper-resistant/ abuse deterrent formulations represented an option that would continue to increase sales as these messages (tamper-resistant, abuse deterrent) would give physicians a sense of security that they could safely prescribe opioids for their patients. This strategy was consistent with Defendants' existing marketing themes (namely, that opioids can be used without risk, discussed in Section III below) and continued for years.

185. However, even the sales of the new, allegedly safer, product formulations such as Opana ER would be impacted by the opioid crisis. For example, by 2017, the FDA determined that the benefits of Opana ER use no longer outweighed the risks. Endo, in discussion with the FDA, withdrew Opana ER from the market on September 1, 2017.[336] Still, Teva was considering bringing new opioids to the marketplace, such as Vantrela (hydrocodone extended release, Teva) in about 2017.[337]

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[334] Wakeland W, Schmidt T, Gilson A, Haddox J and Webster L. System Dynamics Modeling as a Potentially Useful Tool in Analyzing Mitigation Strategies to Reduce Overdose Deaths Associated with Pharmaceutical Opioid Treatment of Chronic Pain. Pain Medicine 2011; 12:S49-S58.

[335] E.g., Kadian LAO Decision-Making Process, Altier (Allergan) Deposition Exhibits 17 & 18; Haddox (Purdue) Deposition, pp.320 -340 and Exhibits 26 and 27; Patient Exploration for CEP-33237 (tamper resistant hydrocodone), TEVA_FL_00013743 (Day (Teva) Deposition Exhibit 34).

[336] The FDA requested that Endo remove Opana ER from the market in June of 2017. The cease shipping date was negotiated with the FDA and set for August 31, 2017. During the summer, Opana ER was still shipped to Customers and was accompanied by a 20% price reduction aimed at increasing shipments to wholesalers before the product withdrawal. Endo claims this was to ensure an adequate supply of Opana ER for those who may need it during the transition. This is certainly a consideration, however, from a marketing perspective this would also serve to limit losses on Opana ER sales due to the product withdrawal. Walker (Endo) Deposition, pp.464-475 and Exhibit 23.

[337] 2016 US Regional Brand Plan Vantrela ER, March 19, 2015, TEVA_MDL_A_08773244; Vantrela ER Strategic Brand Plan, March 20, 2014, TEVA_MDL_A_08778248, and Naik Santosh 6/13/2014 cover email; CLAD, Core Leadership in Abuse Deterrence, Core Team Meeting, December 4, 2013, TEVA_MDL_A_01261647; 2014 Vantrela ER Launch Plan DRAFT, December 23, 2013, TEVA_MDL_A_01204103; Vantrela ER Strategic Brand Plan, March 18, 2014; Ryan Daufenback 1/24/2014 email, TEVA_MDL_A_01204102; CLAD, Core Leadership in Abuse Deterrence, Vantrela ER Market Access Strategy and Tactical Review, February 21, 2014,

B. Defendants Sought to Identify Customer Needs

186. A key principle of marketing is to identify an unmet need and work to fill that need. Opioid manufacturers', including Defendants', marketing plans and other documents focused on the issue of meeting Customer needs.[338] Acknowledging and addressing these Customer concerns was important to Defendants because it would enable them to appear to be meeting Customers' needs.[339]

187. Marketing theory suggests that *if* products existed that could satisfy these Customer needs, prescribing habits should change because these would be significant therapeutic advances in pain treatment. While the pharmacology (the chemical structure, mechanism of action, adverse events, half-life, structure and function relationships, receptor binding, elimination and clearance, etc.) of opioids did not change, Defendants' marketing of opioids was substantially different.[340] More specifically, Defendants' opioids were not new; how they marketed and positioned opioids in Customers' minds is what changed.

TEVA_MDL_A_00857858; Matthew Day 12/21/2017 email, TEVA_MDL_A_02974065; https://www.drugs.com/cdi/vantrela-er.html (last accessed March 26, 2020).

[338] Schedule 6: Defendants' Marketing Plans, e.g., 2003 Actiq Marketing Plan, TEVA_CHI_00042882; 2005 Actiq Marketing Plan, TEVA_CHI_00043010 (TEVA_FL_00001312). See also e.g., Kadian Marketing Update, September 13, 2012, ALLERGAN_MDL_0007290; 2011 PCS East Business Plan, Cephalon, Randy Spokane, PCS East Regional Sales Director, TEVA_MDL_09088727; Kadian LAO Decision-Making Process, Altier (Allergan) Deposition Exhibits 17 &18; FAST Team Meeting January 18, 2007, (Fentora Assessment Strategy Tactics), TEVA_CHI_00006142.

[339] E.g., JAN-MS-00306327, Duragesic Evolution Overview, 2003.

[340] U.S. Department of Justice, Statement of United States Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executives for Illegally Misbranding OxyContin, May 10, 2007, 2007, https://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf (last accessed August 10, 2020); U.S. Department of Justice, Statement of United States Attorney Michael Mukasey and Acting United States Attorney Laurie Magid on the $425 million settlement for off-label drug marketing of Actiq, September 29, 2008. https://www.justice.gov/sites/default/files/civil/legacy/2014/01/09/Cephalon%20Press%20Release.pdf (last accessed January 25, 2020).

188. The quest to understand and be responsive to Customer needs was seen across many of the documents (e.g., the marketing plans), and testimony I reviewed. In one example related to understanding Customers, Deborah Bearer (Teva/Cephalon) discussed a "market access strategy" that was being developed:

> To develop a strategy, you can either have advisory boards, you can do market research, you identify—you have a third party to identify a population representative of, say, commercial payers. It's blinded. The third party engages. There are objectives and research. And that research comes back and it is taken into consideration as you're developing your value proposition for the payer and messaging.

In this example, Ms. Bearer was referencing an email communication between herself and Jeffrey Dierks regarding a managed care article that had been commissioned by Matt Day. There was apparently a lack of internal communication regarding this publication, but this example demonstrates how marketing research, advocacy, thought leadership and Customers must all be aligned (i.e., integrated). She was asked if this was done for the drug Fentora and her reply was, "that would be – that would be the norm."[341]

189. In addition to qualitative marketing research, Defendants identified and disseminated research and other work that supported their desire to promote opioids as safer and better for treating pain than existing treatments. One study, frequently cited by Defendants, and other opioid manufacturers, in marketing materials, was authored by the well-known, industry-supported opioid expert, Dr. Russell Portenoy,[342] which

[341] Bearer (Teva) Deposition, pp.261-273, and Deposition Exhibit 21 (Jeffrey Dierks 11/18/2015 email).

[342] Dr. Portenoy consulted with and received grants from pharmaceutical companies. Defendants used his work as part of their marketing efforts. Relationships between Defendants and KOLs such as Dr. Portenoy create the potential for commercial bias and conflicts of interest. E.g., Altier (Allergan) Deposition, pp.269-284 and Altier Exhibit 14; Moskovitz (Janssen) 30(b)(6) Deposition, regarding KOLs and advisory boards, pp.80-82, 218-223; Riddle (Purdue) Deposition, pp.107-108, 289, 320, 340; Spokane (Teva) Deposition, pp.40-41, 93-98, 264-266.

concluded, based on research with 38 patient cases, that "…opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse."[343] Another fundamental piece of support for opioid manufacturers' claims about the safety of opioids came from a 1980 letter to the editor in the New England Journal of Medicine, which concluded that addiction was rare in hospitalized patients with no history of addiction.[344]

190. Teva, including Cephalon, and Endo also worked to create materials for publication, often through the use of prominent KOLs (that were paid consultants and influential with advocacy groups), to support their products.[345] For example, the Endo patient brochure, *Understanding Your Pain: Taking Oral Opioid Analgesics*, was edited by Dr. Portenoy.[346]

C. Defendants' Marketing Strategy for Opioids

191. In my analysis of Defendants' marketing of opioids, I reviewed many marketing and business documents. The examples that I have cited in my Report are representative of the larger set of documents I have reviewed. Further, the documents cited reflect the activities commonly used by pharmaceutical marketers and provide ample insight into

[343] Portenoy R and Foley K. Chronic use of opioid analgesics in non-malignant pain: Report of 38 cases. Pain 1986; 25:171-186.

[344] Porter J and Jick H. Addiction rare in patient treated with narcotics. New England Journal of Medicine 1980; 302:123. See also comments reported by Sam Quinones in the book *Dream Land*, regarding the use of the Porter and Jick letter, TEVA_FL_00017243, Condodina (Teva) Deposition Exhibit 24.

[345] E.g., Beckhardt (Teva) Deposition, pp.366-372, and Deposition Exhibits 29 and 30. See also the Hassler MDL deposition regarding publications to support the use of opioids. (Hassler (Teva) Deposition, pp.327-328)

[346] ENDO_OPIOID_DEPMAT-000006093, Understanding Your Pain.

Defendants' marketing activities. Finally, the marketing documents I reviewed were developed by Defendants for use nationally, including in Florida.[347]

192. Defendants worked to create inappropriately aggressive[348] [349] marketing strategies for opioids, which served to distort needs, wants, and demand for opioids. Evidence that Defendants' marketing was aggressive is seen in marketing and brand plans,[350] tactical plans, sales training,[351] and other documents[352] and communications cited throughout this Report.[353] [354]

[347] Altier (Allergan) Deposition, p.356; Snyder (Allergan) Deposition, p.271. See also Teva Regional Brand Plan Core Document, where alignment between global and regional brand plans was emphasized, TEVA_MDL_A_00763927.

[348] The term aggressive, from a marketing perspective, refers to how extensively, diligently and vigorously marketing strategies are developed and implemented.

[349] Dr. Portenoy, an industry opinion leader and pain advocate also believed that Purdue aggressively marketed its OxyContin. (Portenoy Oklahoma Deposition, 1/24/2019, p.189)

[350] See Schedule 6: Defendants' Marketing Plans.

[351] See Schedule 8: Sales Training Manuals and Scripts. See also e.g., Fentora Sales Training and Development Business Plan 2007, where specific goals for sales training are enumerated, TEVA_MDL_A_00007006; Breakthrough Science – Clinical Proficiency, Leader Guide, TEVA_MDL_A_00001194.

[352] PKY180268536; PPLP003420448, OxyContin 2012 ACAM Part II; Tapentadol Business Plan 2008, JAN-MS-00442020.

[353] There was pressure on sales reps to push higher dosage formulations, E.g., ALLERGAN_MDL_01112579 (Patient Adherence Program)

[354] Defendants also created audio/video marketing pieces intended for a variety of internal and external audiences, some of which have a commercial tone. E.g., TEVA_MDL_A_00717855 (Actiq sales training); TEVA_MDL_A_00715630 (News clips); TEVA_MDL_A_00717114 ("Doug" a construction worker); TEVA_MDL_A_00717111 (Converting Actiq prescribers); TEVA_MDL_A_00717116 (Actiq v Fentora); TEVA_MDL_A_00717117 (Pain Lingers); TEVA_MDL_A_00717110 (Patient and Doctor, BTP); TEVA_RI_00000002 (A Few Good Men); TEVA_RI_00000003 (Introducing Fentora, Relief at Effervescent Speed); TEVA_RI_00000004 (Fentora, FBT / BTP); TEVA_RI_00000005 (Dr. Evil, Fentora); JAN-MS-02364493; JAN-MS-04212484, Dr. Rosenbery / Nucynta; JAN-MS-04212411, Dr. Fine / Nucynta; JAN-MS-04212293, Dr. McCarberg, unbranded message;

193. Defendants' aggressive[355] marketing put patient welfare at risk through increased prescribing of opioids and the increased risk of dependence, tolerance, addiction, withdrawal, and death that is associated with the increased use of opioids.[356] Defendants designed their marketing strategy for opioids to turn drug features into drug benefits, create desirable positioning in Customers' minds, and stimulate prescriptions for opioids. These activities are consistent with marketing principles, but not with a concern for patient safety or industry standards.

Marketing Information Bias Toward Benefits and Away From Harms

194. Defendants claim to provide fair balance in their communications with Customers.[357] However, a review of multiple data points in this analysis revealed a different conclusion: an information bias skewed toward product features and benefits, and away from harms. From a marketing perspective, Defendants' bias towards the benefits of using opioids, and away from risks of these drugs is a deceptive or misleading form of overpromotion that would encourage Customers to also downplay opioid risks and prescribe these drugs more liberally.

[355] Reference is also made to aggressive marketing by Defendants and others, e.g., Riddle (Purdue) Deposition, pp.33-34, 134; OxyContin Launch Plan, 1995, PURCHI-003286149; Cohen, June 28, 2011 email, ALLERGAN_MDL_00132475; ENDO-OPIOID_MDL-00439663; Van Zee, A. The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy. Am Journal of Public Health, 2009; 99(2): 221-227; Exhibit Endo-Chapman-6, Statement of Unites States Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and its Executives for Illegally Misbranding Oxycontin; Note: Mr. Gasdia at Purdue did not personally agree with this characterization of Purdue's marketing, yet, described efforts that fit a marketing definition of aggressive marketing (Gasdia (Purdue) Deposition, pp.126-136).

[356] TEVA_MDL_A_03272549.

[357] E.g., Nataline (Allergan) Deposition, p.115; Altier (Allergan) Deposition, p.58; Balzanti (Allergan) California Deposition, pp.84, 106, 122-123; Hepp (Allergan) California Deposition, pp.171, 205-206, 275-283; Killion (Allergan) California Deposition, pp.62, 126, 196, 208-216; Bingol (Endo) Deposition, pp.97, 104, 328; Chapman (Endo) Deposition, pp.201-203.

195. To a limited degree, Defendants' marketing documents sometimes referenced safety information ("important safety information" or "ISI") for drugs, consistent with FDA-approved indications and prescribing information contained in the PI.[358] For example, the Actavis (Allergan) sales training entitled "Introduction of Oxymorphone Hydrochloride Extended-Release Tablets CII" provides sales training for generic oxymorphone (generic equivalent for Opana ER). About one-third of the content is devoted to ISI. However, because this was a generic medication, clinical messages (benefits or harms) about the drug were not provided by PSRs. Rather, the key messages were based on product availability of the new generic, including that the product was being stocked by all major wholesalers.[359]

196. In some 2011 Kadian plans, PSRs were specifically directed to discuss safety considerations with prescribers during sales calls.[360] However, in this example, safety information was limited and far less content was devoted to safety information than product benefits and selling features.

197. The same was true for Teva's "Core Visual Aid" (CVA) for Fentora. The CVA was a booklet, and later an iPad application, that would be shown to the prescriber during a sales call but not left behind with the prescriber.[361] The CVA contained numerous pages touting the benefits of Fentora and only one page on "serious" side effects, and an additional page on "common" side effects. Even though the CVA contained the required black box warning (and PI at the end), it was not balanced in its presentation of the benefits and harms of Fentora.

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[358] While cautionary statements were noted in the PIs of all Defendants, as noted above, the PI itself is not generally relied on in personal selling situations.

[359] Snyder (Allergan) California PMK Deposition Exhibit 17, ACTAVIS0506802.

[360] E.g., Kadian Marketing Overview, Sales Representative Training October 2011, ALLERGAN_MDL_00007268; Kadian Marketing Overview, Sales Representative Training, July 2012, ALLERGAN_MDL_00026506.

[361] Optimize onset with FENTORA, TEVA_MDL_A_00551447.

198. Defendants' marketing plans (Schedule 6), which comprehensively mapped the strategies for their products, seldom mention plans, strategies or tactics to deliver messages focused on harms from opioid use.[362]

199. Focusing on the benefits and minimizing harms was seen in the Fentora Learning System (FLS), a comprehensive sales training backgrounder for Fentora that PSRs were required to study.[363] This 70-page sales training piece taught PSRs about the pathophysiology of pain, pain evaluation, and issues in pain management. Examination of this primer on pain revealed three key findings related to benefits and harms. First, the space devoted to harms was limited. Second, when potential harms were presented, they were framed as objections to overcome, or their relevance was minimized. Finally, the FLS supported the favorable marketing messages most important to Teva (presented in Section III of this Report).

200. For example, the "issues in pain management" section of the FLS described undertreatment of pain and enumerated the barriers to treating pain with opioids, along with the theme that cancer pain is undertreated; both arguments suggest greater use of opioids.[364] The FLS also noted that JCAHO guidelines addressed the undertreatment of pain, and included new standards for pain management (circa 2001) that JCAHO monitored as a requisite for accreditation, which is required for health care organizations (Customers) to be eligible for third party reimbursement. Tolerance and physical dependence were presented as routine, manageable outcomes of opioid use

[362] A balance of benefits and harms was not expected to be seen in all marketing plans or sales trainings. For example, plans that focused on payers instead of the clinical aspects of opioids would not be expected to include safety information.

[363] Fentora Learning System, TEVA_MDL_A_00390409.

[364] In the Fentora Learning System, Teva cites to several of the advocacy organizations supported by Defendants in this matter. This provides support for the proposition that Defendants' marketing is intertwined and that the marketing was well coordinated. Working with advocacy, and entities such as the Joint Commission, Defendants were able to promote and advance their marketing themes.

that are different than addiction.[365] One paragraph of the FLS is dedicated to addiction. In this paragraph, addiction is briefly defined and the paragraph ends with the claim: "[p]ain appears to reduce the euphoric effects of opioids, so people taking opioids to manage their pain may be at a lower risk for addiction."[366] This message was one frequently communicated through Defendants' marketing. (See Table 2: Defendants' Marketing Messages)

201. Teva sales training also included the Fentora Scenario Resource Cards.[367] This resource presented five patient scenarios that focused on issues important to the success of Fentora. Each scenario describes a patient case, suggests probing questions, and provides suggested messages, including product features and benefits. Only one of these scenarios (Fentora Scenario #1) makes any mention of harms, and this is in the form of a reminder at the end of the staged scenario: "And remember, Cephalon [Teva] foremost has a commitment to patient safety – the SECURE program is designed to ensure that only appropriate patients receive Fentora and the risks of overdose, abuse, and diversion are minimized."[368] In my opinion, this sales resource for PSRs, designed to

[365] For example, "Symptoms of physical dependence are easily prevented by tapering the opioid dose instead of stopping it abruptly if discontinuing opioid therapy." Fentora Learning System, p.48.

[366] On p.48 of the FLS, a call out box notes as a helpful "Tip" that "Constipation, an adverse effect associated with many opioids, may not diminish as tolerance develops." The selection of this opioid side effect is consistent with a focus on benefits over harms in that it does not point to the very real and devastating effects of opioid use such as respiratory depression, but rather a common, less destructive opioid side effect: constipation. Further, this tip could be misconstrued by PSRs undergoing this training to be fair balance given that PSRs in this matter appear to equate the mention of a side effect to providing fair balance. This issue is discussed in detail below.

[367] Fentora Scenario Resource Cards, TEVA_MDL_A_00150310.

[368] The SECURE program was essentially the RiskMAP that was created by Cephalon (Teva) for Fentora. It included three broad objectives to minimize risks associated with: 1) Use of Fentora by non-tolerant individuals; 2) Misuse, abuse, and diversion of Fentora; and 3) unintended (accidental) exposure to Fentora. Condodina, Cynthia (Teva) MDL Deposition, p.284;

teach them how to interact with Customers, fails to instruct PSRs on how to meet fair balance requirements; it does not convey a net impression of balanced benefit and risk information. PSRs present the information they are taught and, in this example, benefits and harms are not equally presented.

202. In another Teva example, Randy Spokane, an Area Sales Manager, created a presentation in 2003 entitled, "A Managers Perspective on Actiq." Here, Mr. Spokane presented "Key Core Messages," which included:

- "Clinically Viewed Relief in 5-10 Minutes
- No Acetaminophen
- Superior Patient Control
- Less Potential for Abuse
- Short Duration of Action
- Favorable Side Effect Profile
- Up to 4 Units/Day
- 86% of Patients Titrated Above 200mcg
- 200mcg Actiq = 5mg Percocet"

These core messages included only one potential harm (less potential for abuse) that was, again, framed as a product benefit, rather than risk or potential harm.[369]

203. Watson sales training also minimized serious opioid risks in its training. PSRs were taught, for example:[370]

- [I]n general, tolerance to the analgesic effect does tend to parallel tolerance to side effects like respiratory depression and sedation. Therefore, if a patient needs larger opioid doses for analgesia because of

Beckhardt (Teva) Deposition, pp.151-153, and Beckhardt Deposition Exhibit 8, TEVA_CHI_00028341 (@ TEVA_CHI_00028347).

[369] A Manager's Perspective on Actiq, TEVA_MDL_A_09062111.

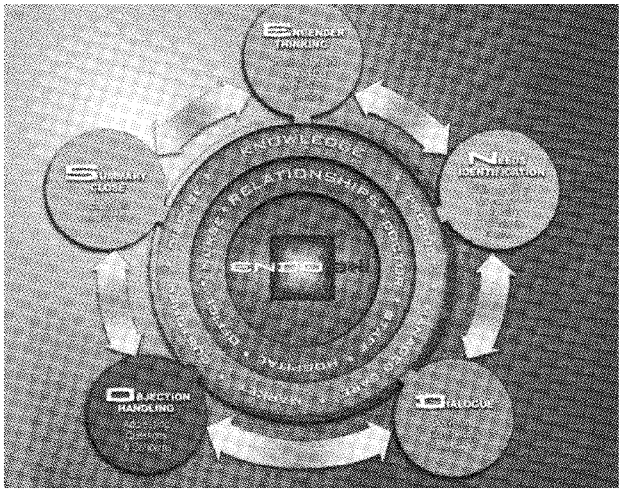
[370] Norco Training Binder, ALLERGAN_MDL_03255938.

tolerance, he or she will usually also be tolerant to the respiratory depression and will therefore be able to withstand the higher dose.

- Although physical dependence is common in patients receiving opioids for pain, addiction is quite rare.
- Hydrocodone has a lower risk of respiratory depression and lower abuse potential than most other opioids (eg, [sic] morphine, meperidine, hydromorphone, and oxycodone).

This PSR training consistently focused on the messages aimed at alleviating prescribers' opioid fears and encouraging opioid prescriptions.

204. The 2006 "ENDOSell" training program titled, "Engender Thinking and Needs Identification Workshop," touted as "Your custom guide to selling success," walked PSRs through a five-step process (see insert below) coaching sales personnel in the art of selling.



This PSR training taught powerful sales techniques designed to capture business. It enforced the need for pre-call planning, so that PSRs could ask Customers the right

questions, leading to the right answers to guide and direct the flow of information between the PSR and the Customer. For example, the materials suggested that pre-call planning might include: "Does the physician know what the appropriate patient looks like to Rx [prescribe] Opana ER?" The content of this training is on selling skills, and not drugs; however, it provides a strategy for taking Customers through a process favorable to Endo's product. There is no mention of the need to provide fair balance or safety information even as a disclaimer in this training program. [371]

205. Teva's "Model Sales Call Behavior" trained PSRs to deliver the company's core messages on every call, including: early onset of relief, readily absorbed across the buccal mucosa, unique OraVescent Technology, convenient, discreet, sugar-free, and acetaminophen-free. However, this training was lacking in attention to potential harms. [372] The model sales call did note that "[d]iscussion of the efficacy of Fentora must also include a fair balanced discussion regarding the safety profile of the product," but, unlike the beneficial core messages listed above, safety information was not enumerated. This training also continued to encourage PSRs to engage Customers with "questions" that led to discussions of chronic pain, and BTP, even though prior discussions with DDMAC had highlighted concerns over this approach and the potential for this to encourage off-label inquiries.[373] Finally, the Model Sales Call ends with the instruction to close the sales call with the "Chronic Pain Assessment Tool" which references BTP but not cancer. (See insert below)

[371] 2006-07 ENDOSell Training Program, ENDO-OPOID-MDL-02489842 or ENDO-OPIOID_MDL-00678661.

[372] Model Sales Call Behavior, TEVA_MDL_A_00359434.

[373] TEVA_MDL_A_00359434.

questions, leading to the right answers to guide and direct the flow of information between the PSR and the Customer. For example, the materials suggested that pre-call planning might include: "Does the physician know what the appropriate patient looks like to Rx [prescribe] Opana ER?" The content of this training is on selling skills, and not drugs; however, it provides a strategy for taking Customers through a process favorable to Endo's product. There is no mention of the need to provide fair balance or safety information even as a disclaimer in this training program. [371]

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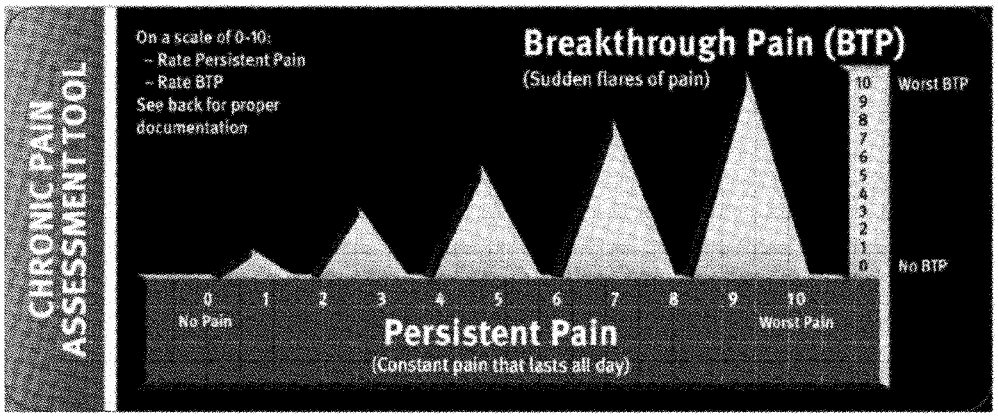
[372] Model Sales Call Behavior, TEVA_MDL_A_00359434.

[373] TEVA_MDL_A_00359434.



206. An Endo Opana ER with Intac training presentation entitled "Meeting the Challenge" discusses many aspects of the brand's marketing strategy. This overview of the Opana ER brand strategy identifies pages of core messages. However, in the entire document only one sentence describes adverse reactions (nausea, constipation, dizziness, somnolence, vomiting, pruritus, headache, sweating increased, dry mouth, sedation, diarrhea, insomnia, fatigue, appetite decreased, and abdominal pain). One additional sentence mentions the word "risks," but no other harms are noted by Endo; there is no mention of dependence, tolerance, addiction, withdrawal, or death.[374]

207. A sales training manager at Endo, Nicholas Albert, distributed a medical presentation intended for training new PSRs. This presentation, entitled "Opioid Overview & the Opana Brand of Products," by Dr. Errol Gould, was a scientific overview of opioids, including oxymorphone ER clinical trial results. This presentation contained more information on adverse events than most, if not all, of the presentations I reviewed. Of the 120 slides in this presentation:

- 13 slides noting the prevalence of adverse events in the clinical studies reviewed

[374] Opana ER with INTAC Technology Brand Overview, EPI000435768.

- 1 slide discussed the dichotomy between needing to treat pain and issues with abuse and diversion – described as "barriers"
- 1 slide listed the clinical signs of opioid withdrawal
- 3 slides listed warnings about use with alcohol
- 2 slides covered the Black Box Warning
- 1 slide discussed proper patient selection and suggests evaluating risk factors for abuse and addiction

However, even this example, where harms *were* included, Endo's conduct falls short of setting a good example for how to comply with fair balance requirements, given that product benefits were the subject of most of the presentation.[375]

208. Another Endo sales training document authored by Demir Bingol, Sr. Marketing Director, "Mission: Deliver the Difference for the Opana Brand in POA II," lacks any mention of harms. Copies of a sales aid included in this presentation do include lists, but no details on adverse events.[376] Finally, Endo also used a comprehensive Opana ER strategic platform that would guide activities of Opana ER through its product life cycle. This platform provided strategic direction for Opana ER, including the messages that Endo would communicate in the marketplace, but this presentation lacked reference to the potential harms of Opana ER.

209. The preponderance of Defendants' PSR training and promotional messages focused on translating drug features into drug benefits, and downplayed information that would serve to discourage prescribing, including potential harms. For example, in the Nucynta pain franchise planning document cited above, the final summary slide reiterates the "core" messages to be conveyed to customers. Janssen PSRs are directed to "stay true to core message – and consistently deliver." These core messages focus on the

[375] Opioid Overview and the Opana Brand of Products, ENDO-OPIOID-MDL-01408500.
[376] Mission: Deliver the Difference for the Opana Bran in POA II, ENDO-CHI_LIT-00555275.

mechanism of action, proven tolerability and efficacy profile, acute pain relief benefits, the savings cards, and creating awareness and advocates for Nucynta.[377] The ISI is conspicuously missing from this summary of what the PSR should focus on as "core" messages. Other Janssen programs provided similar training themes with a focus on benefits and selling, including a 2010 PriCara training presentation with 41 slides, none of which mention harms, or reasons to be cautious with opioids.[378]

210. Generally, for Janssen and other Defendants, when safety information was presented, it was often couched in terms of how this was really a benefit of the product (e.g., *less* nausea and vomiting, or a *reduction* in treatment limiting side effects).

211. These examples, and others I have seen, provide support for the proposition that PSRs delivered the messages they were taught to deliver. Marketing documents, including PSR training materials, were biased toward product features and benefits, and away from harms. The data points presented here are representative of others reviewed and support the general proposition that Defendants' training materials and related documents were biased toward benefits of their opioids, and away from the harms.

PSRs and Fair Balance

212. Defendants' PSRs were trained to sell their employers opioids and were rewarded for sales performance. This must be considered when evaluating the role of the PSR in providing balanced benefit and risk information.

213. Ms. Altier, a marketing professional at Actavis from about 2010 to 2013 noted, with respect to Actavis, "we made sure that all of our marketing materials were fair balanced so that they could provide that safety message along with the efficacy message."[379]

[377] E.g., JAN-MS-00011705, Nucynta / Nucynta ER Situation Assessment.

[378] E.g., Sales Training – Nucynta; Nucynta Workshops, PriCara AI/GI Sales Force Meeting Cycle 3, 2010, JAN-MS-00059606.

[379] Altier (Allergan) Deposition, pp.15-16, 58.

Teva, in its 2014 Fentora Fast Start, encouraged PSRs to make every sales call a "complete" call by providing fair and balanced messaging.[380] Mr. Wood, a Janssen PSR, described his goal as a sales representative.

> That was my goal as a sales representative to provide as much fair and balanced content around my product so that he or she could then make an educated decision based off of whatever doctor/patient dialogue occurred about that specific patient. My goal was that this – the doctor would have my product as a reliable, trustworthy, and available product of [sic] he – if he or she felt it was right for the patient. My – my hope, my goal was that my presentation of my product made it a viable option for him or her in his decisionmaking [sic] – his or her decisionmaking [sic] process with the patient type.

This statement informs this analysis in the context of the bias ingrained into PSRs through their training, toward product benefits. Mr. Wood engaged with Customers to "educate" and convince them the product was "reliable," "trustworthy," and "available," with no mention of the fact that it could be dangerous and lead to many side effects, including addiction or even death.[381]

214. However, even given these views, PSRs communicate to Customers what they are taught,[382] and as noted above, the training materials used to teach PSRs were biased toward benefits, and away from risks.

215. Using the PI to ostensibly provide fair balance was viewed by Defendants as an acceptable way to provide this FDA required information. It was not. For example, this marketing behavior was seen in a sales training "Telesales Script" for the promotion of Kadian. The script provides Kadian marketing messages important to Allergan first, followed by "As you know, there are also risks associated with the use of Kadian." The

[380] 2014 Fentora Fast Start, TEVA_MDL_A_00763943.

[381] Wood (Janssen) California Deposition, p.107.

[382] E.g., Fitch (Allergan) California Deposition, pp.60-61, 109-110; Hagy (Allergan) California Deposition, p.44; Knobloch (Allergan) California Deposition, p.117; Killion (Allergan) California Deposition, p.202.

risks are presented differently than the benefits. In fact, in this example, the risks are more extensively delineated than the short, bullet points of the benefits. If this information were indeed communicated this training would be a good example of how to provide fair balance. However, telephone marketing time, like the PSRs face time with Customers, is limited. It is not likely that the sales call would be able to make it through all the "fair balance" information, which Allergan recognized. This training instructs agents that if they are unable to complete the discussion of the fair balance information, they are to "inform the HCP that a copy of the PI will be sent for the HCP's information and proceed to CLOSE."[383]

216. Telephone sales contacts by Allergan in the above example poses interesting questions for the communication of product information, including fair balance requirements for opioid manufacturers. The decision to engage Customers via phone contact poses the risk that the agent will be cut off, and the full message (i.e., the harms) may not be communicated. Yet, in this script it appears that Allergan was willing to take this risk. In the alternative, fair balance could have been provided in each part of the communication as required by the FDA.[384] This way, if cut short communications would *still* be balanced over the scope of what information was covered within the limited time frame. Choosing to cover the product features that encourage sales, and placing at risk the communication of information to balance product selling points clearly demonstrates a bias toward product benefits, and away from harms. If a telephone call was cut short, the result would be a Customer that received a one-sided message, which is misleading.

[383] Altier (Allergan) Deposition Exhibit 22, (ACTAVIS0335906) Email and Telesales script.
[384] FDA March 26, 2009 letter to Cephalon regarding Fentora and Treanda.

217. Mr. Hepp, a sales professional, sales manager, and sales trainer at InVentiv, Actavis' contract PSR sales force provider,[385] had another view of fair balance.[386] In his California deposition he claimed:

> [PSRs] were never allowed to be in the field and discuss Kadian without providing what we would call fair balance, and fair balance involved mentioning on every single call in every office the fact that there are adverse events that could occur between everything from constipation to addiction, you know, and so we had to make that – that point known on every single call that we made.

He went on to say:

> [T]he one thing that we worked especially hard on with our reps was that probably 50 percent of the calls we make are 30 seconds to a minute in length because it's a physician in between patients, running back, okay, what have you got? I have Kadian, a great alternative to generic, you know, oxymorphone, you know, or OxyContin. And we always had to get in the fair balance message, so even when a physician would walk away, we'd have to say, Doctor, I need five more seconds and we have to make sure we let you know that this is an addictive medication, it does have its adverse events, and provide them with the package insert so that they will have full reference to it. That was something that we practiced. I don't see that with most companies today.

Based on his testimony, I agree that at least for Mr. Hepp and some of the individuals he trained and supervised, some risk information must have been communicated to Customers. However, based on his own estimates, the scenario he provided as an example suggests that between about 9% and 17% of his messages (5 seconds out of 30 seconds, and 5 seconds out of a 60 second sales call) focused on possible harms.[387] This

[385] See, e.g., 2102 SOW for Media Campaign, contract between Endo and InVentiv. (EPI000005372)

[386] Hepp (Allergan) California Deposition, pp.205-206, 276-280.

[387] I realize this scenario was not intended to represent all sales calls. Mr. Hepp claimed that the 30 seconds to one-minute time limit for a sales call occurred about "50 percent or more" of the time. (Hepp (Allergan) California Deposition, pp.205-206, 276-280) I also understand that the amount of time devoted to messages alone should not be the only indicator of fair balance. The need to devote time to PSR communications about risks is dependent on the time spent discussing benefits.

scenario, that Mr. Hepp stated was part of sales training, would not be needed if PSRs were trained to provide a potential harm for each benefit discussed during each part of their discussions with Customers, as expected by the FDA. Further, provision of risk information in the manner expected by the FDA would vaccinate PSRs against arriving at the end of a sales encounter and realizing that the mandatory balance was missing, and being confronted with the need to "chase" after a prescriber in order to get "five more seconds" to provide at least some balance into their message.

218. Further support for the proposition that PSRs slanted their communication with Customers toward benefits and features, rather than risks or harms, was seen in field coaching reports,[388] such as the ENDOSell Coaching Reports. For example, in the May 2007 coaching report for Gae Lasorda, her District Manager, Maricel Foley, summarized selling expectations by focusing Ms. Lasorda on "hypertargeting" her top five prescribers, focusing on benefit selling, reinforcing and supporting Opana ER efficacy and advantages, use of the master visual aid (MVA), using an effective close on every call, and maximizing speaker program attendance. At no point is she given feedback or coaching on her presentation of balanced information about Opana ER. Given that PSRs communicate what they are taught, and do what they are instructed, the information Ms. Lasorda provided would be focused on the points noted which are biased toward product benefits and selling, not the potential harms.[389] [390]

[388] Defendants used coaching reports, performance improvement programs, ride-a-longs, etc., to evaluate the performance of PSRs.

[389] E.g., Gae Lasorda Report, ENDO_FLAG-00131724. See also e.g., Oscar Farach, 7-11-2007 ENDOSell Coaching Report, ENDO_FLAG-00166407.

[390] Other ENDOSell Coaching Reports can be seen at, e.g., ENDO_FLAG-00166447; ENDO_FLAG-00166467; ENDO_FLAG-00209176; ENDO_FLAG-00222606; ENDO_FLAG-00241089; ENDO_FLAG-00241094; ENDO_FLAG-00241099; ENDO_FLAG-00241109; ENDO_FLAG-00241114; ENDO_FLAG-00241119; ENDO_FLAG-00241139; ENDO_FLAG-00241185; ENDO_FLAG-00241190; ENDO_FLAG-00270285; ENDO_FLAG-00270357; ENDO_FLAG-00270361; ENDO_FLAG-00270577.

219. The proposition that features and benefits were favored over potential harms was further supported in other similar reports. For example, Endo District Manager Mark Webb instructed PSR Tracey Fields to provide "[f]eatures with a BENEFIT [emphasis in original] on every call," but never coaches, instructs or reminds Ms. Fields to balance each benefit with a potential risk, or harm.[391] District Manager Maricel Foley reminded PSR Oscar French, "Please remember, even on a quick call, to mention a feature with a benefit to solidify prescribing behavior."[392]

220. The analysis of the bias toward product benefits noted in this Report is consistent with independent research on PSR communications that has found that PSRs "rarely" inform physicians about serious adverse events.[393] Barbara Mintzes of the University of Sydney reported in the Journal of General Internal Medicine (2020), based on her research of 69 opioid promotions by 16 different companies, that while the benefits of opioids were discussed in 78% of opioid promotions, in 54% of the cases, no adverse events were mentioned at all.[394] Serious adverse events were mentioned in only 12% of promotions.

[391] Tracey Fields ENDOSell Coaching Report, 6-25-2007, ENDO_FLAG-00270638.

[392] ENDOSell Coaching Report, Oscar French, 7-11-2007, ENDO_FLAG-00128800.

[393] Mintzes B and Lexchin J. The "Nuts and Bolts" of Opioid Marketing: Promotional Messages to Family Doctors in Sacramento, Vancouver, Montreal, and Toulouse. J Gen Intern Med. DOI: 10.1007/211606-019-05584-5; Mintzes B, Lexchin J, Sutherland J, Beaulieu M, Wilkes M, Durrieu G, and Reynolds E. Pharmaceutical Sales Representatives and Patient Safety: A Comparative Prospective Study of Information Quality in Canada, France and the United States. J Gen Intern Med 28(10):1368-75.

[394] Mintzes B and Lexchin J. The "Nuts and Bolts" of Opioid Marketing: Promotional Messages to Family Doctors in Sacramento, Vancouver, Montreal, and Toulouse. J Gen Intern Med. DOI: 10.1007/211606-019-05584-5.

Internal research at Purdue also confirmed a very low rate of communication of adverse events.[395] [396]

221. These data points do not support the proposition that Defendants accurately communicated the true nature of the benefit/harm issue. These data instead provide support for the proposition that PSR's messages to Customers were biased toward information that would sell more product rather than alert prescribers to safety concerns.

222. In my analysis I considered that almost universally the PSRs, and others deposed in this matter, claimed to provide fair balance.[397] Many deponents talk about how fair balance was part of their training and interactions with Customers. However, when pressed for details, they provided examples that demonstrated far less communication of risk information than benefits and product features. However, it is evident that some risk information was communicated in PSR communications, especially through company-approved written sales materials. The risk information in these materials likely explains the PSRs inaccurate characterization of their communications as fair and balanced.

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[395] Rosen (Purdue) Deposition Exhibit 2, pp.70-72, 2016 Purdue Field Optimization Update. Other Defendants also analyzed Customer recall of their marketing messages. See also e.g., Message Recall Tracking Study, Fentora, May 23rd, 2012, TEVA_MDL_A_00501903; TEVA_MDL_A_00499863; Strengthening Fentora's Position in the TIRF Marketplace, HCP Wave 2 Tracker, July 2013, TEVA_MDL_A_00881680.

[396] What is most concerning about the Mintzes research is that even though information was biased in its presentation to prescribers, doctors generally "judged the information positively and stated their willingness to prescribe." (Mintzes B and Lexchin J. The "Nuts and Bolts" of Opioid Marketing: Promotional Messages to Family Doctors in Sacramento, Vancouver, Montreal, and Toulouse. J Gen Intern Med. DOI: 10.1007/211606-019-05584-5) Mintzes conclusion is consistent with the discussion above regarding the role and impact of PSRs in persuasive communication.

[397] See. e.g., Balzanti (Allergan) California Deposition, pp.84, 106, 122-123; Ciampi (Teva) California Deposition, pp.86, 183-184; Hepp (Allergan) California Deposition, pp.171, 205-206, 275-283; Killion (Allergan) California Deposition, pp.62, 126, 196, 208-216; Nataline (Allergan) Deposition, p.115; Altier (Allergan) Deposition, p.58.

223. Mr. Ciampi, at Teva, was asked if he always employed fair balance. His response was: "With my accounts it was always brought up, not specifically every single visit but in whole with the account in time, yes."[398] Mr. Balzanti at Actavis (Allergan) was the lone witness who seemed to understand fair balance expectations. He defined fair balance as: "[y]ou provide and spend just as much time on the positives as you do on the negatives."[399]

224. I have not seen evidence in the record that Defendants' PSRs provided equal treatment to the discussion of benefits and risks, even when they did communicate some risk information. I hold the opinion that Defendants' PSRs view the term "fair balance" to simply mean "risk information."[400] The data points indicate that Defendants' PSRs considered messages fairly balanced any time they provided *any* risk information. In other words, if they mentioned any risk information (including risk information presented as a product benefit), they had provided fair balance.

225. The amount of risk information required naturally depends on the nature of the statement of benefits. With respect to time and fair balance, Mr. Killion at Actavis was asked to provide a sense of what a typical sales call would be for one of his PSRs selling Kadian. He stated:

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[398] Ciampi (Teva) California Deposition, pp.183-184.

[399] Balzanti (Allergan) California Deposition, p.123.

[400] Consider testimony such as that of Mr. Killion. He was asked about the kinds of messages Actavis area business managers were trained to convey to customers. His response was "They were – yes, they were trained to provide promotional messages as well as fair balance messages." (Killion (Allergan) California Deposition, pp.196-197) He further stated on p.208 of this same deposition when asked about Kadian having less risk of addiction than any other medicine or any other opioid: "Because it was in our package insert that it says if we were ever asked does Kadian have a lower abuse potential, the answer is no, you know, Kadian has an abuse potential similar to that of other opioids, and that was part of our fair balance training, so you couldn't say that. That would have been completely an off-label, you know, contraindicated statement." (Killion (Allergan) California Deposition, p.208)

> Sure. I mean, so a typical call, I mean, honestly in today's age, and even back then, your calls weren't going to be - you are not going to go into a doctor's office and make a 20-minute call while they are sitting there seeing patients. You might get one to five minutes. And so, you know, you are going in there, if you are talking to a provider, and it may be talking about dosing strengths, sometimes it may be a managed care reimbursement update. It all depended on what it was that you were there to talk to - maybe the time before the doctor is, Yeah, I'm concerned about reimbursement, so you come back the next time, you've got a Form Trak template ready to go. But even with that, you still would have to say to the doctor, you know, even with the -- you leave the sales sheet, Just as a reminder, Doctor, **and then you would throw in a quick, you know, fair balance blurb,** [emphasis added] even if you are talking about managed care because you are still giving the good but you've got to make sure that you are always making sure that they are aware of the potential, you know, the fair balance part of it.[401]

The act of throwing in a quick "fair balance blurb" is not indicative of a presentation of information that gives comparable treatment (including time spent) to both the benefits and harms.

226. These examples are representative of others I have reviewed and support the proposition that PSRs did not routinely provide fair balance in their communications with Customers. Rather, these data points support the proposition that PSRs distill the contents of the PI into their own talking points that do not reflect a fair and balanced discussion.

Early Opioid Bias

227. The preferential communication of product benefits over harm information was seen from the early stages of opioid marketing. A good example of the bias toward benefits over harms was seen in early discussions at Purdue related to Customer perceptions of OxyContin.[402] In 1997 Purdue's OxyContin team explored inaccurate Customer

[401] Killion (Allergan) California Deposition, p.214.

[402] "Position" is used in this instance as the marketing term of art for how a company creates a specific perception of its product in customers' minds.

perceptions of the drug. The discussion suggested that Purdue intended to allow incorrect perceptions (i.e., oxycodone is weaker than morphine) to live on in Customers' minds even though oxycodone is more potent than morphine on a milligram per milligram basis. Purdue's rationale was that allowing the misperceptions to continue was desirable from a sales perspective because it had resulted in physicians using OxyContin earlier to treat non-cancer pain, a much larger market with more sales potential than the cancer-pain market.[403] [404]

228. The OxyContin team further noted that Purdue must be, "careful not to change the perception of physicians toward oxycodone when developing promotional pieces, symposia, review articles, studies, etc." In other words, Purdue decided to allow the false perceptions of its product to continue to exist by strategically withholding information that would correct marketplace misunderstandings about its product.[405] [406]

229. These actions would benefit Purdue, Defendants, and all other opioid manufacturers through the spillover effect. Allowing inaccurate Customer perceptions of OxyContin to remain intact provided a foundation for other opioid manufacturers, including Defendants, to skew their own messages toward benefits and away from harms. Purdue's actions in this regard were important to Defendants because Duragesic and OxyContin were in direct competition.

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[403] PKY180774040, Michael Cullen email.

[404] Cancer and non-cancer pain markets are examples of possible target markets for OxyContin as discussed in the background marketing materials introduced at the outset of this Report.

[405] See other similar communications where Purdue seeks to control perceptions of its OxyContin, positioning it where it desires, regardless of the science or pharmacology of the drug, e.g., PDD1508224775, Friedman 5-28-97 email; PDD17014600004, Friedman 5-29-1997 email; PDD1701819202, Friedman email 5-29-1997.

[406] The OxyContin Team meeting notes were distributed to the highest levels within the company, including to members of the Sackler family.

Aggressive Sales Techniques

230. The art of influencing Customers through persuasive communication is a powerful marketing principle.[407] Defendants aggressively emphasized persuasive selling techniques that also supported discussions of benefits over risks to increase awareness of core messages and generate prescription sales. For example, when it came to communication of some of the most significant potential harms stemming from opioid use, Defendants' PSRs were trained on how to handle this potential objection,[408] or to divert attention from this issue as noted above.

[407] Persuasive communication strategies are powerful in effecting change and include the following principles: reciprocity, consistency, social proof, liking, authority, and scarcity. The principle of reciprocity creates a need within people to return a favor or to pay back others. We see this in pharmaceutical marketing frequently when, for example, PSRs provide meals or free CME. When e.g., lunch has been provided, the receiver feels inclined, even obligated, to conform to the request. Scarcity is explained by the belief that things that are in short supply, or scarce, are valuable, and therefore desirable. Product availability announcements may tap into this principle. When people base decisions on others whom they believe to be experts, or more knowledgeable than they themselves are, the principle of authority is at play. Marketers rely on KOLs and thought leaders because people are less likely to say no to these kinds of individuals. Commitment and consistency describe how individuals, as creatures of habit, desire to be consistent in their actions to avoid dissonance. Sampling or free trials of products create commitment in Customers leading to product loyalty. People are also less likely to say no to someone they like. When "liking" increases, so does the effect of this principle. Finally, the principle of consensus, also called social proof, implies that we frequently observe the behaviors of others when making decisions. When a decision is needed, we learn or watch what others are doing and factor this into our decision-making. Peer-to-peer marketing relies on this principle. See, e.g., Influence: The Psychology of Persuasion. Robert B. Cialdini, Ph.D., Revised Edition. HarperCollins e-books (original text was published in 1984; Cialdini, R.B.: The Science of Persuasion. Sci. Am. Mind. 2004; 284:76–84; Cialdini, R.: Harnessing the science of persuasion. Harv. Bus. Rev. 2001; 79:72–79; Clark, W.R., Tennessee, M.: Using the Six Principles of Influence to Increase Student Involvement in Professional Organizations: A Relationship Marketing Approach. J. Adv. Mark. Educ. 2008; 12:43–52. The FDA also has an online video training module designed for health care professionals that provides a good overview, using case studies, of persuasive communication techniques.

[408] E.g., 2011 Opana ER New Objection Handler, END00195234. See also the ENDOSell Coaching Reports where PSRs were instructed to "not get caught up in Oxy abuse discussions" but rather sell Opana ER. (ENDO_FLAG-00241099)

231. Endo trained PSRs to respond to physician concerns using a technique known as Clarify, Respond, Confirm, and Transition (CRCT).[409] This, and other methods, taught PSRs to address concerns about abuse with statements that verbally agree with concerns, reframe the issue, and refocus (distract) the prescriber with messages such as: "Doctor, can I discuss a few key advantages and benefits that OPANA® ER (oxymorphone) may offer those in need of an opioid for moderate to severe pain?" Further, Endo taught PSRs that "objections" are "opportunities."[410]

232. Aggressive sales techniques are not appropriate for dangerous prescription medications. At the least, these techniques minimize potential harms; at worst, they dismiss safety issues entirely, providing support for the proposition that Defendants minimized concerns over the use of opioids and their messages focused on benefits and away from harms.

Risk Evaluation and Mitigation Strategies

233. A balanced focus on risk communication should have been seen in the process (creation and dissemination) and content of the RMP and Risk Evaluation and Mitigation Strategies (REMS) developed for long-acting opioids. The data here supports the proposition that Defendants did work collaboratively to create industry-wide REMS,[411]

[409] https://www.amanet.org/training/articles/i-object-four-steps-to-handling-objections.aspx (last accessed July 2, 2021); Jackson (Endo) Deposition, pp.326-329, 332-333; Endo also used other persuasive techniques such as "Engendered Thinking"; Jackson (Endo) Deposition, pp.167-169, 276-277 and Exhibit 16 (ENDO-OPIOID_MDL 02489842), ENDOsell Training Program: Your Custom Guide for Selling Success, p.6.

[410] See, e.g., ENDO-OPIOID_MDL-02489844, Objection Handling Workshop, An objection is an opportunity!

[411] Boothe (Allergan) Deposition, p.402. See also a sales training and development document containing a timeline of the events leading up to the REMS for opioid analgesics, TEVA_FL_00002127 (TEVA_MDL_A_00349300).

but the REMS were viewed by Defendants (discussed below) as ineffective and lacked the kinds of strategies that could lower the risk of harms from opioids.

234. For example, Actavis' Doug Boothe described its REMS program as one that would "educate physicians who were writing the prescriptions for long-acting opioids."[412] In my opinion, the fact that a REMS program was needed indicates that the drugs in question were dangerous, and Defendant's marketing alone was deemed insufficient to protect patients from the existential risks of opioids. REMS were needed to supplement the information Defendants provided through their marketing to ensure safe opioid use.

235. Mr. Barto, an experienced regulatory affairs manager at Endo, expressed the view that the coalition-developed REMS had taken a long time to develop due to many differing views and a lack of consensus. He also indicated he had concerns about how effective the resulting REMS would be and referred to the REMS as "window dressing" with respect to solving the abuse and addiction problems the FDA was trying to address.[413] Mr. Barto also expressed opinions on how to make the REMS more effective, such as implementing a direct-to-the-pubic educational campaign about the dangers of opioids, but this strategy was not incorporated into the REMS that was developed and approved by the coalition. Further, Endo did not support other proposed efforts to address abuse and addiction, such as, for example, patient registries that were expected to reduce opioid sales, proprietary data sharing, and sales force competency assessments.[414]

236. In July of 2011, Cephalon (Teva) received a letter from the FDA informing the company of why it [the FDA] believed a REMS for Fentora was needed: namely, the high off-label

[412] Boothe pp.404-405

[413] Barto (Endo) Deposition, pp.143-185, 241, 243 and Exhibit 31, where Mr. Barto wrote to Tara Chapman, another regulatory affairs colleague, "I agree that the new formulations just push abusers somewhere else. We said this would be the case all along and that this whole REMS effort is just "window dressing."

[414] Barto (Endo) Deposition, pp.304-310 and Barto Deposition Exhibits 9 and 37.

use of Fentora and associated patient deaths. The proposed REMS for Fentora would soon require both the doctor and patient to sign consent forms indicating that these drugs were to be used only for breakthrough pain in opioid-tolerant patients with cancer. Teva's response was to instruct its PSRs, such as Ms. Valerie Kaisen, to take advantage of this "window of opportunity" before the requirement took effect, rather than proactively discuss the REMS issues with Customers. PSRs were instructed not to discuss the REMS unless asked about the REMS.[415] Fair and balanced communication is proactive and doesn't wait for Customers to ask the right questions in order for them to learn about the potential harms of a drug.

237. These examples support the proposition that Defendants' actions related to managing risk (RMPs or REMS) were focused on meeting requirements and protecting sales, but not at reducing risks.

FDA Warning Letters

238. The FDA warning letters to opioid manufacturers also provide direct support for the proposition that Defendants minimized risk information in their marketing. These FDA letters describe the agency's position on certain marketing for MS Contin, Duragesic, Avinza, Fentora, Ultram, Embeda, Kadian, and Nucynta.[416] For example, on February 18,

[415] Kaisen (Teva) Deposition, pp.244-252 and Exhibits 31 (Letter to PSRs) and 32 (July 20 FDA letter to Cephalon).

[416] E.g., November 20, 1996 FDA Warning Letter to Raymond Sackler, President, The Purdue Frederick Company (MS Contin); March 5, 1998 Warning Letter to Jacqueline Brown, Janssen Pharmaceutica (Duragesic); May 11, 2000, FDA Warning Letter to Beth Connelly, R.N., Purdue Pharma L.P. (OxyContin); January 17, 2003 Warning Letter to Michael Freidman, Purdue Pharma L.P., The Purdue Frederick Company (OxyContin); March 24, 2008 Warning Letter to King Pharmaceuticals (Avinza); March 26, 2009 Warning Letter to Carole S. Marchione, Cephalon, Inc. (Fentora and Treanda); May 12, 2009 Warning Letter to Johnson and Johnson (Ultram); February 18, 2010 Warning Letter to Doug Boothe, Actavis US (Kadian); March 15, 2010 Warning Letter to Marci Schentzel, King Pharmaceuticals, Inc. (Embeda); August 26, 2011 Warning Letter to Roxanne McGregor-Beck, Ortho-McNeil-Janssen Pharmaceuticals, Inc. (Nucynta). See also FDA

2010 the FDA wrote to Doug Boothe, Chief Executive Officer at Actavis US (Allergan) about the omission or minimization of serious risks, broadening of indication or failure to state the full indication, and unsubstantiated superiority and effectiveness claims.[417] This letter noted that Kadian sales aids favored benefit over risk information, and therefore the sales aids (Comparison Detailer and Co-Pay Assistance Program brochure) misbranded Kadian. A letter written to Carol Marchione, Senior Director of Regulatory Affairs at Cephalon, noted with respect to Fentora (and Treanda) that Cephalon had omitted risk information and failed to communicate **"any** risk information" [bold included in original]. This letter noted: "For promotional materials to be truthful and non-misleading, they must contain risk information in each part as necessary to qualify any claims made in that part."[418] [419]

239. The examples cited here demonstrating how Defendants and other opioid manufacturers failed to balance benefits and harms are representative of other documents I have reviewed. Sales training materials provided Defendants' PSRs with

communications such as 7/11/2018 FDA letter to Nicola Waters Allergan Sales, LLC Associate Directo of Regulatory Affairs regarding a Kadian sNDA, ALLERGAN_CA_00021905.

[417] FDA 2/18/2010 Warning Letter to Doug Boothe, CEO, Actavis US, ALLERGAN_MDL_00638086 (Leitch MDL Exhibit 8).

[418] FDA March 26, 2009 letter to Cephalon regarding Fentora and Treanda.

[419] In addition to warning letters there were also other communication from the FDA pointing out deficiencies in labeling, actions and communications (i.e., communication of misleading information, overstatements, or minimization of risks, off-label use, the Actiq RMP) such as: the FDA letter to Ms. Parker, Senior Manager of Regulatory Affairs at Cephalon, TEVA_MDL_A_00267691; the June 27, 2005 FDA response to the supplemental new drug application dated November 22, 2004 proposing changes to the Actiq RMP, TEVA_MDL_A_01583458; FDA response letter and minutes of the August 30, 2004 meeting of Cephalon and DDMAC (now called OPDP), where DDMAC "expressed significant concerns," TEVA_MDL_A_01584978; 6/29/2004 letter to Carol Marchione in advance of the planned July meeting with the FDA (July 14, 2004), TEVA_MDL_A_03317918; FDA Discipline Review Letter, 8/29/2006, TEVA_MDL_A_08399245; FDA letter to Penny Levin, Director of Regulatory Affairs regarding the sNDA dated November 9, 2007 for Fentora; Faxed letter to Carole Marchione on March 26, 2009 regarding Fentora and Treanda, TEVA_MDL_A_06378821.

effective sales skills; however, the share of voice[420] between benefits and harms was skewed toward benefits. Most of the documents I reviewed provided little or no information on the risks of opioids. When this information was included, it was with respect to how to minimize objections to opioid use.

240. Dr. Russell Portenoy framed this phenomenon, a focus on the benefits and not the harms, with respect to opioid manufacturers as "for understandable reasons, [opioid manufacturers] would take the positives, distill out the positives for their messaging."[421] He went on to explain:

> I think the - - I think that the purpose of doing that was to improve the sales of their drug. And in order - - and obviously to the extent that physicians were given a sense of assurance that the risks were not significant, the drug would do better in the marketplace.
>
> So that there was that overarching consideration, I think, in the way that the pharmaceutical industry decided to market its products, to speak about the benefits that people like myself were writing about without providing the context related to risk and the caution in selecting the right patient, because the message was more likely to lead to marketing advantage if they did not include the negatives.

241. Defendants' aggressive marketing of their bias towards the benefits of using opioids would be expected to encourage Customers to also downplay opioid risks and prescribe more opioids. The data points and analysis here support the proposition that benefits were favored over harms in Defendants' communications with Customers.[422]

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[420] Share of voice is a term of art that describes the degree to which a company's messages dominate the conversation in a market, competitive category or subject.

[421] Portenoy Oklahoma Deposition, 1/24/2019, pp.166-167.

[422] Dr. Russell Portenoy, a key contributor to marketer driven opioid paradigm shift, believes that unbalanced communications from opioid manufacturers and their vendors encouraged opioid prescribing. (Declaration, Russell K. Portenoy, M.D., 12/13/2018, PLTF_2804_000003809 and Spencer email PLTF_2804_000003808)

242. Certainly, the opioid catastrophe we are experiencing also lends support to this proposition. The manipulation of information, lack of communication of harms, and overpromotion of opioids in the marketplace to encourage sales of dangerous drugs was, in my opinion, deceptive (e.g., untrue, false or misleading) and would be expected to lead to the exact outcome that we are experiencing today: a marketer-made catastrophe caused by increased use of and supply of opioids.[423]

Defendants' Marketing Messages

243. Using the proven marketing techniques described in this Report, the overarching goal of Defendants' marketing was to remove barriers to prescribing opioids and move opioid prescribers from trial to adoption, rapidly and durably, to maximize sales. To accomplish these goals, Defendants, and other opioid manufacturers, needed to increase awareness of their drugs and overcome barriers related to prescribing opioids, including:[424]

- Redefining who will be treated with opioids.
- Destigmatizing opioid use.
- Convincing prescribers, payers, and other Customers that pain should be treated with opioids first.
- Convincing stakeholders that opioids are less risky, have less abuse potential, and fewer side effects than existing perceptions dictate.

244. Defendants utilized specific marketing messages to accomplish the goals of increasing awareness of their opioids, and removing barriers to opioid use. Defendants'

[423] E.g.,Day (Teva) Deposition, p.252; Spokane (Teva) Deposition, pp.255-256; Shusterman (Endo) Deposition, p.389.

[424] E.g., the relevant sections (competitive landscape, SWOT analyses, etc.) of marketing plans cited in this Report such as ACTIQ 2002 Marketing Plan, Pyfer (Teva) Deposition Exhibit 18 (TEVA_MDL_A_00454816).

messaging[425] can be generally grouped into three (not mutually exclusive) general themes that worked together to create the new positioning of opioids in Customers' minds, namely:

- ***Dependence, tolerance, addiction, and withdrawal should not be a concern in prescribing opioids.*** This included messages such as, for example, patients taking opioids for pain do not become addicted; extended release (e.g., every 12-hour dosing) formulations prevent peaks and valleys, which in turn prevents euphoria and addiction; extended release formulations are hard to abuse, so there is less danger in prescribing them; tolerance is not a concern because doses can be increased without limit; withdrawal/physical dependence is not a problem because patients can easily be tapered off opioids.
- ***Opioids are effective for, and improve functioning in, patients taking them for long-term and chronic use.*** This theme includes the expansion of the indication for patients who require opioid therapy for "more than a few days" into "chronic use" as well as the claim that there is evidence of improved functioning in patients taking opioids for chronic pain.

[425] Table 2: Defendants' Marketing Messages provides a sampling of messages, not an exhaustive list of messages. It must also be noted that Table 2 includes only messages from Defendants, and not all messages communicated by other opioid manufacturers. This is an important consideration because of the spillover effects that exist in the marketplace from other opioid manufacturers' marketing. Other opioid manufacturers focused on the same themes as presented in Table 2. With respect to generics that utilized primarily price, access or quality in their marketing, branded messaging was integral to the creation of the market and success of a generic product offering. Therefore, even generic opioid manufacturers benefited from the spillover created by branded product messages communicated in the marketplace.

- ***Opioids should be first-line therapy for pain.*** Using knowledge of their products and Customers, Defendants turned product features into product benefits by transforming the first two themes into a third: pain should be treated with opioids first. The rationale for this was clear. If dependence, tolerance, addiction, and withdrawal are not concerning, and if opioids make the pain patient's life better, why not start with opioids? This theme also included the comparative messages that other drugs to treat pain, namely NSAIDS, are dangerous to use.

Using these three themes, Defendants' marketing changed how prescribers viewed and effectively repositioned these drugs in Customers' minds.

Theme One: Dependence, tolerance, addiction, and withdrawal should not be a concern in prescribing opioids.

245. Historically, one of the barriers to opioid prescribing has been the potential for, and fear of, addiction. Since the early 1990s, numerous marketing messages used by Defendants communicated information that supported a change in the paradigm regarding the link between addiction and opioids.[426] [427] Other marketing messages claimed patients with legitimate pain cannot become addicted because their pain protects against

[426] See Table 2: Defendants' Marketing Messages. Table 2 is organized by the topic or theme of the marketing message. It should be noted that the categories may not be mutually exclusive.

[427] Sales personnel were trained on how to handle objections to multiple issues including concerns over addiction. E.g., Objection Handling Workshop, ENDO-OPIOID_MDL-02489844; Taking Aim at Objections, Combunox, ALLERGAN_MDL_03502668; Managers Meeting 2007, Sales Training, TEVA_MDL_A_00358559 (focus on managed care); Fentora Training, TEVA_MDL_A_00359511; Taking Aim at Objections, Combunox, ALLERGAN_MDL_03502668; Revopan™ Workshop, December 9, 2010, ENDO_FLAG-00106120; ENDO-OPIOID_MDL-00367321; Delivering the Difference, ENDO_GAAG-00116317.

addiction.[428] Defendants also taught Customers that when the signs of addiction are present, it is just a symptom of undertreated pain or "pseudoaddiction," and the "solution" to pseudoaddiction is to prescribe higher doses of opioids.[429]

246. Fears were also minimized through Defendants' marketing communications that indicated problems like addiction occur only when opioids are abused or used illegally,[430] and if opioids are taken as prescribed, the risk of addiction is rare.[431] Defendants further downplayed addiction by carefully defining the terms "tolerance" and "pseudo-tolerance" to justify marketing the highest doses of opioids to patients.[432] According to Defendants' messaging, each of these conditions has a common solution: taking higher doses of opioids.

247. Defendants also minimized addiction in patient materials, attacked mainstream thinking about dependence, claiming that patients can easily be tapered off opioids,[433] claimed that dependence is not a significant concern,[434] and taught prescribers that even patients at high risk of addiction (including drug abusers and addicts) can be treated with opioids if appropriately monitored.[435]

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[428] Table 2: Defendants' Marketing Messages, e.g., Part D.

[429] Table 2: Defendants' Marketing Messages, e.g., Part E.

[430] Table 2: Defendants' Marketing Messages, e.g., Part F.

[431] Table 2: Defendants' Marketing Messages, e.g., Parts A, C, D, E, F and H; Objection Handling Workshop, ALLERGAN_MDL_00405512.

[432] Table 2: Defendants' Marketing Messages, e.g., Parts D, E, I, and J.

[433] Table 2: Defendants' Marketing Messages, e.g., Part I.

[434] Table 2: Defendants' Marketing Messages, Part J.

[435] Table 2: Defendants' Marketing Messages, Part K. See also e.g., advocacy materials supported by opioid manufacturers such as PKY183043997 a consensus statement from the American Academy of Pain Medicine and the American Pain Society), which states, "Furthermore, experience has shown that known addicts can benefit from the carefully supervised, judicious use of opioids for the treatment of pain due to cancer, surgery, or recurrent painful illnesses such as sickle cell disease." In pharmacy, it is understood that this use of opioids may be appropriate in some patients with these conditions. Yet, this document also suggests that "commonly held assumptions [regarding addiction] need modification," including

248. Allergan marketing messaging also sought to minimize concerns over addiction, tolerance, and dependence through claims that extended-release and every 12-hour dosage opioids reduced the risk of addiction while providing around-the-clock analgesia.[436] [437] Defendants used this type of messaging to differentiate their newer formulations from older, competing drugs with the same active ingredients. For example, Fentora[438] (fentanyl buccal tablets, transmucosal immediate release fentanyl or "TIRF") was introduced with claims to solve two opioid concerns: (1) the addiction risks of opioids such as OxyContin; and (2) "Breakthrough Pain."[439]

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the common "misunderstanding" of addiction and mislabeling of patients as addicts which the authors believe results in unnecessary withholding of opioids, citing "studies indicate that the de novo development of addiction when opioids are used for the relief of pain is low" and challenges respiratory depression, tolerance and diversion.

[436] See Table 2: Defendants' Marketing Messages, e.g., Part A.

[437] With respect to the formulations of Duragesic, Janssen sought to differentiate its product by claiming its "reservoir" technology was superior to the competition's "matrix" transdermal delivery technology because it was harder to abuse and had lower "street" value. This was the marketing message until Janssen switched to the same matrix technology in about 2008 and initiated studies to suggest there is not data to support any difference between reservoir and matrix formulations. The economic and marketing reasons to change the Duragesic formulation seemed to outweigh concerns over abuse. Further, this example demonstrated that new formulations were not different. JAN-MS-02410536, 2010 email with subject FW: DURAGESIC – FDA teleconference – meeting summary (70% more residual fentanyl in the matrix patch compared to reservoir); JAN-MS-00280657, 2009 email chain with subject RE: Duragesic – Field voice mail, "I would STRONGLY encourage no proactive communication by the field as I believe it would create a compliance/regulatory issue. I remember if the field mentions DURAGESIC as a CII drug…they have to present an updated PI for compliance and it could lead to what has changed in the PI vs. the old. Plus it could create a question as to our 2004 position on matrix vs. today. A key DURAGESIC prescriber could surface all the issues above."; JAN-MS-02108736, Vorsanger 2006 email with subject RE: Abuse data, "Are there antioxidants in Duragesic? :)," "Very interesting – anyone for tea?"

[438] E.g., the 2009 Fentora Brand Plan, TEVA_MDL_A_02031609; 2010 Brand Plan, TEVA_MDL_A_00363031; Marketing Plan 2007, Fentora, TEVA_MDL_A_00364495 (TEVA_FL_0037198); Fentora Marketing 2008, TEVA_MDL_A_00375244; Fentora 2011 Brand Plan, TEVA_MDL_A_00556008 (see also TEVA_MDL_A_01184456, TEVA_FL_00014109); Fentora Brand Plan 2008, TEVA_MDL_A_00361434.

[439] TEVA_MDL_A_00730456 (third-party, paid study essentially creating "BTP"); see also TEVA_MDL_A_00369565.

249. Other messages included claims that extended-release drugs had fewer peaks and valleys in absorption and elimination, with less highs and lows, and therefore less chance of addiction and abuse, and that abuse deterrent formulations reduce abuse and are safer than non-deterrent formulations.[440] [441]

Theme Two: Opioids are effective for, and improve functioning in, patients taking them for long-term and chronic use.

250. In addition to minimizing concerns over dependence, tolerance, addiction, and withdrawal, Defendants' marketing messages also sought to communicate that for those in pain, opioids can make life better. Communicating messages to Customers like "[g]ive your patients the freedom of a life uninterrupted by chronic pain,"[442] Defendants' sought to change the belief that using opioids results in a decline in functioning (a barrier to opioid use).

251. Allergan's messaging sought to change the belief that using opioids results in a decline in functioning (a barrier to opioid use). The Kadian Learning System states: "Although the effect of the therapy in reducing the patient's pain is of primary importance, the improvement in the patient's ability to function is considered the gold standard of chronic pain treatment."[443]

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[440] E.g., Kadian 2011 National Sales Meeting, "Putting it all together," ALLERGAN_MDL_00010637; Actiq 2002 Marketing plan, TEVA_CHI_00042831; February 2013 Kadian sales training presentation, ALLERGAN_MDL_00001525; September 13, 2012 Kadian Marketing Update, ALLERGAN_MDL_00072907; Objection Handling Workshop, inVentiv Health, Kadian, July 2010, ALLERGAN_MDL_00405512; ENDO-CHI_LIT-00550036.

[441] Regarding fewer peaks and valleys in the dose response curve, it should be noted that while there is a theoretical advantage to this feature, I have not seen evidence to support claims that fewer peaks and valleys results in less abuse or better analgesia.

[442] JAN-MS-00306286, Life Uninterrupted, Duragesic CII. "Now I have the freedom to worry less about my chronic pain." See also JAN-MS-02757583, Game, uninterrupted, 106 shots….and counting (information for the pharmacist).

[443] E.g., ALLERGAN_MDL 01610520, (Kadian Learning System attached to this Jennifer Altier email). See also ALLERGAN_MDL_00436784, Kadian Learning System.

252. This was evidenced in the Opana platform as well, with the tagline, "Opana ER protects me from pain for a full 12 hours so I can go about my daily activities,"[444] and other Opana ER documents stating:

> Maximum improvement in functionality, consistent pain relief and the best tolerability profile in its class. Enables patients to function better throughout the day, sleep well through the night, and achieve the QoL they desire, with minimal cognitive and other side effects.[445]

253. Part of Endo's marketing targeted veterans[446] through the Veterans Administration (VA)[447] and focused on using opioids for all types of pain with a rationale that quality of life as a patient outcome is a reason to consider opioid therapy. Some examples include:

- An Opana ER branded slide set on Managing Chronic Osteoarthritis Pain where elderly patients are targeted for opioid therapy: "All patients with moderate to severe pain, pain-related functional impairment or diminished quality of life due to pain should be considered for opioid therapy."[448]
- An Endo project brief for an Opioid Patient Brochure highlights "Reasons to Believe" and lists "Good for constant pain no matter the cause."[449]

[444] ENDO-OPIOID_MDL-02150882, Module 3, Opana Risk Management Program, 2006 Endo Pharmaceuticals.

[445] EPI001100502, Opana ER Strategic Platform, Chronic Pain, September 2012.

[446] Cephalon was also interested in communications aimed at military veterans. See, e.g., email from Stacey Beckhardt, Associate Director of Product Communications related to the APF Treatment Options Guidebook to Soldiers and Family Members, TEVA_MDL_A_01090493; TEVA_MDL_A_06610742, Exit Wounds.

[447] ENDO-OPIOID_MDL-00988846.

[448] Opana ER For the Management of Chronic Osteoarthritis (OA) Pain, ENDO-OPIOID-MDL-00919968.

[449] Creative/Project Brief, Project Name: Opioid Patient Brochure, ENDO-OPIOID_MDL-00475419.

254. With respect to the question of improved functioning resulting from pain treatment, Kadian's marketing was the subject of an FDA warning letter to Actavis (Allergan) in February of 2010.[450] The FDA wrote: "The Copay Assistance Program brochure and Comparison Detailer are false and misleading because they omit and minimize the serious risks associated with the drug, broaden and fail to present the limitations to the approved indication of the drug, and present unsubstantiated superiority and effectiveness claims." The FDA explained its rationale with respect to specific elements in the Copay Assistance Program marketing piece:

> The above claims [those enumerated in the FDA letter contained in the marketing piece] and presentations misleadingly imply that Kadian has been shown to be superior to MS Contin or generic controlled-release morphine because Kadian's pharmacokinetic properties will lead to less breakthrough pain and more consistent pain relief.

Further,

> The FDA is not aware of any substantial evidence or substantial clinical experience that support these claims and presentations.

Actavis complied with the FDA by engaging a contracted sales force to deliver corrective messages[451] to counterbalance the false and misleading information in its Copay Assistance Program brochure.[452] The corrective messages appeared to have little or no impact on sales,[453] which suggests little change in the product's position in the minds of prescribers. Actavis' (Allergan) experience in this instance makes sense because

[450] FDA 2/18/2010 Warning Letter to Doug Boothe, CEO, Actavis US, ALLERGAN_MDL_00638086 (Leitch MDL Exhibit 8).

[451] A 3-4-page brochure to be displayed in prescribers' offices. (Hepp (Allergan) California Deposition, p.46) See also Corrective Message Training, ALLERGAN_MDL_01051295; Actavis letter response to the FDA (DDMAC) March 4, 2010, ALLERGAN_MDL_01237697. See also testimony of Ms. Altier, Altier (Allergan) Deposition, pp.84-94; Leitch (Allergan) Deposition, pp.164-175; Nataline (Allergan) Deposition, pp.103-123.

[452] Hepp (Allergan) California Deposition, pp.44-47, 112-114.

[453] Hepp (Allergan) California Deposition, pp.161-162 and Hepp Deposition Exhibit 10, Natalie Leitch 2/2/2011 email.

marketing principles confirm that once a position for a product has been created in a Customer's mind, this position is not easy to change.[454]

255. As noted in Table 2: Defendants' Marketing Messages, other opioid marketing messages included, for example:

- Defendants' opioids improve function and will make your life better without risk.[455]
- Opioids have no maximum dose. If you are in pain, more opioids can be given without additional risk ("titrate to effect").[456]

256. In at least some of the opioid marketing, there did not appear to be any boundaries as to who would be targeted with opioid messaging. In a Janssen presentation related to the "Imagine the Possibilities Pain Coalition," Janssen lays out comprehensive plans to reach out to several target groups including youth, advocating to "[r]each early: elementary school level; via respected channels, e.g., coaches" to deliver a "practical message" that "[p]ain is your body telling you something important."[457] Janssen also focused on messages encouraging the use of opioids for all types of pain, with the rationale that quality of life as a patient outcome is a reason to consider opioid therapy.

[454] Consider the discussion *supra* of the durability of attitude formation and information processing, and the discussion of corrective measures in advertising. At the least, corrective advertising needs to be monitored, and from the data available so far in this case Actavis gathered signatures to demonstrate corrective materials were delivered but did not assess the impact of the corrective messaging.

[455] E.g., Actiq 2002 Marketing plan, TEVA_CHI_00042826, p.27; Table 2: Defendants' Marketing Messages.

[456] See, e.g., "doctor, there is no established ceiling dose for Nucynta ER." (Note, Janssen did follow this statement here with a recommendation not to exceed 500 mg doses) Nucynta ER Frequently Asked Questions, JAN-MS-00016372, p.8; Table 2: Defendants' Marketing Messages.

[457] JAN-MS-02057431, Imagine the Possibilities Pain Coalition, reaching out to youth; Vorsanger (Janssen) Deposition, Vol.2, pp.673-675 and Vorsanger Deposition Exhibit 23.

For example, Janssen promoted opioid use for any condition with the line, "Consider for all patients with moderate to severe non-cancer pain, but weigh the influences."[458]

Theme Three: Opioids should be first-line therapy for pain.

257. Communicating the message that treating pain patients with opioids first, giving these analgesics preference over other standard pain management regimens, provided Defendants a means to increase overall use of opioids and expand the market for these drugs. Defendants' key marketing messages associated with this theme (Table 2: Defendants' Marketing Messages) include messages such as "[Actiq] will encourage pure opioid therapy at a much earlier point in treatment than the WHO ladder currently recommends."[459]

258. In addition to promoting the need to treat pain, Teva created a market for "Breakthrough Pain (BTP)." BTP was important in expanding overall demand for opioids because it provided a new Customer need that could be met with opioids. It was a key message that could benefit sales of drugs designed to treat BTP or drugs claiming to minimize the occurrence of BTP.[460] In fact, the 2002 marketing plan for Actiq stated that Actiq marketing would center on several goals, including: "[e]stablish a solid public relations campaign to begin raising awareness of BTP and ACTIQ among targeted patient populations."[461]

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[458] JAN-MS-00653426 p.19, Chronic Pain: Prevalence and Impact.

[459] TEVA_CHI_00042826, p.24, Actiq 2002 Marketing plan.

[460] E.g., TEVA_MDL_A_00454816, Actiq Marketing Plan; Breakthrough pain Misunderstood, Actiq 2002 Marketing plan, TEVA_CHI_00042826 p.6; TEVA_MDL_A_01496786, 2008 Pain Care Franchise, 2008 Expense Budget; TEVA_CHI_00004938, OralVescent Fentanyl, Managed Markets Pre-Launch & Launch Plan;

[461] Pyfer (Teva) Deposition Exhibit 18, 2002 Actiq Marketing Plan, p.5. By this time, Cephalon would now be the third owner of Actiq, previously owned by Abbott and Anesta. See also e.g., Stacey Beckhardt 12/18/2006 email, TEVA_MDL_A_07417449.

259. Defendants also worked to change existing thinking about opioids as first line therapy for pain by asserting other marketing messages, including:

- Undertreated pain should be treated with opioids.[462]
- There is more risk of leaving pain untreated than using opioids to treat pain.[463]
- Opioids offer more effective pain control and are safer than alternatives.[464]

260. As detailed in Table 2, Defendants' marketing messages were aimed at shifting Customers' thinking regarding the use of opioids for the treatment of pain. This change in the prescribing paradigm included seeking to treat more pain patients with opioids first. This is a good example of marketing messages and themes that would have the effect of expanding the market for opioids, not just capturing market share.

D. Defendants' Marketing Violated Industry Standards

261. One of the research questions for this case study was to assess the degree to which Defendants' marketing may have violated pharmaceutical industry marketing standards. In my opinions, there are six standards from which pharmaceutical marketers should not deviate, if these marketers put patient safety first. Given that there are industry standards for all products that are established by marketing principles, including pharmaceutical products, it is evident that pharmaceutical marketers should adhere to additional standards when compared to other products because of the nature of pharmaceuticals.[465] These standards are not laws, rules or regulations determined by

[462] Table 2: Defendants' Marketing Messages.

[463] Table 2: Defendants' Marketing Messages.

[464] E.g., Your guide to better days and nights," (Avinza) END00014041-58; See also Table 2: Defendants' Marketing Messages.

[465] In some respects, the marketing of prescription medications may be viewed in a similar manner as tobacco or alcohol, which are also held to different standards than other consumer goods for their advertising.

the State or other entity, but rather a set of propositions related to marketing conduct, for which there is no disagreement.[466] Specifically:

- Pharmaceutical marketers should support and promote the safe use of medicines, putting patient safety before profit.
- Pharmaceutical marketing must always be truthful. A pharmaceutical marketer must never mislead the medical community, other stakeholders, or the public.
- Pharmaceutical marketers must always accurately disclose information about the risks of their product, in addition to the benefits being marketed, in a fair and balanced manner.
- Pharmaceutical marketing efforts should not be disguised as science or education.
- Pharmaceutical marketing should be based on good science to provide an unbiased, non-commercial basis for the use of medication.
- Pharmaceutical marketers should be transparent about who or what they financially support.

262. To assess Defendants' adherence to these industry standards it was necessary to draw conclusions about the marketing messages. I was asked to assume that the plaintiff's expert Reports rendered in this case would hold that the common messages delivered by the Defendants' marketing were untrue, false, misleading, inaccurate, or designed to misstate the risks and benefits of Defendants' opioids. Making this assumption was consistent with the case study methodology applied in this analysis. After making this assumption, I have since reviewed other expert Reports in the MDL and have seen the

[466] *Supra*, Opinion 4, and Sections 1B (1-3), Why Pharmaceutical Marketing has a Heightened Standard, Concerns with Opioid Marketing, and Standards that apply to Pharmaceutical Marketing. These standards were assembled from published works and statements of numerous pharmaceutical industry stakeholders world-wide.

conclusions of experts (i.e., Kessler, Ballantyne, Lembke[467] and Schumacher) who assessed the nature of the marketing messages, and that confirm the original assumption. Having reviewed these reports, and agreeing with their content based upon my professional skill and training, no further assumption was necessary.[468]

263. Further, I have always held the independent opinion that the assumption regarding the nature of Defendants' marketing was consistent with data points in this analysis (e.g., the FDA warning letters cited in this Report), the pharmacology of opioids, and my experience as a Customer of the pharmaceutical industry. Finally, based on my own analysis of Defendants' marketing, the data confirm that Defendants' marketing carried a bias toward benefits over harms. This provides independent support for the proposition that their marketing was untrue, false, misleading, and/or deceptive.

264. The delivery of untrue, false, misleading, and/or deceptive information to the medical community, and the marketing methods used to disseminate this information, violates pharmaceutical industry standards. Further, in marketing, when part of a company's message is untrue, false, misleading, and/or deceptive, its entire marketing program is tainted and has the likelihood of deceiving customers. This is because the goal of marketing is to create a product-position, or perception, in customers minds that will

[467] Dr. Lembke evaluated each category of Defendants' marketing messages and provided the opinions that Defendants promoted numerous misconceptions concerning opioid use. These include, but are not limited to: overstatement of benefits of long-term use for chronic pain, making inaccurate understatements of the risks of addiction to opioids, inaccurate claims as to the levels to which doses can be safely increased, mischaracterizing addictive behavior as "pseudoaddiction" and tolerance as "breakthrough pain," claiming addiction is easily reversible, and generally making misleading marketing claims to promote the misconceptions. (Expert Report of Anna Lembke, M.D. March 25, 2019, MDL No. 2804)

[468] I note that the assumption regarding the truthfulness of the marketing messages was only necessary for the opinion related to adherence to pharmaceutical industry standards.

change their behavior.[469] This "position" is based on the sum total of the integrated marketing messages delivered to Customers through the various channels of communication, not any one message.[470]

265. Moreover, the very foundation of Defendants' opioid marketing was built on a positioning strategy that required untrue, false, misleading, and/or deceptive messages to be promulgated for the new product positioning to succeed. Defendants' challenge in creating this new position (perception) in Customers' minds was to convince prescribers to stop thinking of opioids as dangerous drugs that should be reserved for use under limited circumstances and begin thinking of opioids first and favorably.[471] This new position in Customers' minds is exactly what Defendants' marketing sought and accomplished. Defendants' marketing plans detail the strategies and tactics Defendants utilized to create the messaging designed to ensure the success of Defendants' product positioning strategy.[472] These carefully crafted messages all worked in synergy to ensure Defendants' success in changing the way Customers thought about opioids.

266. Defendants' violation of pharmaceutical marketing standards also included the misuse of influencers such as KOLs, and professional (advocacy) organizations that Defendants funded and influenced to deliver their false and misleading messages. Defendants were not forthcoming about their support of these people and activities and Defendants' influence over the opinions and conclusions drawn by advocacy. Concealing their

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[469] According to Kotler (*supra,* pp.191-201), "[a] person's buying choices are further influenced by four major psychological factors: *motivation; perception; learning; and beliefs and attitudes."* Defendants' marketing messages attempted to influence each of these factors. (Section III)

[470] Product positioning is discussed *supra,* Section I, A4.

[471] Marketers refer to this as creating "top of mind awareness" – to be thought of "first and favorably."

[472] See Schedule 6: Defendants' Marketing Plans and other citations to marketing plans in this Report and Section III, Defendants' Marketing Messages.

support of these influencers gave Defendants' messages more credibility with the medical community and the public, creating perceptions of unbiased, and more scientific, information. This played into Defendants' strategy to reposition opioids by downplaying or minimizing the risks of these drugs while emphasizing the benefits.

267. Defendants' use of advocacy groups to further their marketing efforts supports the proposition that these behaviors were designed to, and to a reasonable degree of certainty did, mislead, or deceive Customers about the impartiality of the messages and about the safe use of opioids. Therefore, this analysis must conclude that the nature of Defendants' untrue, false, misleading, and/or deceptive marketing violated pharmaceutical industry standards.[473] In my opinion, Defendants' marketing methods and themes are not consistent with the safe and effective use of opioids.

E. Marketing Messages Over Time

268. Defendants' marketing messages over time retained the three major themes identified above. These messages downplayed the health and safety risks of opioids and communicated false and misleading messages to Customers.[474] The messaging used around the time of OxyContin's introduction to the marketplace established in Customers' minds a new way of thinking about prescribing opioids.[475] Along with other messages, Purdue taught the medical community that new science showed the risk of addiction in patients taking opioids was less than 1% (before 2007), low or rare (pre- and post-2007),[476] and repositioned opioids in the medical community as safer to use.

[473] See, *supra*, Section 1B (3), Standards that Apply to Pharmaceutical Marketing.

[474] See, *supra*, paragraphs 226-227 and notes 479-483; notes 373, 374. (Purdue/Cephalon 2007 & 2008 settlements and plea agreements.)

[475] In marketing, the new paradigms are related to the marketing constructs: perceptions, beliefs, attitudes, and intentions.

[476] Mr. Cramer said in his deposition with respect to OxyContin, "once any reference to the risk of addiction was removed [from FDA approved labeling], we never referred to it again." (Cramer (Purdue) Deposition, p.245.) From a marketing perspective, beliefs, attitudes, and

Creating this new opioid paradigm expanded the use of opioids, attracted new competition, and laid the foundation for a distortion in opioid demand that would last for nearly two decades.

269. The spillover effects of Purdue's early marketing benefited Purdue and each company (branded and generic) that marketed opioids. The marketing of each opioid manufacturer was intertwined with its competition and as a whole, Defendants and other opioid manufacturers, promulgated marketing messages that encouraged prescribers to set aside existing views of abuse and addiction, to use opioids earlier in the course of treating pain and for more types of pain, and at higher doses to improve patient function - all without concern for potential harms.

270. By about 2007, Defendants' own marketing planning and metrics revealed concerns about opioid use were emerging in the marketplace. Defendants' marketing, after years of aggressively laying the foundation for opioid use and maintenance of opioid demand, would have to respond to stakeholders' re-emerging concerns about opioids.[477] These concerns would stimulate the development of tamper resistant / abuse deterrent dosage forms. Additionally, patent expirations led to more generic competition that also shifted market dynamics as Customers became more price sensitive. However, the impact of the early marketing that was so effective in shifting prescribers' paradigms about opioids, would be durable and resistant to change.[478]

271. The aggressive marketing practices and overpromotion employed by Defendants created the new opioid paradigm that resulted in blockbuster sales and created a

intentions, once created, are durable in Customers' minds. Purdue's marketing would therefore be expected to have lasting impact.

[477] In addition to general media reports from this period, Defendants' marketing plans noted that negative media attention to opioids was growing. See, e.g., 2005 Actiq Marketing Plan, Marchione (Teva) Deposition Exhibit 16.

[478] It is understood in marketing that customer beliefs, attitudes, and intentions are relatively durable and once created, difficult to change.

durable demand for opioids. Marketing principles teach us that two decades of Defendants' marketing aimed at this paradigm shift will take time and effort to correct.[479] [480] Finally, I have not seen evidence to support the proposition that

[479] E.g., Katz D. Attitude Measurement as a Method in Social Psychology. Social Forces, 15(4):479-482; Lutz R. Changing Brand Attitudes Through Modification of Cognitive Structure. Journal of Consumer Research, March 1975; 1:49-59; Krugman HE. The Impact of Television Advertising: Learning without Involvement. The Public Opinion Quarterly. 29(3):349-356; Petty RE, Cacioppo JT and Schumann D. Central and Peripheral Routes to Advertising Effectiveness: The Moderating Role of Involvement. Journal of Consumer Research, September 1983; (10):135-146; *Consumer behavior: buying, having and being*. Michael R Solomon. Upper Saddle River, NJ.: Pearson Prentice Hall c2009; Blackwell R, Miniard P and Engel R. *Consumer Behavior*, Ohio: Thomson Learning, 2001. My own research involving the attitude construct is documented in my CV. E.g., Rollins B, Ramakrishnan S and Perri M. An Experimental Examination of Consumer Attitudes, Behavioral Intentions and Information Search Behavior After Viewing A Predictive Genetic Test Direct-to-Consumer Advertisement. International Journal of Pharmaceutical and Health Care Marketing. 2013; 7(3): 285-295; Shinde S, Knut A, Hagtvet, Slaughter E, and Perri M, Modeling the Mediation of Consumer Involvement between DTC Ads and Consumer Attitudes. Business and Health Administration Proceedings, DP Paul III and RS Curtis (Eds) 2002:261-268; Wolfgang AP and Perri M. Older Adults and Generic Drugs: An Analysis of Attitudes and Intentions, Journal of Pharmaceutical Marketing and Management 1990; 5:97-106; Carroll NV, Wolfgang AP, Kotzan JA., and Perri M. Consumer-Attitudes and Actions Toward Generic Drugs. Journal of Pharmaceutical Marketing and Management 1988; 2:87-99; Perri M. and Dickson WM. Consumer and Physician Attitudes Toward Direct-to-Consumer Advertising. Journal of Pharmaceutical Marketing and Management 1987; 2:3-25.

[480] E.g., Pharmaceutical Marketing, Ch. 2, Rollins, B.L. & Perri, M. (eds.) (2013), p.244. Consider also, exposure to advertising leads to increased awareness of products but may not generate product trial or adoption. Defendants' marketing acknowledged that there were attitudinal barriers to opioid prescribing that needed to be overcome for its products to be successful. The information processing model (Figure 2) provides insight into the durability of Defendants' messages, including the early messages crafted by Purdue. Initially, Purdue's marketing focused on both increasing awareness of its products and changing attitudes (a composite of beliefs, feelings, and intentions) with respect to the barriers to opioid prescribing. By examining the Information Processing Model (Figure 2) we can develop an understanding of how Purdue's two-pronged strategy (increasing awareness and changing attitudes) created more durable prescribing habits. First, information processing describes how external stimuli are encoded into memory, where product information is available for use in the decision-making process. However, when barriers to product use are present, trial and adoption will be limited and changes in attitudes (external influences, Figure 2) are required to overcome barriers. In marketing, attitudes toward a product (or a company) are formed more easily than they are

Defendants' marketing ever sought to correct the false perceptions of opioids created early on that resulted in the dramatic expansion of the opioid market.

F. Defendants' Marketing Was Effective

272. By minimizing concerns over opioid use with these key messages, opioid manufacturers including Defendants', marketing nationally and in the state of Florida, effectively deconstructed the barriers associated with opioids for the treatment of pain. Many marketing documents identified concerns over opioid use as just a barrier to be overcome through marketing and not as a public health concern.[481] After reviewing thousands of marketing documents, including those applicable to Florida, describing Defendants' marketing planning and execution spanning more than 20 years, it is my opinion that Defendants' approach to marketing opioids was purposeful, pervasive, aggressive, and effective in increasing sales. The marketing outcomes, assessed through Defendants' own internal metrics,[482] support the fact that the Defendants were able to persuade prescribers and other stakeholders to increase the use of opioids for treating pain.

273. The impact of marketing efforts can be assessed by examining sales or by how well specific marketing goals were met. Defendants' marketing plans and metrics reveal many such goals and confirm that opioid marketing resulted in sales. In the pharmaceutical market, sales are measured through dollar sales figures or by proxy

changed. Further, attitudes can be formed and changed even when product claims are not true. There is an extensive body of literature devoted to attitude formation and change.

[481] E.g., JAN-MS-00478579, "Prevent abuse issues from impacting performance of DURAGESIC." 2002 Duragesic Business Update.

[482] Defendants' marketing metrics document the effectiveness of their marketing and continued spending on marketing efforts. See, e.g., Schedule 6: Defendants' Marketing Plans, and Schedule 10: Evaluation of Marketing Impact by Defendants.

variables such as the numbers of prescriptions written for a drug (TRx), the numbers of "new" prescriptions (NRx), and changes in dose/strength over time, or market share.[483]

274. For example, Janssen's Duragesic demonstrated high year-over-year growth averaging almost 31% a year between 1996 and 2002. With sales on track for a yearly total of $692 million in 2002, the company had a vision for $1 billion in sales by 2004 and $2 billion by 2008. These sales figures led Janssen to conclude that Duragesic's product life cycle was still in the growth phase nearly 10 years into its marketing. Most products are in the maturity or decline phases of the product life cycle this far past their introduction.[484] However, due to generic competition, Duragesic sales expectations began to slip after about 2003, but the business plans mapped strategies to continue the brand's success.[485]

275. However, marketing success is relative: not all products achieve the same levels of utilization. For some products, minimizing expected loss of sales, or gaining only small increases in TRx or market share could be viewed as success. For example, Actavis experienced difficulties with its marketing of Kadian and studied ways to increase its share of the long-acting opioid market.[486] While Kadian never achieved blockbuster sales levels, its marketing created loyal customers that persisted in writing Kadian prescriptions even after marketing for this drug ceased. Kadian marketing also slowed its decline, until Actavis stopped marketing the product entirely.

[483] Schedule 6: Defendants' Marketing Plans (where Defendants identify the metrics that will be used to assess goal achievement), and Schedule 10: Evaluation of Marketing Impact by Defendants.

[484] Duragesic 2002 Business Update, JAN-MS-00478579.

[485] Duragesic Business Update, 2004, JAN-MS-00479441.

[486] Kadian LAO Decision-Making Process, Altier (Allergan) Deposition Exhibits 17 &18.

Pharmaceutical Marketing Metrics

276. Knowing if marketing is achieving the desired goals is important to all marketers. In pharmaceutical marketing there are many goals and associated metrics. For example, sales figures are indicators of success in reaching marketing goals and may also be used to monitor corporate goals and even individual (e.g., PSR) performance.

277. Based on established metrics, marketers can assess the overall effectiveness of their marketing (e.g., how many customers are we reaching, how often, etc.), specific advertisements and tactics, or an individual, group, or region by looking at performance over time.[487] [488]

278. Strategies and tactics can be tested using common metrics (e.g., TRx, NRx, customer satisfaction) before and after an asset is deployed, messages are communicated, or programs are implemented.[489] For example, in the May 2012 Fentora Brand Review,

[487] A relevant metric for a sales professional might be the number of prescriptions (TRx) or the number of "new" prescriptions (NRx) stimulated in a geographic area or for a specified period. See also e.g., Passion Per-4-Mance Impact presentation by Cephalon where various metrics are followed including sales performance of PSRs to goal, TEVA_FL_00019183.

[488] Janssen's Behavioral Insights to Optimize Marketing Mix (BIOMM) project mapped the interactions of health care professionals related to Nucynta. This detailed tool provided Defendants with a way to access and analyze data from which marketing decisions could be made. It provided data for marketing mix decisions, feedback to the marketing process and tracking of results. It was defined as a visualization tool that enabled brand teams to view activity across all sales & marketing channels, and TRx, coordinated across multiple stakeholders. See, e.g., JAN-MS-00288318; JAN-MS-00288433; JAN-MS-00430026; JAN-MS-00657666; JAN-MS-00658637; JAN-MS-00658637; JAN-MS-00659608; JAN-MS-00659609; JAN-MS-00659610; JAN-MS-00767409; JAN-MS-01062329; JAN-MS-01062330; JAN-MS-01063280; JAN-MS-01067464; JAN-MS-01098312; JAN-MS-01099325; JAN-MS-01099421; JAN-MS-01099423; JAN-MS-01100057; JAN-MS-01100061; JAN-MS-01100867; JAN-MS-01100868.

[489] See generally, the marketing plans cited throughout this Report which contain reference to planned metrics and Schedule 10: Evaluation of Marketing Impact by Defendants; TEVA_MDL_A_11575042; TEVA_MDL_A_11575560 TIRF; TEVA_MDL_A_11577231, CNS and Pain Care General Business Session (Managers Meeting); TEVA_MDL_A_12517315; TEVA_MDL_A_08714297. See also documents such as TEVA_MDL_A_01317332, CNS Weekly

various metrics were monitored, including one related to the new Fentora RX Savings Card. In this document, Teva tracked TRx and noted a substantial increase following the implementation of the new savings card.[490] Defendants used these metrics, and others, to monitor the impact of their marketing and to adjust their efforts to help ensure that marketing goals were met.[491]

279. A good example of the variety of metrics used by Defendants was seen in the Kadian patient adherence program. This program, which was conducted by Actavis between August 2009 and May of 2010, involved sending an average of three letters to Kadian patients and tracking results. The letters included information designed to encourage patient-prescriber discussions of their pain treatment.[492]

280. Marketing metrics are also useful to track and document marketing activities so that resources can be applied to the most productive assets.[493] In the case of the Kadian adherence program above, the measured and relatively low impact of the program likely led to the decision to discontinue it after only a few months. However, this action does provide support for the proposition that marketers used their metrics to evaluate, and modify marketing plans moving forward.

281. Other marketing initiatives such as, but not limited to, promotional and non-promotional CME programs, lunch and dinner meetings, presentations at professional

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Sales File email; weekly sales data spreadsheet, TEVA_MDL_A_01317334; ENDO-NMAG-00233037.

[490] 2012 Fentora Brand Review, TEVA_MDL_A_00763828.

[491] E.g., Jackson (Endo) Deposition, pp.215-217, 221, 234-235; Bearer (Teva) Deposition, pp.350-369; Boothe (Allergan) Deposition, e.g., pp.48, 140, 148, 166; Boyer (Teva) Deposition, pp.51-54, 190, 244-251;

[492] Snyder (Allergan) Deposition Exhibit 3; Leitch (Allergan) Deposition pp.53-54; 2014 Performance Management Report, Day Matthew M, TEVA_MDL_A_08802273.

[493] E.g, ALLERGAN_MDL_01742612; ALLERGAN_MDL_00450169; Kadian Patient Persistency and In-Class Case Study, 5.27.2009, Adheris, in inVentiv health company, ALLERGAN_MDL_00450170.

or scientific meetings, journal ads, journal articles, distribution of marketing materials (leave behind articles, leaflets, brochures, prescriber tools, patient aids, etc.), contacts with pharmacies, PBMs, formulary decision makers, TPPs, electronic communications, website access, and technology (DVDs, etc.) were created for use nationally, including in Florida, and were tracked to assess their impact. These metrics provide important feedback to marketers for monitoring and evaluation of their marketing efforts.

282. The data provided by marketing metrics seen in the marketing plans (e.g., TRx or NRx, LRx, product switching, restarting, new prescriptions, refill prescriptions, or location of service such as long-term care, hospital or community, mail order) are very detailed for example, breaking down TRx or NRx to the prescriber or zip code level.[494] [495] These metrics are used to benchmark performance and are also useful in identifying potential market growth or opportunities.

283. The use of prescriber-identifiable data (i.e., IQVIA) permits manufacturers to precisely monitor and improve the effectiveness of their marketing by evaluating and compensating PSRs based on their individual results.[496] [497]

284. In addition to sales metrics, Defendants also tracked data for other business outcomes and processes. For example, in a July 12, 2004 letter Carol Marchione wrote to Dr.

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[494] E.g., TEVA_MDL_A_00700492, prescriber visits/prescription tracking spreadsheet; PPLPC029000182401, IMS, Fueling New Growth Opportunities for the Pharmaceutical Industry, 2006; PPLP004001344; PPLPC019000906695, EOT Update, p.3.

[495] Sales Force Metrics, PPLPC029000132250 p.15. Sometimes metrics are also reported in the aggregate, such as in the Fentora Executive Committee Presentation, October 19, 2009, TEVA_MDL_00008516.

[496] Kesselheim AS, Mello MM, Studdert DM. Strategies and practices in off-label marketing of pharmaceuticals: a retrospective analysis of whistleblower complaints. PLoS Medicine 2011; 8(4):e1000431.

[497] The capture of accurate prescribing data is important to pharmaceutical marketers as was seen in the efforts of Mr. Spokane who investigated why Dr. Steven Chun in Florida was not appearing in prescriber reports from IMS (now IQVIA) even though Dr. Chun was one of the "highest" volume prescribers of Fentora in Florida. (TEVA_MDL_A_00399726)

Rappaport at the FDA about the off-label use of Actiq and the Actiq RMP.[498] This RMP required Cephalon to notify physicians by letter and subsequent visits by a PSR about Actiq's indication whenever Cephalon learned that a practitioner was prescribing Actiq outside of its labeled use. However, Ms. Marchione explained, when "sales representatives learn of off-label use by a physician they are required to remind the physician of the product's indication. We do not track the number of representatives that learn of a physician prescribing off-label." In my opinion, a company adhering to pharmaceutical marketing standards, i.e., putting patient safety first, would track this metric for a potentially dangerous drug like Actiq with a very narrow indication. Given the enormous level of Actiq's off-label use, Cephalon's PSRs would likely have been inundated by the need to "remind the physician of the product's indication," potentially explaining why Cephalon did not track this metric. The marketing implications of physician reminders for specialties that were not legitimate Actiq targets are significant: it opened the door for Cephalon PSRs to visit these prescribers more liberally, ostensibly to provide the indication reminder.

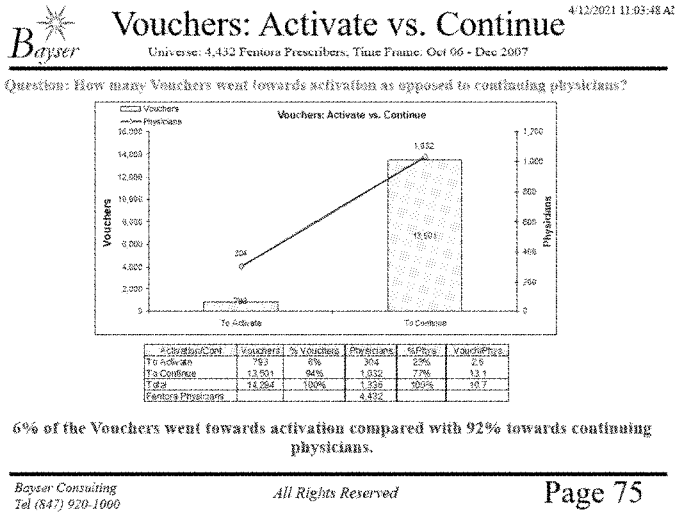
285. Return on Investment (ROI) is also used to determine the relative value of competing marketing strategies and tactics.[499] For example, with the help of the vendor Bayser, Teva examined the relative contributions of many of its integrated marketing activities, including detailing activity, e-detailing, the use of prescription vouchers and educational programs for its Fentora product.[500] From this detailed analysis, Teva could draw

[498] TEVA_MDL_A_01575259, July 12, 2004 letter to Dr. Rappaport at the FDA. (Also at TEVA_MDL_A_01575251)

[499] E.g., JAN-MS-00309600, Strike Force Sales Rep Alignment: Feasibility analysis from ROI Perspective; JAN-MS-00315375, Duragesic Coupon ROI Analysis.

[500] E.g., Promotional Response of Fentora, Findings, TEVA_MDL_A_01543547. See also marketing plans or sales training documents where information on the integration of various marketing activities was presented, e.g., 2003 Actiq Sales Training, TEVA_MDL_A_05304016, 2003 Core Tactics, Strategically Addressing Key Issues; FEBT Launch Playbook, Steering

conclusions about the most cost-effective ways to "activate" and "continue" its Customers. (See example data in the insert below)[501]



Vouchers: Activate vs. Continue

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Universe: 4,432 Fentora Prescribers. Time Frame: Oct 06 - Dec 2007

Question: How many Vouchers went towards activation as opposed to continuing physicians?

Activation/Cont	Vouchers	% Vouchers	Physicians	%Phys	Vouchers/Phys
To Activate	793	6%	304	23%	2.6
To Continue	13,501	94%	1,032	77%	13.1
Total	14,294	100%	1,336	100%	10.7
Fentora Physicians			4,432		

6% of the Vouchers went towards activation compared with 92% towards continuing physicians.

Bayser Consulting
Tel (847) 920-1000

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286. Janssen utilized a coupon program for Duragesic that was used nationally and in Florida which provided five, three-day patches, or one-half a month of therapy for free. In fact, according to a Janssen National District Ranking, the Miami, Florida district was among the top nationally (number 18) for distribution and redemption of the Duragesic coupons.[502] However, the coupon program provides insights into Janssen's marketing beyond ROI assessment. For Janssen, positioning the coupons to generate a free trial is a way for patients to sample the product, where "sampling" is not permitted. Sampling has been a longstanding and successful method of generating prescription trial for

Committee Presentation, May 18, 2006, TEVA_MDL_A_00365382; FEBT 2005-2006 Marketing Plan, TEVA_FL_00017308.

[501] Promotional Response of Fentora, Findings, TEVA_MDL_A_01543547.

[502] Janssen Pharmaceutica Duragesic National District Ranking for Duragesic coupons. (JAN-MS-02971159)

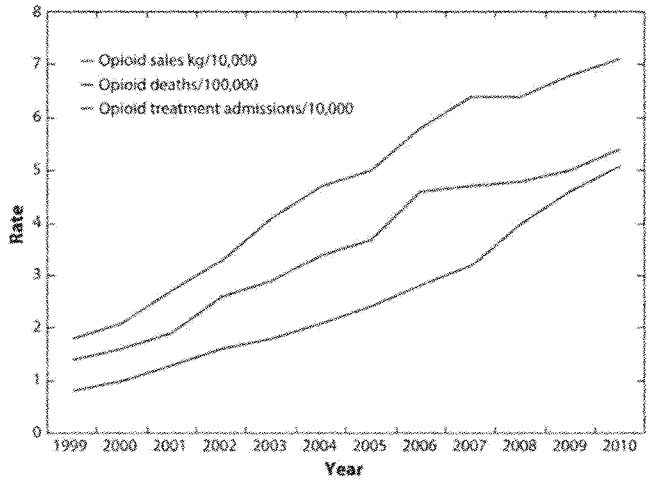
pharmaceutical products aimed at both capturing market share and expanding total sales, even though by law, scheduled opioids may not be sampled.

287. However, marketers also use other less quantitative metrics such as "return on objective" or ROO. ROO is best suited to assessing the results of work with, for example, advocacy groups where achievement of an objective is the outcome desired. While alliance building, peer-to-peer relationships, customer engagement, and support of advocacy are all marketing activities and important to sales, the success of these activities (e.g., on goodwill, customer loyalty) cannot be fully measured though sales.

288. When marketing plans are carefully developed and implemented, evaluated using the proper metrics, and revised and adjusted as needed, sales personnel will be successful in winning sales.[503] Based on the metrics I have seen in Defendants' marketing plans and other documents, there is substantial support for the proposition that opioid marketing, in the state of Florida, increased the size of the opioid market, expanded sales, and increased the use of opioids. Figure 4 shows how this increased use correlates with opioid overdose deaths and substance abuse treatment admissions.

[503] Hepp (Allergan) California Deposition, p.133.

Figure 4: Opioid Sales, Overdose Deaths and Substance Abuse Treatment Admissions 1999-2010[504]



289. The efforts and resources devoted to opioid marketing were designed to change prescribers and other stakeholders' perceptions about opioids. Given the association between opioid utilization and patient outcomes, including increased analgesia, side effects, diversion, overdose, and death,[505] it is my opinion, Defendants expanded

[504] Vital Signs: Overdoses of Prescription Opioid Pain Relievers—United States, 1999-2008," *MMWR: Morbidity and Mortality Weekly Report* 60 (November 4, 2011), 1487-1492, Figure 2, updated by Andrew Kolodny et al., "The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction," *Annual Review of Public Health* 36; (2015): 559-574, Figure 1.

[505] Hadland S, Rivera—Aguirre A, Marshall B, and Cerda M. Association of Pharmaceutical Industry Marketing of Opioid Products with Mortality from Opioid-Related Overdoses. JAMA Network Open. 2019; 2(1)e186007; Spokane (Teva) Deposition Exhibit 43, National Vital Statistics System, Drug Enforcement Administration, Prescription Opioid Sales and Deaths, 1999-2013 (TEVA_FL_00002133); Khan 8/24/2015 email with subject "CI News – Opioid Use Disorder – The Continued Rise of Opioid Abuse and Misuse," TEVA_FL_00012328; See also, RiskMap document JAN-MS-01057540 where Janssen notes, "Despite the regulatory controls that are in place to prevent the misuse, abuse, and diversion of Schedule II drugs, data show that as the number of prescriptions for opioid drugs increases, so does the frequency of misuse, abuse, overdose, and drug-related fatalities."

demand for opioids, and substantially contributed to the opioid catastrophe in the United States, including in Florida.[506]

G. Generic Drug Marketing

The Market for Generics

290. Brand name pharmaceutical manufacturers market single-source medications and have exclusive rights to market their patented drugs until patents expire or products are licensed to other companies. The stakeholders in the market for generics are the same as those for branded drugs. (Figure 5) Before patent expiration, brand manufacturers extensively advertise and promote their drugs to prescribers, PBMs, TPPs, and others to increase overall demand and market share for their products. When manufacturers are effective in creating demand for a drug this benefits the branded medication and creates opportunities for future generic entry to the market.[507] Branded advertising before generic introduction is both a benefit and threat to generic manufacturers: branded advertising can expand the market and create loyalty for branded products, thereby making it harder for generics to gain sales once patents have expired.

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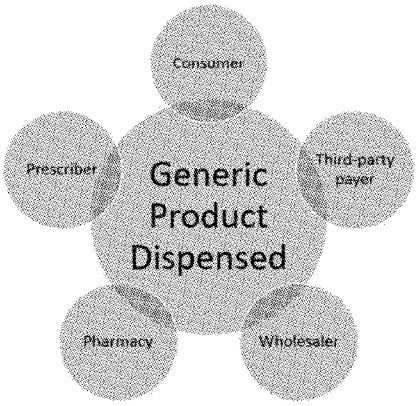
[506] I considered the alternative explanation that increased awareness of the need to treat pain was a driver of more opioid use. However, the data revealed that Defendants' marketing communicated this message to Customers by creating the mindset that pain is the "fifth vital sign." This theme was integral to Defendants' marketing especially with respect to involvement with pain advocacy organizations. When considered in the context of other messages aimed at using opioids in more types of pain patients, earlier in the treatment process, at higher doses, and for longer periods of time, the alternative explanation was rejected.

[507] Kappe, Pharmaceutical Lifecycle Extension Strategies, Chapter 8, pp.225-254, in Ding et al. (eds.), *Innovation and Marketing in the Pharmaceutical Industry.* International Series in Quantitative Marketing 20, DOI:10.1007/978-1-4614-7801-0_24, © Springer Science+Business Media New York 2014. See also, Grabowski HG, and Kyle M. Generic Competition and Market Exclusivity Periods in Pharmaceuticals. Managerial and Decision Economics. 2007; 28: 491-502; Saha A, et al. Generic Competition in the US Pharmaceutical Industry. International Journal of Economics of Business. 2006; (13) 1:15-38; Scott Morton, FM. Barriers to entry, brand advertising, and generic entry in the US pharmaceutical industry. International Journal of Industrial Organization. 2000; 18:1085-1104.

Figure 5: Generic Market Stakeholders



291. Generics are almost always cheaper than their branded counterparts. The competition that results from generic entry typically results in prices about 85% less than the brand name drug.[508] Recognizing the potential for cost savings, PBMs, TPPs, and consumers alike have contributed to the extensive use of generic opioids in the U.S. In fact, Chris Meyer, Senior Manager of Sales Operations at Cephalon, noted in 2004 that the generic portion of the pure short acting opioids represented 82% of the market nationally.[509]

292. Generic manufacturers produce drugs that are chemically identical and bioequivalent[510] (same active ingredient and same processing within the body) to the respective brand-name medication and must meet all FDA and industry manufacturing standards (including all current good manufacturing practices (cGMPs)). However, generic

[508]www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/genericdrugs/ucm167991.htm (last accessed February 18, 2019).

[509] Meyer 12/13/2004 email to Sales Directors, TEVA_MDL_A_00024254.

[510] Pharmaceutical Marketing, Ch. 2, Rollins, BL & Perri, M. (eds.) (2013).

manufacturers do not have to conduct safety or efficacy studies needed for the new drug approval process.

293. Generic manufacturers seek markets for medications with higher pre-patent-loss revenues,[511] higher hospital sales, and drugs for chronic diseases because these markets offer high potential for profits.[512] The key variables generic manufacturers consider when deciding to enter a new generic market include demand and commercial potential, other market dynamics,[513] technical manufacturing issues,[514] manufacturing costs, supply chain considerations, clinical risk of the drug, competition, and the regulatory landscape including any lingering patent (intellectual property) issues, such as patent extensions or legal challenges to generic production.[515]

294. The potential for sales, which is to a degree dependent on brand-name sales revenue,[516] is typically the primary driver of the "go-no-go" decision to enter a generic market.

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[511] Higher sales could be a result of increased advertising spending by brand manufacturers before patent loss or due to other characteristics of the drug, such as it being a significant improvement over previous therapy.

[512] Scott-Morton F. Barriers to Entry, Brand Advertising, and Generic Entry in the US Pharmaceutical Industry. International J of Industrial Organization 2000; 18:1085-1104; Reiffen D and Ward ME. Generic Drug Industry Dynamics. Review of Economics and Statistics 2005; 87:37-49.

[513] In marketing, careful assessment of the external environment is critical: this includes, for example, analyzing strengths, weaknesses, opportunities and threats, social, legal or regulatory issues. A good example of this is how access to controlled substances is more restrictive than most other drugs, representing a potential limitation in the market that should be considered in the decision to enter a market.

[514] Some medications are technically more difficult to produce and a manufacturer that has special skills with these more difficult drugs might have a competitive advantage over other producers. Quality control considerations may present challenges for medications that are more technically difficult to produce.

[515] A good example of market entry planning and decision-making can be seen in the Actavis Pipeline Committee Meeting, October 19, 2011, Acquired_Actavis_00895387 at pp.2-7, 67-70.

[516] See, e.g., Reiffen D and Ward ME. Generic Drug Industry Dynamics. Review of Economics and Statistics 2005; 87:37-49; Fiona M Scott-Morton. Entry decisions in the generic pharmaceutical industry. RAND Journal of Economics 1999; 30(3):421-440; Frank R. G. and D. S. Salkever (1997) "Generic Entry and the Pricing of Pharmaceuticals," Journal of Economics and

Generic manufacturers carefully evaluate where resources should be focused and balance multiple inputs when deciding to enter a new market. The goal of the generic manufacturer is to maximize ROI.[517] Successful generic manufacturers have a strategic focus, carefully evaluate risks, and maximize ROI by carefully managing their product portfolio.[518] [519] These considerations are optimized as generic manufacturers leverage their strengths to gain competitive advantages and sell products.

295. In the prescription opioid market, the market for branded drugs expanded quickly after the introduction of OxyContin in 1996, making the opioid market attractive for future generic entry. In some cases, to maximize sales, branded manufacturers marketed both branded and generic products.[520] The growth in opioid use, resulting from the marketing efforts of brand-name opioid manufacturers (including Defendants), resulted in dramatically higher opioid sales and higher profit potential for generic entrants. For example, in 2011, oxycodone tablets and fentanyl patches were the number one and number two products for Actavis with over $100,000 million in sales and net sales

Management Strategy, Vol. 6, pp.75–90; Iizuka T. Generic Entry in a Regulated Pharmaceutical Market. Jap Economic Review 2009; 60(1):63-81.

[517] In addition to the ROI, the financial criteria generally used to measure project success include internal rate of return, cash flow, and payback period. E.g., Actavis, Marketing Department Overview, Allergan-Myers-028, Acquired_Actavis_01367234.

[518] See, e.g., Suchak K and Murray LJ. Generic portfolio management: A paradigm for minimizing risk and maximizing value. J of Generic Medicines 2017; 13(2):60-63.

[519] A product portfolio for a pharmaceutical manufacturer is the full scope of products manufactured by a company. These products are managed by selecting those with the best strategic fit for the company, optimizing the mix of products to draw on company and market opportunities and to continuously monitor the portfolio for possible changes over time. This process is commonly referred to as portfolio management. E.g., Boyer (Teva) Deposition Exhibit 20, US Generics: New Product Launch Opportunities. March 25, 2017; Boyer (Teva) Deposition Exhibit 23, Operations Planning Summit, June 2, 2015.

[520] For example, Purdue/Rhodes, Allergan/Actavis, or Teva/Cephalon.

growth of 55% and 39% respectively.[521] These factors supported the "go" business decision for generic manufacturers to enter and stay in the opioid market.

Defendants' Generic Drug Marketing

296. Pharmaceutical companies who sell generic drugs, like their branded counterparts, are sophisticated in their use of data and knowledge of the prescription market. These companies analyze their own capabilities, supply, and demand for products, and the expectation of profitability upon market entry.[522]

297. Entry into any generic market is ultimately based on the potential for drug sales and profitability. When considering entry into a generic opioid market, the prototypical "go-no-go" market decision, manufacturers of generic opioids consider key factors, such as:

- The marketing associated with the branded drugs that increased the demand for these drugs, making the category more attractive from a sales potential. In fact, in some cases generics were being sold to replace a branded drug by the same manufacturer.
- The nature of the drugs, e.g., efficacy, black box warnings, side effects, and their addiction and abuse potential.
- The complex and therefore more expensive distribution process in the supply chain at the wholesale and retail levels due to the Schedule II narcotic status.
- The need to continually reevaluate generic sales as market dynamics (e.g., prices, competition, regulations, market demand, product

[521] "Realizing our vision," Building a Global Leader in Generic Pharmaceuticals, February 2012, authored by Actavis VP of Sales and Marketing, Michael Perfetto and its Marketing Director, Jinping McCormick. (Boothe (Allergan) Deposition Exhibit 15, and pp.251-255)

[522] E.g., "Realizing our vision," Building a Global Leader in Generic Pharmaceuticals, February 2012, authored by Actavis VP of Sales and Marketing, Michael Perfetto and its Marketing Director, Jinping McCormick. (Boothe (Allergan) Deposition Exhibit 15, and pp.251-255)

perceptions) change. In my opinion, Defendants manufacturing generics would have periodically reevaluated all market dynamics, including the national attention focused on abuse, addiction, and death from opioids in its decision to sell generic opioids.

298. Generic marketers thoroughly analyze the market before entry to ensure profit potential and a fit between the company and the markets selected for entry. The "go" decision, based on detailed analysis of all salient market entry criteria, implies these manufacturers possessed and viewed favorably the information on the market dynamics including positive and negative consequences (e.g., dependence, tolerance, addiction, withdrawal, abuse, diversion, or death) related to their decisions. The marketing analysis of the go-no-go decision and marketing plans noted in this case study support the proposition that Defendants' pre-market analysis led to a "go" decision to market generic opioids.[523]

299. Defendants carefully assessed and analyzed the generic opioid market before entry to optimize their portfolios and maximize profits.[524] Yet, each manufacturer of generics

[523] The "go-no-go" decision and the product portfolio mix is continually monitored by manufacturers of generics as they consider their product portfolios. E.g., Boyer (Teva) Deposition Exhibit 10, Teva Global Generic Medicines. Boyer (Teva) Deposition Exhibit 11, US Generics Market Review 2016; Boyer (Teva) Deposition Exhibit 13, Doug Sommerville 12/5/16 email; TEVA_MDL_A_02974065.

In addition to Defendants' ongoing internal analysis and metrics, market dynamics related to generic drugs are the subject of news reports. See, e.g., Lumpkin and Hancock, February 7, 2019. Trump Administration Salutes Parade of Generic Drug Approvals, But Hundreds Aren't for Sale. https://khn.org/news/trump-administration-salutes-parade-of-generic-drug-approvals-but-hundreds-arent-for-sale/ (last accessed February 9, 2019).

[524] E.g., Pipeline Committee Meeting, 29 August 2012, Acquired_Actavis_02380481; Pipeline Committee Meeting, June 20, 2012, Acquired_Actavis_00459602; Pipeline Committee Meeting November 23, 2011, ALLERGAN_MDL_00185492; Boothe February 10, 2010 email ALLERGAN_MDL_01748522; Pipeline Committee Meeting, 27 February 2013, Acquired_Actavis_02605441; generic market analysis, ALLERGAN_MDL_03722181; TEVA_MDL_A_12517315; TEVA_MDL_A_12644206, S&OP Review; Boyer (Teva) Deposition Exhibit 7, Marketing Department Overview, ACTAVIS0321896 (TEVA_FL_00032394).

still decided to enter the opioid market. A decision to enter the generic opioid market meant that profit potential outweighed any barriers or potential negative aspects of market entry, including any concerns over the risks – or ramifications - of selling opioids. Generic opioid manufacturing defendants entered the market with a focus on harnessing the potential for profits based on high demand for opioids created by the aggressive marketing of brand-name opioids and the distorted, increased demand for these drugs.

300. For generic medications, the marketing process is different than, but in some cases dependent on, branded drug marketing.[525] Manufacturers of generic opioids primarily target pharmacies and wholesale distributors to generate sales but may also target TPPs or PBMs when formulary access is a concern.[526] For generics, the chemical entity selected by the prescriber is usually available from multiple manufacturers who are all competing for market share.[527] While prescribers still choose the medication to use, it is the pharmacy provider, sometimes working in concert with, and subject to, the desires of wholesalers, TPPs or PBMs, who typically selects the manufacturer that will supply the generic medication. Consequently, companies manufacturing generic pharmaceuticals typically focus their promotional marketing efforts on pharmacy providers (e.g., retail-chain pharmacies or mail-order pharmacies) and wholesalers.[528]

[525] Branded drug marketing creates sales for a medication. When patents expire, generic manufacturers take advantage of the opportunities created by brands, before generic entry. More aggressive brand advertising can lead to more attractive generic markets. This too is a type of spillover effect.

[526] E.g., "Realizing our vision," Building a Global Leader in Generic Pharmaceuticals, February 2012, authored by Actavis VP of Sales and Marketing, Michael Perfetto and its Marketing Director, Jinping McCormick. (Boothe (Allergan) Deposition Exhibit 15, and pp.251-255)

[527] For example, generic Lipitor® – atorvastatin – might be available from generic manufacturers Ranbaxy, Teva, and Mylan.

[528] E.g., Boyer (Teva) Deposition Exhibit 6, US Generics, Operations Leadership Team Meeting, October 15, 2014; Boyer (Teva) Deposition Exhibit 15, David Myers 3/27/2013 email regarding promotional programs and target customers.

The key marketing messages are focused on competitive prices and the assurance of a consistent supply (availability) of quality generic medications.[529] [530]

301. Unbranded marketing may also increase sales of generic medications. For example, in 2014 and 2015 Teva conducted an unbranded initiative called "Pain Matters" that ran as a documentary on the Discovery Channel, on the internet, and at pain management conferences.[531] Teva's 2015 budget for the Pain Matters campaign was approximately $1 million, and Teva carefully tracked the results.[532] The Pain Matters campaign focused on the use of opioids for chronic pain with messages such as: "At Teva Pharmaceuticals, we understand that chronic pain affects more than 100 million Americans. . . Prescription opioid medications are an important part of a treatment plan for people living with chronic pain."[533] Teva executives acknowledge that the Pain Matters campaign was a promotional program that was not tied to any of Teva's branded

[529] E.g., Stevenson (Endo) Deposition, pp.92-96; Snyder (Allergan) California PMK Deposition written responses, p.5; Boyer (Teva) Deposition Exhibit 4; Boyer (Teva) Deposition Exhibit 16, Buprenorphine & Naloxone Shared Marketing Plan Summary.

[530] Brand name manufacturers also market to pharmacies for the purpose of ensuring product availability, cost (e.g., provision of copay cards, vouchers, etc.) and to provide medical information.

[531] See documents related to the Pain Matters website, e.g., TEVA_FL_0013520; TEVA_FL_00013521; TEVA_MDL_A_00765424; TEVA_MDL_A_00765360; TEVA_MDL_A_00765491; TEVA_MDL_A_00765493; TEVA_MDL_A_00765634 (Podcast, Dr. Brennan); TEVA_MDL_A_00765638; TEVA_MDL_A_00765639; TEVA_MDL_A_00765780; TEVA_MDL_A_00765944; TEVA_MDL_A_00766164; TEVA_MDL_A_00765014; TEVA_MDL_A_00765015, Multimedia news release, draft; TEVA_MDL_A_00765017; TEVA_MDL_A_00765058 (formatted for mobile devices); TEVA_MDL_A_00765104 (1 page promotion of the Pain Matters unbranded effort, delineating the components of the program including healthcare professional resources, pain perspectives (e.g., experts), patient experiences, and patient resources; TEVA_MDL_A_00765105, American Pain Society Annual Meeting screening of Pain Matters; TEVA_MDL_A_00765108.

[532] Day (Teva) Deposition, pp.229-233, and Exhibit 24 (Teva_MDL_A_08657218).

[533] Day (Teva) Deposition Exhibit 26, Pain Matters | Information & Resources for Chronic Pain. This resource also includes information about "Rx Abuse" related to pain.

opioids but, instead, was run while Teva was manufacturing and distributing only generic opioids.[534] [535]

302. Teva also planned to reach out to patients directly who had received the brand Suboxone (buprenorphine/naloxone) product, presumably to convert these patients to generic products by Teva.[536] Additionally, Teva collected addresses and phone numbers for some 13,000 physicians practicing in Buprenorphine Physician Treatment Centers and State Agencies, presumably for use in contacting these Customers.[537] However, I was not able to determine if any of these programs were implemented.

303. Generic marketing is not without clever strategy. Kadian, for example, was marketed by Actavis as a branded drug. When competition (Watson) offered a generic morphine sulfate, Actavis responded with its own authorized generic for Kadian. Keeping the Kadian sales team in place, Actavis sought to maximize its sales by marketing both brand (Kadian) and generic morphine sulfate extended release using an interesting strategy: to position its generic Kadian as an alternative to generic MS Contin rather than its own brand, Kadian. Research had shown (see insert below)[538] that cost was a driving factor for some prescribers, but that in many cases prescribers preferred the features and benefits of Kadian to generic MS Contin. This strategy was designed to increase share of new patients and capture share from generic MS Contin rather than cannibalizing Kadian sales.[539]

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[534] Morreale (Teva) Deposition, p.212.

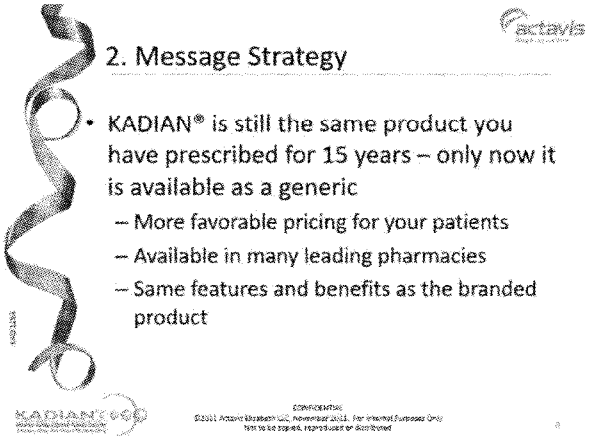
[535] This example demonstrates the use of, and powerful nature of unbranded marketing.

[536] Boyer (Teva) Deposition Exhibit 15, David Myers 3/27/2013 email; Boyer (Teva) Deposition, pp.217-227, and Boyer Deposition Exhibit 17, Boyer 2/17/2013 email.

[537] Boyer (Teva) Deposition Exhibit 18, Buprenorphine Naloxone Address/Phone List.

[538] Acquired_Actavis_00369839

[539] Generic Kadian would be marketed as an alternative to MS Contin and generic MS Contin for price sensitive audiences, with marketing messages focusing on its more favorable pricing and availability.



304. According to it sales training documents, positioning (and differentiating) Kadian and Actavis generic Kadian in this manner was expected to grow total sales for Actavis. Actavis' marketing of its generic Kadian was based on the message that generic Kadian has the "Same features and benefits as the branded product," conveying to Actavis' generic all the messaging associated with Kadian and demonstrating how generic and brand marketing are interrelated.[540]

305. Julie Snyder at Actavis, however, claims the company had no branded marketing messages designed to have any effect on the Actavis Generics Entities' generic business. She further stated that there is no evidence that Actavis ever tracked the effect its promotion of branded Kadian might have had on generic opioid sales. She stated that "given the goal of substitution for other similar opioid pain medications, logic suggests that any promotion of branded Kadian would only decrease prescriptions for

[540] Regional Meetings November 2011, Generic Kadian Sales Team Training, Acquired _Actavis_00369839.

bioequivalent generics." However, Ms. Snyder's position is incorrect. Her views are only reasonable in the limited circumstance of a single prescription encounter when a decision is being made between a brand and generic medication. She does not consider her company's own research on consumer preferences for its products, the overall impact of opioid marketing and spillover effects, or market dynamics related to price and third-party reimbursement. Further, she seems to limit her analysis to the trade-offs between Kadian and the Actavis generic product, ignoring other manufacturers' marketing efforts (spillover effects).[541]

306. In another example of generic marketing savvy, generic manufacturers developed a marketing plan to apply to the generic Suboxone.[542] This plan, also cited above, was designed to benefit the market "[a]s a whole. Because it is designed as a shared program between manufacturers, it does not target specific accounts." This extensive marketing planning document described an "initial blitz" of physicians, pharmacists, and patients, followed by secondary targets including PBMs, KOLs, advocacy and others. The document laid out plans to use national level press releases, "followed swiftly by a mix of independent and customer-sponsored campaigns, and more targeted print media outreach over time." The balance of the plan outlined specific messages, timelines, media, and estimated costs. The use of an industry-wide, detailed plan shows a high degree of marketing skill. While I could not determine the exact origin of this plan, Mr. Boyer at Teva attributed it to Watson or Actavis (Actavis was the current manufacturer of the generic tablet dosage form). He described the plan as a way for generic

[541] (Snyder (Allergan) California PMK Deposition written responses, pp.4-6)

[542] Suboxone was manufactured by Indivior, a former subsidiary of Reckitt Benckiser. Indivior was spun off as a separate entity in about 2014. Federal prosecutors charged Indivior of falsely marketing its film technology as less addictive and safer than other drugs containing its active ingredients. (https://abcnews.go.com/Business/suboxone-maker-reckitt-benckiser-pay-14-billion-largest/story?id=64274260 (last accessed March 25, 2020).

manufacturers to combat the brand company's attempt to evergreen its buprenorphine/naloxone product with the introduction of film technology.[543]

307. However, price sensitivity is usually the most important driver in generic markets. As seen with the Kadian example above, some Customers are more sensitive to the price variable of the marketing mix and may defer purchase, or purchase an alternative product, if the price does not represent a good value. This includes patients without prescription insurance, patients with high copayments or deductibles, patients who are in the Medicare "donut hole" and must pay for prescriptions out-of-pocket, and others.[544] For these customers, making a lower priced generic available will increase access to medications in the market because any price barrier is reduced or removed. Therefore, generics work to expand the market by making available lower priced alternatives that patients can more easily afford. Also, lower priced generic drugs are routinely given preferential formulary status (e.g., automatic coverage, preferred tiers, removal of prior authorization requirements) by third-party prescription plans and PBMs, thus reducing insurance coverage barriers to obtaining these drugs and increasing utilization.

308. Manufacturers of generic opioids increase the supply and contribute to the expansion of the opioid market by manufacturing, distributing and creating awareness amongst Customers of the availability of lower priced generic opioids.[545] [546] These additional

[543] Boyer (Teva) Deposition, pp.228-239 and Boyer Deposition Exhibits 15 (Acquired_Actavis_02290885), 16 (Acquired_Actavis_01178983), 17 (TEVA_MDL_A_12682371), and 18 (TEVA_MDL_A_13470477).

[544] "Others" could include, for example, patients who simply wish to pay cash for their prescription opioid and not work through their prescription insurance.

[545] Market expansion can be seen e.g., in Schedule 13: DEA Production Quotas and Requests; see also e.g., Colleen McGinn 3/10/2015 email, TEVA_MDL_A_01465597.

[546] E.g., Snyder (Allergan) California PMK Deposition Exhibit 32; Snyder (Allergan) California PMK Deposition Exhibits 52, 53, 57, 58, 59, and 60; Jennifer Altier, 10/24/2012 email, ALLERGAN_MDL_01001415.

doses of generic opioids potentiated the opioid catastrophe by providing a lower cost alternative to the more expensive branded opioids. Lower priced opioids meant greater access for most insurance plans (since generics are usually covered in preferential tiers) and for cash paying customers. Greater access due to price implies increased use of opioids further expanding the market. This benefit to cash paying patients is also important because cash payments by patients are considered a clue to potential drug abuse and diversion.[547]

H. Marketing is an Integrated Process

309. In this Report I have described the marketing process of pharmaceutical marketing and the science behind why marketing works, how marketing impacts Customers' decision making, the methods, strategies, tactics, and messages used by Defendants to achieve their marketing goals, and how marketing success was measured by Defendants. Marketing integration was seen in Defendants' strategic approach to coordinating a complex network of goals, decisions, messages, and communication of highly technical information, to a researched, well-defined, and targeted audience, using time-tested tactics and methods through multiple channels of communication.

310. Figure 2 in this Report maps the pathways for how the information provided by pharmaceutical marketing is used in prescribing decision making. This model suggests, and marketing principles confirm, the best, and most impactful marketing would tap into multiple information pathways identified in Figure 2. In the marketing and business documents I saw, Defendants used multiple, well-coordinated strategies, and the associated business tactics, to influence prescribing.

[547] The level of cash payments for prescription opioids is used by wholesalers and drug enforcement personnel as an indicator of potential abuse. However, cash payments must be considered along with data on employment, insurance coverage, and formulary considerations. When a pharmacy has a high proportion of cash payments for opioids it can spark increased scrutiny or investigation.

311. All the marketing plans I reviewed demonstrated this integration of marketing activities. The Fentora Q4 2012 Brand Team Meeting provides a good example of how all the activities that were part of the Fentora brand plan worked together toward achieving Teva's marketing goals. This plan describes how PSR and other channel messaging is customizable to individual target markets, references the "Digital Sales Aid," web based pharmacy finder applications, speaker training, speaker programs, field-based Fentora programming, live and satellite events, on-demand content, assessment of the TIRF REMS program, monitoring of publication plans related to Fentora, presentations at scientific meetings, marketing research, access issues (reimbursement, and presence at pain advocacy conventions.[548] Teva also worked with outside vendors that also ensured the integration of its marketing activities, including for REMS programs that coexisted with other marketing activities.[549]

312. Endo's marketing plans also demonstrated high levels of integration. For example, the Opana ER Tactical Plan, September 2012, describes Opana ER vision, positioning and objectives, along with strategies and how the promotional mix will be used to reach the company's goals.[550]

313. This integrated approach to marketing provided a seamless experience for Customers who were the targets of Defendants' opioid marketing by aligning the messaging delivered through advertising, personal selling, sales promotions, public relations, and branded and unbranded marketing.[551] After reviewing many data points related to

[548] A Brand New Day, Fentora Q4 2012 Brand Team Meeting, TEVA_MDL_A_00881567.

[549] E.g., Fallon Medica LLC, Securing the Future of Fentora: The Launch of the Secure REMS Program in Support of Fentora and Actiq (Cephalon), TEVA_MDL_A_00679308.

[550] Opana ER Tactical Plan, September 2012, ENDO-OPIOID_MDL-00508844.

[551] E.g., the Pain Council 2004, Steering Committee Conference Call (December 11, 2003) where plans for integration of clinical, policy, research and other issues were discussed such as branding chronic pain as a disease and creating public relations activities to support this effort were documented. There are many documents in the record, and cited in this report, that reflect

Defendants' opioid marketing, it is my opinion Defendants' level of marketing integration was impressive, and dramatically increased opioid prescriptions.[552]

314. Marketing principles provide foundational support for the belief that each component (e.g., the message itself, channel of communication, frequency of exposure) of a marketing program works to shape product position in Customers' minds. Durable product positioning results when customers consider *all* the messages disseminated, through all channels or routes of persuasion.[553] [554] Given the extensive nature of Defendants' marketing and the multiple messages delivered (related to the three major marketing themes), an integrated approach to marketing was essential, and was successful in durably changing opioid prescribing paradigms.

315. The sum of all the parts of Defendants' marketing had one key metric: opioid sales in the form of a prescription.[555] The metric "TRx" has significant meaning to opioid marketers because it represented success; proof that the full scope of marketing messages that were disseminated had worked. This metric does not, however, carry with it the impact an opioid prescription can have on the patient who consumes the opioid.

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this strategic, integrated approach to carefully crafting product perceptions in Customers' minds. (JAN-MS-00315240)

[552] This opinion was also expressed about marketing effectiveness in relation to the integration of marketing activities within the Defendant companies as evidenced through their extensive marketing and business communications.

[553] The channels of distribution of Defendants' marketing messages are presented in Section I, Common Marketing Techniques Used to Influence Prescribing.

[554] Haya Taitel describes the integration of messages in the NEO Pathways message platform, referring to this effort as "largest nonbranded market penetration effort in company [Ortho-McNeil] history." Ms. Taitel said in her deposition "They [NEO Pathways messages] were conveyed through peer-to-peer education, and they were conveyed through, later on, rep communication, again, in an unbranded, non-product specific format." (Taitel (Janssen) Deposition, pp.116-119)

[555] See the section above on marketing metrics where Defendants monitored the impact of their marketing efforts on TRx and other metrics.

316. TRx, like marketing, has no conscience and the individual patient is invisible and not considered in TRx. Through their metrics, Defendants' sales data demonstrated that their marketing worked. Yet, hidden inside their carefully crafted messages and the outcomes from their sales was the potential for their drugs to impact the lives of patients. Opioid use means pain will be temporarily relieved for some and that serious harms will emerge for others, including dependence, abuse, addiction, withdrawal, and even death.

IV. ACTIONS NEEDED TO CORRECT THE RESULTS OF AGGRESSIVE OPIOID MARKETING

317. Defendants reached a substantial number of Customers with their inappropriately aggressive, untrue, false, misleading, and/or deceptive marketing of opioids that increased prescriptions (sales) of opioids. As a result, patients have and will likely continue to overuse powerful opioids when other less abuse-prone and non-addictive pain relievers are available.

318. Defendants' marketing was based on incomplete, untrue, false, misleading, and/or deceptive messages that aimed to:

- Expand the definition of who should be treated with opioids.
- Destigmatize opioid use.
- Encourage the use of opioids as first-line therapy for pain.
- Promote the false notion that opioids improve functioning.
- Re-educate prescribers and other stakeholders with the false beliefs that opioids are less risky and have less abuse potential and fewer side effects than previously understood.

319. Defendants used time-tested marketing strategies and techniques to accomplish their marketing goals. The result was a shift in the paradigms in prescribers' minds (specifically, shifts in beliefs, attitudes, and intentions) associated with opioid prescribing. This resulted in a substantial increase in the sales and use of opioids in the

United States. Defendants' aggressive marketing of opioids created a lasting impact on prescribing behavior, and in my opinion, efforts are needed to correct the impact of this marketing.

320. The marketing principles and literature relied upon in this Report support the proposition that pharmaceutical marketing creates prescribing habits that are hard to change. Therefore, efforts aimed at correcting years of Defendants' aggressive and successful marketing of opioids are needed, and could include the following:

- Pharmaceutical companies should do a better job of not only adhering to laws and standards, but in self-regulation.
- As noted above, Defendants' own metrics reveal the success of their opioid marketing. Therefore, there should be only limited marketing of drugs with addictive properties.
- Opioid marketing[556] should not be directed toward consumers. Defendants sought to impact patients' perceptions of opioids and their use. Examples of materials meant for consumers seen in this case encourage drug use by suggesting that nearly all problems can be addressed through medication, fueling the man-made opioid catastrophe. At the very least, DTC marketing should adhere to pharmaceutical marketing standards and be limited to non-product specific, help-seeking ads that generate accurate awareness of disease or possible treatment.[557]

[556] Direct-to-consumer marketing, as noted earlier in this Report, is different than the more limited media advertisements we are familiar with as "direct-to-consumer-advertising."

[557] Non-product specific ads would be ads for a condition, disease, or symptoms without the mention of a drug name. Current FDA regulations do not require "brief summary" or "adequate provision" for non-product specific ads. These are also referred to as help-seeking ads.

- There should be no payments from pharmaceutical companies to physicians who prescribe their drugs. The conflict of interest inherent in this practice is unacceptable because it influences prescribing decisions.
- Corrections to the information disseminated through Defendants' marketing are needed in the marketplace. This could be done in medical education curriculums, and by the re-education of current prescribers through CME or "academic" or "counter detailing." Academic detailing uses individuals such as medical, nursing or pharmacy school faculty, without financial interests in the success of a product and who are therefore not commercially biased, to conduct in-person, educational visits to prescribers. Counter-detailing should focus on correcting misinformation that was disseminated in Defendants' marketing messages, providing scientific evidence rather than commercially biased promotional messages.[558] The content of medical education, or re-education of current prescribers, should focus on communication of unbiased, scientific evidence related to opioids and their use (e.g., unbiased clinical practice guidelines, lower starting doses, use of immediate release products over long-acting opioids, maximum daily MME limits, etc.). A focus on the highest prescribers makes sense because these were the primary targets of Defendants' messages and represent the most opportunity for change.
- Based on the outcome of marketing activities seen in this case, Defendants should refrain from marketing opioids through some additional strategies. Specifically, Defendants should not:

[558] Avorn J. Academic Detailing "Marketing" the Best Evidence to Clinicians. JAMA. 2017; 317(4):361-362.

- Hire prescribers to act as key opinion leaders, to serve on advisory boards, or to become paid promotional speakers due to financial conflict of interest.
- Sponsor non-branded patient or prescriber education through their use of advocacy organizations.
- Distribute vouchers or co-pay cards that circumvent formulary decisions aimed at restricting the use of certain medications, including opioids, by using economic incentives.
- Engage any thought or opinion leadership activities through third parties, including patient or disease advocacy and support groups.
- Sponsor, fund, or create website links to, or distribute materials created by, these third parties that promote or encourage the use of opioids.

V. CONCLUSION

321. Marketing works to sell products. The science behind why marketing works is extensive. In this analysis I have examined, using a case study methodology, the how, why, and the results of Defendants' opioid marketing.

322. The aggressive marketing of opioids by Defendants, including marketing in the state of Florida, using time tested and science-backed strategies resulted in the creation of new medical thinking about pain and its treatment. This new thinking encouraged well-meaning physicians to prescribe more opioids, for more types of pain, sooner, at higher doses, and for longer periods of time, without adequate concerns for possible harms.

323. Through their marketing, Defendants violated pharmaceutical marketing standards by putting profits before patients, creating and disseminating untrue, false, misleading, and/or deceptive marketing messages that downplayed or minimized the risks

associated with opioids, while emphasizing the benefits of their drugs, and by disguising their support of activities aimed at increasing sales of their products.

324. Defendants' deceptive marketing targeted Customers with carefully crafted, well-coordinated messages designed to overcome barriers related to opioid prescribing by focusing on three general themes:

- Dependence, tolerance, addiction, and withdrawal should not be a concern in prescribing opioids.
- Opioids are effective for, and improve functioning in, patients taking them for long-term and chronic use.
- Opioids should be first-line therapy for pain.

325. Each of these themes focused on downplaying or minimizing the negative aspects of Defendants' products and convincing prescribers to use opioids sooner, at higher doses, and for more types of pain. Armed with these deceptive themes, Defendants used a battery of specific marketing messages designed to increase product awareness and systematically remove existing barriers, effectively changing how Customers viewed opioids. Other experts and I evaluated the nature of these messages and provided the opinions that Defendants' marketing messages were untrue, false, misleading, and/or deceptive, or designed to misstate the risks and benefits of Defendants' drugs. I agree with these assessments and further conclude that the pharmacology of opioids, which has not changed since the introduction of these drugs, did not support Defendants' marketing claims.

326. Defendants' marketing activities with influencers such as KOLs, and professional/advocacy organizations gave their messages more credibility because Defendants disguised their funding and influence of these people and groups from the medical community and the public. This created the perception that the information

from these influences was unbiased and more scientific, which mislead Customers about the impartiality and credibility of the messages.

327. The aggressive marketing strategies and tactics Defendants used were effective at gaining market share and durably expanded the overall market for opioids which was confirmed by their own marketing metrics. This led to a dramatic rise in utilization of opioids in the United States, including in the state of Florida. Coordinated efforts will be required to reverse the crisis, including the one in Florida, that has been created by Defendants' marketing of opioids.

VI. SIGNATURE

328. I reserve the right to amend my opinions in this matter considering any new or additional information.

Matthew Perri III BS Pharm, PhD, RPh

July 29, 2021

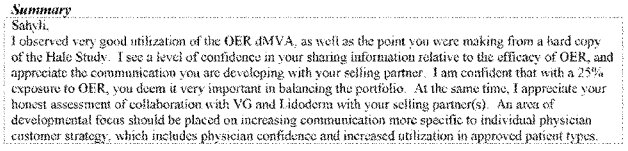
Date

List of Schedules

Table 1: Defendants' Sample Call Log Florida

TEVA_MDL_A_02416207	08/09/2000	Saw Dr for lunch he is very interested in actiq and he said he will defenately try it we spent an hour going the product and he seemed to have a good feel for it. He also works at Moffat ca . willl follow up.
	09/09/2004	full product discussion on actiq then gabitril. Went over delivery, dosing titration, low abuse potential, onset, potency. they both seemed interested. dr corpuz thinks it sounds good but needs to get used to it. gabitril mathias. comp to neuro. medicaid issues. poa actiq w/ corpuz, gabitril w/ abdo
	02/14/2001	spoke w/ Cathy-nurse, using Percocet for breakthrough bc of cost, pts can get generic for a very low cost, she thought of specific pts who could benefit from Actiq, discussed reimbursement program, she wants to order safety kits.
	06/20/2003	Lunch; discussed onset and he knows that Actiq is the fastest. Concerned about the indication because it says patients must be opiod tolerant. Said he will start them on percocet and then go to Actiq. Siad over 85% of his practice pays out of pocket for their meds.
	02/25/2004	Actually saw Dr Ossi, his partner. He said he uses Actiq for breakthrough, though many other things as well. He reports he uses it for head and neck problems, he uses it so people can eat. He uses it for many things that he knows are off label. Left vouchers.
	08/21/2003	New formuation. Had patient in at time that did not like them. Asked me to talk to her. He listened and agreed that he need to be proactive in telling patients about the change. Titration discussed as well as risk mngt.
	07/02/2001	Dr tried Actiq with one cancer pt but still seemed reluctant on using for noncancer; Also money is a concern because he has many self pay pts
	03/25/2004	actiq fast acting. he joked about pushing actiq so i could pay for my house. ha ha mama needs a new pair of shoes. talked about his new house. invited to cme dinner. he may try to come.
	06/05/2002	he is very concered w. abuse and diversion, thinks the patch is being abused, explained dosing and titration, risk mgmt, pharmacy stocking, comparison to pills
	06/10/2004	confirmed Drs attendance to Actiq / Dr Sharfman CME program. Reinforced drs opportunity to alleviate concerns around abuse potential and liablitiy
	03/02/2001	Spoke to Dr. at length on addiction and the doctors and patients misconceptions on addiction.

	03/07/2002	inservice w. office, a little hesitant-concerned about cost and abuse, addiction less than 1% with all opioids, wants more info in nonmalignant pain use, interested to see if it would work acutely
	08/23/2002	inservice with staff, has not rx'd Actiq yet, however, they identified pts whom would benefit, dosing, titration, risk mgmt
	11/26/2001	Met with PA and Dr. They have heard of Actiq, but not written due to comfort level. I talked to all concerns, set-up lunch and he actually wrote a script while I was in the office.
	09/04/2003	Will attend CME with Steve. Said he wants to start using more Acitq but still has reservations regarding short acting opioids and abuse potential. Story about Dr. Hussey on golf course where one of Dr. Hussey guests was using Actiq while he played. Discussed increased functionality .
Allergan_MDL_01540065	08/18/2005	discussed his practice in pain medicine, addiction, morphine, no ceiling dose. pexeva advantages and indications.
	01/30/2007	lunch went to kram kornick addiction vs psuedoaddiction policies procedures referals
	08/28/2006	kek's reminder, discussed his increase in oxy scripts & the importance of getting these pts switched to kadian, identified pt for kadian -next pt he was seeing , received survey from pt enrolled
	08/28/2006	asked them to look for 10 patients to switch over! no loss for patient or doc
	10/30/2006	excellent lunch, gained 2 switches for kadian, stacey, khan, vargas have a much better knowledge of kadian features, identified generic morphine patient as candidate. they said they always bid avinza which is a huge opportunity
	09/17/2007	Discussed smooth plasma levels, slow titration, upcoming 10mg, less side effects, managed care, and KCC.
	08/13/2008	Ok w/samples. Discussed: FP use, identifing appropriate patient types, coverage & stocking. Kadian easier/safer than Oxy/Duragesic.
	03/29/2006	aps guidelines-oral vs patch preferred; adv of assym dosin-focus flex; does preceive kad as safer than other opioids; shared easier to get off pills - kad vs patch
	04/12/2006	Said they would "make it a Kadian day"- reviewed Chau study and formulary.

	09/19/2006	reinforced coupons and how to use them.. Wrote a script for me while there and used coupon. Patient had a 90 day supply wasn't sure if could only use 1 coupon or more.
	11/06/2006	uses methadone not only cuz of price but for Neuropsthic pain, wrote for kadian 60bid from methadone 30.on medicaid & formulary reimbursement, says itd my turn for opioid rotation
	04/25/2007	Great call, convinced him to write kadian for all mser commercial. Need to follow up with him to continue to reinforce, said I will be happy with numbers.
	12/06/2007	MLDP: u say u like k. teach me what clinic sep k comp to other la opioids...like low abuse potential, titration possibilities & conv cards ct: yes for comm pts nco: sasaki for elderly
	11/07/2005	will bring lunch and discuss slides w dr. and melissa; will expand hours 1-2 days a week to help pat - may be good opport to visit; kad less pot abuse;
	12/13/2005	Discussed results of Chau. Safety and abuse is concern/ talked about smoother blood levels of kadian -may be less abusable. . .
Endo Call Log: ENDO_FLAG-00000002 Leave Behind Log: ENDO_FLAG-00000008 For commentary related to sales calls, see, e.g., the ENDOSell Coaching Reports cited in this Report.	Various	Endo call logs that I have seen do not contain commentary regarding the nature of the discussions with Customers. However, there are numerous "ENDOSell Coaching Reports" (ECRs) that I have reviewed. The ECRs document various aspects of the PSRs interactions with Customers and provide insight into the feedback provided by Endo's sales managers to PSRs. For example, the excerpt below notes several aspects of a sales call: use of the dMVA (digital master visual aid), the leave-behind article (Hale Study) and areas for development (e.g., collaboration, communication).  ***Summary*** Sahyli, I observed very good utilization of the OER dMVA, as well as the point you were making from a hard copy of the Hale Study. I see a level of confidence in your sharing information relative to the efficacy of OER, and appreciate the communication you are developing with your selling partner. I am confident that with a 25% exposure to OER, you deem it very important in balancing the portfolio. At the same time, I appreciate your honest assessment of collaboration with VG and Lidoderm with your selling partner(s). An area of developmental focus should be placed on increasing communication more specific to individual physician customer strategy, which includes physician confidence and increased utilization in approved patient types. Sample ENDOSell Coaching Reports and related documents: ENDO_FLAG-00106823 ENDO_FLAG-00106823 ENDO_FLAG-00106823 ENDO_FLAG-00128800 ENDO_FLAG-00131724

		ENDO_FLAG-00166371 ENDO_FLAG-00166390 ENDO_FLAG-00166407 ENDO_FLAG-00166415 ENDO_FLAG-00166447 ENDO_FLAG-00166493 ENDO_FLAG-00209176 ENDO_FLAG-00222606 ENDO_FLAG-00241089 ENDO_FLAG-00241094 ENDO_FLAG-00241099 ENDO_FLAG-00241109 ENDO_FLAG-00241114 ENDO_FLAG-00241119 ENDO_FLAG-00241129 ENDO_FLAG-00241134 ENDO_FLAG-00241139 ENDO_FLAG-00241144 ENDO_FLAG-00241149 ENDO_FLAG-00241185 ENDO_FLAG-00241190 ENDO_FLAG-00270285 ENDO_FLAG-00270289 ENDO_FLAG-00270357 ENDO_FLAG-00270361 ENDO_FLAG-00270411 ENDO_FLAG-00270434 ENDO_FLAG-00270555 ENDO_FLAG-00270577 ENDO_FLAG-00270588 ENDO_FLAG-00270600 ENDO_FLAG-00270630 ENDO_FLAG-00270634 ENDO_FLAG-00270638 ENDO_FLAG-00270664 ENDO_FLAG-00270668 ENDO_FLAG-00270672 ENDO_FLAG-00294968

Table 2: Defendants' Marketing Messages

A. Extended-release drugs and/or q12 dosing- had fewer peaks and valleys and less chance of addiction and abuse.

Bates	Date	Contents	Defendant
ENDO-CHI_LIT-00550036 Opana® ER with INTAC® Digital MVA Navigator	11/2/2015	"The original formulation delivered consistent plasma levels that lasted with low peak and trough fluctuations through 12 hours."	Endo
ALLERGAN_MDL_01290412 Kadian Comparison Detailer cited in DDMAC Warning Letter		Fewer peaks and valleys. Smooth steady-state plasma levels compared with controlled-release (CR) morphine tablets q12h and q24h	Allergan
ALLERGAN_MDL_00815516 2005 Publication Plan	2005	Discussion of drugs and mentions PK profiles/peaks and troughs, "Current Promotional Tagline – Kadian provides consistent pain relief without the peaks and valleys."	Allergan
ALLERGAN_MDL_00001525 Kadian Sales Training Presentation	02/2013	Steady blood levels with few Peaks and valleys	Allergan
ALLERGAN_MDL_00072907 Kadian Marketing Update	9/13/2012	Kadian produced higher trough concentrations and a smaller degree of peak-to-trough fluctuations	Allergan
ALLERGAN_MDL_00405512 Objection Handling Workshop	7/30/2010	Few peaks and valleys	Allergan
Allergan_MDL_01466334 FDA Transmittal Of Advertisements – Behind the Scenes: The KADIAN Capsules Story	6/24/2009	"Fewer peaks and valleys. Smooth steady-state plasma levels compared with controlled-release (CR) morphine tablets q 12h and q24h."	Allergan
Allergan_MDL_01290412 FDA Transmittal Of Advertisements – "KADIAN, When you can prescribe the benefits…"	2009	"Fewer peaks and valleys. Smooth steady-state plasma levels compared with controlled-release (CR) morphine tablets q 12 h and q 24h. Allow for less breakthrough pain and more consistent pain relief for patients."	Allergan

ALLERGAN_MDL_01466381 FDA Transmittal – Kadian Sales Aid	2009	"Smooth steady-state plasma levels when dosed q12h and q24h. Better pain control and sleep scores."	Allergan
ALLERGAN_MDL_00026848 Kadian Marketing Overview	10/2011	"KADIAN provides steady blood levels of morphine sulfate with few peaks and valleys."	Allergan
Acquired_Actavis_00369838 Regional Meetings November 2011 Generic Kadian Sales Team Training	11/2011	Are steady plasma levels important to your patients? If so, why is that important to you? - KADIAN® provides steady blood levels of morphine sulfate with few peaks and valleys (show PK charts from Detail Aid)	Allergan
Acquired_Actavis_00369839_Confidential Regional Meetings Nov 2011	11/2011	"KADIAN® provides steady blood levels of morphine sulfate with few peaks and valleys."	Actavis
ALLERGAN_MDL_01234652 Kadain – Less Pain More Options		"Fewer peaks and valleys. Smooth steady-state plasma levels compared with controlled-release (CR) morphine tablets q12h and q24h."	Allergan
ALLERGAN_MDL_00449946_IMAGE.PDF Managing Chronic Pain and the Importance of Customizing Treatment		"Smooth steady-state plasma levels can prevent breakthrough pain and reduce the need for rescue medication."	Allergan
ENDO-OPIOID_MDL-01662840 or ENDO-CHI_LIT-00417068 Opana ER Strategic Platform Chronic Pain	09/2012	"Has better 12-hour efficacy, with true 12-hour dosing, a crush-resistant formulation that minimizes abuse potential, and fewer drug-drug interactions compared with other pain therapies in the class."	Endo

B. Abuse deterrent formulations deter abuse/are safer than non-abuse deterrent formulations.

Bates	Date	Contents	Defendant
ALLERGAN_MDL_00815516 Kadian 2005 Publication Plan	2005	2005 Publication Plan "Remoxy … incorporates several abuse-deterrent properties…Tests indicate that crushing or physically manipulating Remoxy does not defeat its long-acting mechanism."	Allergan

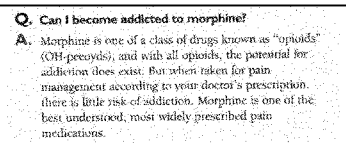
ENDO-CHI_LIT-00556061 Opana ER Customer Satisfaction, Sales Force Effectiveness, Awareness, & Usage Research Program – Wave 3	01/2010	"Low abuse potential is the greatest benefit of a tamper resistant formulation,"	Endo
END00553151 Letter to the Vice President	4/5/2011	"Endo has in development a new oral tamper resistant formulation of long-acting oxymorphone (Opana ER), which is designed to be crush-resistant. This new formulation is being developed in an effort to make available to patients and prescribers a product that may provide an incremental barrier to certain types of misuse and abuse."	Endo
ENDO-OR-CID-00772464 Letter to Julie Suko requested support, Regarding: Reformulated Opana ER (oxymorphone hydrochloride) Extended-Release Tablets, CII with INTAC® technology (Designed to be crush resistant)	11/6/2012	"A study of prescription opioid abusers in a drug rehabilitation program found that 80% tampered with opioid tablets to accelerate drug release by chewing or administering the drug intra-nasally or intravenously. The authors suggest that formulations that incorporate physical or pharmacologic impediments to altering the recommended routes of administration may deter tampering; The attractiveness of an opioid for abuse is in large part dependent on characteristics of the tablet formulation particularly the ease with which it can be crushed or dissolved in fluids."	Endo
END00125376 Larry Romaine on the withdrawal of Oxycontin		"This is a very positive step by the FDA in that it acknowledges the important safety advance that an abuse deterrent formulation offers and prevents easily abusable generics to OxyContin from entering the market."	Endo
END00505817 Opana Steering Committee	2013	"Clear that the role of abuse deterrent formulations is impt- has support from FDA saying so, have data that prescript abuse has overtaken street opioid abuse, and puts Opana ER in a very good position."	Endo
ENDO-CHI_LIT-00417068 Opana ER Strategic Platform	09/2012	"Has better 12-hour efficacy, with true 12-hour dosing, a crush-resistant formulation that minimized abuse potential, and few drug-drug interaction compared with other pain therapies in the class."	Endo

		"true 12 hour dosing and a crush-resistant formula that minimized potential for abuse, misuse, and diversion."	
JAN-MS-00259893 Opioids in the News + Duragesic Product Positioning	6/13/2003	"only AP-48 combines the superior potency of fentanyl with naltrexone in a proprietary formulation to safeguard against unintended usage"	Janssen

C. Minimize concerns about addictive nature of opioids.

Bates	Date	Contents	Defendant
ALLERGAN_MDL_01610520 (Cover email) and ALLERGAN_MDL_01610522 Kadian Learning System (take-home study aid for sales reps) See also ALLERGAN_MDL_00436784 Kadian Learning System	7/1/2010	"Concern about abuse, addiction, and diversion should not prevent the proper management of pain."	Allergan
Taking a Long-Acting Opioid What does it mean to me? ENDO_OPIOID_DEPMAT-000019696		What is the risk of becoming addicted to a long-acting opioid? Addiction is defined as compulsive drug seeking that is beyond a person's voluntary control even if it may cause harm. Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted. Physical dependence, which is different from addiction, may develop when taking opioids for pain relief for a long time. This means that your body adapts to the drug and you will have withdrawal symptoms if the medicine is stopped or decreased suddenly. Taking opioids for pain relief is **NOT** addiction. What if I feel I need more medicine over time? Some people taking opioids may need to take a higher dose after a period of time in order to continue to have relief from their pain. This is a "tolerance" to opioid medications that doesn't affect everyone who takes them, and does **NOT** mean addiction.	Endo

ALLERGAN_MDL_00145639 Oxymorphone Prescribing Information	7/8/11	Oxymorphone Prescribing Information: "Concerns about abuse, misuse, diversion and addiction should not prevent the proper management of pain."	Allergan
Acquired_Actavis_00369188 Kadian Stocking Offer	9/6/2012	Kadian Stocking Offer: "Concerns about abuse, addiction, and diversion, should not, however, prevent the proper management of pain."	Allergan
Acquired _Actavis_00400291 Oxycodone/APAP PI	8/1/2012	Oxy APAP Prescribing Information: "Concerns about misuse, addiction and diversion should not prevent the proper management of pain."	Allergan
Acquired_ Actavis_01406678 Fentanyl PI	7/12/2012	Fentanyl Transdermal System Prescribing Information: "Concerns about misuse, addiction and diversion should not prevent the proper management of pain."	Allergan
Teva, Merris, Exhibit 7	4/3/2004	"He is more hesitant to use Actiq due to a perceived addiction potential. I will need to work on him possibly with a speaker that can come in and help ease his fears." p.10 "She expressed major concern about the safety of Actiq. I convinced her to use it at least in her cancer patients." p.18 "He's still a bit reluctant about using Actiq because of the addition issue. I'll keep working on him." p.18	Teva
ALLERGAN_MDL_02169261 (ACTAVIS0006823) Kadian Personalized Pain Relief patient brochure		"You can become addicted to morphine-based drugs, but it is less likely if you have never had an addiction problem. Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction. It is just your body getting used to the drug. Please be sure to share any concerns you have with your healthcare provider."	Actavis
ALLERGAN_MDL_00449946 _IMAGE.PDF		"Opioids can be used with minimal risk in chronic pain patients without a history of abuse or addiction."	Allergan

Managing Chronic Pain and the Importance of Customizing Opioid Treatment			
TEVA_MDL_A_01399743 Breakthrough Pain – Do you still have pain? A Patient's Guide to Recognizing Breakthrough Pain Flares	3/26/2004	"Concerns about addiction should NOT prevent proper pain management."	Teva (Cephalon)
TEVA_MDL_A_00025496 FENTORA – Overview of Chronic Pain	06/01/2006	"Fear of tolerance and possible addiction should not deter the use of doses that adequately relieve pain."	Teva (Cephalon)
ALLERGAN_MDL_02173994 A Steady Pace Wins the Race		 Q. Can I become addicted to morphine? A. Morphine is one of a class of drugs known as "opioids" (OH-peeoyds), and with all opioids, the potential for addiction does exist. But when taken for pain management according to your doctor's prescription, there is little risk of addiction. Morphine is one of the best understood, most widely prescribed pain medications.	Allergan

D. True patients in pain cannot get addicted – pain protects against addiction.

Bates	Date	Contents	Defendant
ALLERGAN_MDL_02169261 (ACTAVIS0006823) Kadian Personalized Pain Relief patient brochure		"Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction. It just your body getting used to the drug."	Allergan
ALLERGAN_MDL_01610520 (Cover email) and ALLERGAN_MDL_01610522 Kadian Learning System (take-home study aid for sales reps)	7/1/2010	"It is important to recognize that tolerance and dependence (discussed above) do not indicate addiction. Rather, they are an expected consequence of taking opioids in moderate to high doses for a significant length of time."	Allergan
END00366720 Pain Mangement Presentation	4/28/2009	"Opioid addiction unlikely to develop. If pain exists then addiction = 1:10,000	Endo

E. Signs of addiction as simply symptoms of undertreated pain or "pseudoaddiction."

Bates	Date	Contents	Defendant
ALLERGAN_MDL_01610520 (Cover email) and ALLERGAN_MDL_01610522	7/1/2010	"Pseudoaddiction: Behaviors (that mimic addictive behaviors) exhibited by patients with inadequately treated pain."	Allergan

Kadian Learning System (take-home study aid for sales reps)			
ALLERGAN_MDL_01610520 (Cover email) and ALLERGAN_MDL_01610522 Kadian Learning System (take-home study aid for sales reps)	pre-7/1/2010	"The problem is even more complex because some patients who are undertreated for their physical pain show the symptoms of "pseudoaddiction." Pseudoaddiction is a set of behaviors (Table 1-3) that are exhibited by patients with inadequately treated pain, including patients with cancer pain. Pseudoaddictive behaviors are not signs of substance abuse, but rather should be considered symptoms of inadequate treatment."	Allergan
JAN-MS-00465463 Postoperative Pain Management: A Practical Review, part 1	2/9/2012	"Pseudoaddiction superficially resembles addiction but is a direct result of undertreatment of pain."	Janssen
JAN-MS-00465463 Postoperative Pain Management: A Practical Review, part 1	2/9/2012	"Pseudoaddiction superficially resembles addiction but is a direct result of undertreatment of pain."	Janssen
ALLERGAN_MDL_00815516 Kadian 2005 Publication Plan		"It is important for these audiences to understand the difference between addiction and pseudoaddiction, which involves medication-seeking behaviors solely for the sake of pain relief. While 'tolerance' to opioids can occur, a dose increase or switch to another agent will often yield the needed pain relief. 'Tolerance' can also work advantageously for the patient, since it also applies to adverse events."	Allergan
TEVA_MDL_A_02416207 Call Logs	3/3/2003	"Talked about Actiq for BTCP. Discussed how using Actiq can be an alternative to those patients with pseudoaddiction, due to the onset of pain relief." Line 44337	Teva

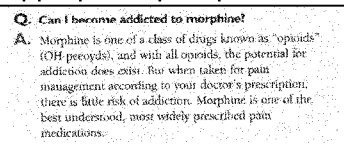
F. Problems only occur when opioids are abused or used illegally- addicts are bad people who knowingly abused the drugs, not good people who were seeking treatment for legitimate ailments.

Bates	Date	Contents	Defendant

ALLERGAN_MDL_01610520 (Cover email) and ALLERGAN_MDL_01610522 Kadian Learning System (take-home study aid for sales reps)	7/1/2010	"Note that persons who are not themselves opioid abusers but who obtain prescriptions for illicit resale are keenly aware of which clinicians in any area are willing to prescribe medications with a high street value. Often these persons appear to be model patients, answering every question in a manner that will ensure their continued supply. Random drug screens are the most effective tool for detecting such individuals, because an appropriately chosen screening panel will be negative for the opioid that is being prescribed."	Allergan
ALLERGAN_MDL_02169261 (ACTAVIS0006823) Kadian Personalized Pain Relief patient brochure		"You can become addicted to morphine-based drugs, but it is less likely if you have never had an addiction problem."	Allergan
JAN-MS-00653403 Optimizing Chronic Pain Management with Duragesic	12/14/2001	"The potential for addiction is in the patient, not the opioid. Where is your patient? ~45% HIGH Long-term exposure to opioids in addicts;<1% LOW Short- term exposure to opioids in non-addict."	Janssen
ALLERGAN_MDL_01052119 Alpharma version (Also, see ALLERGAN_MDL_02157091, undated) Kadian Learning System	3/31/2009	"However, despite the continued unscientific beliefs of some clinicians, there is no evidence that simply taking opioids for a period of time will cause substance abuse or addiction. It appears likely that most substance-abusing patients in pain management practices had an abuse problem before entering practice."	Allergan

G. If taken as prescribed, risk is minimal.

Bates	Date	Contents	Defendant
ALLERGAN_MDL_02169261 (ACTAVIS0006823) Kadian Personalized Pain Relief patient brochure		"Morphine and morphine-like-drugs (also called opioids [oh-pee-oyds]) work well for pain and are safe when taken as directed by your healthcare provider."	Allergan

ALLERGAN_MDL_01234652 _ Image.pdf Kadian Less Pain, More Options		"The Gold Standard in pain control – reliable, with proven efficacy and safety when taken appropriately."	Allergan
ALLERGAN_MDL_00449946 _IMAGE.PDF Managing Chronic Pain and the Importance of Customizing Opioid Treatment		"The gold standard in pain control – reliable, with proven efficacy and safety when taken appropriately."	Allergan
ALLERGAN_MDL_01741588 Managing Chronic Pain and the Importance of Customizing Opioid Treatment	10/27/2009	"Opioids can be used with minimal risk in chronic pain patients without a history or abuse or addiction." p.9	Allergan
TEVA_MDL_A_00026715 FENTORA Efficacy Flashcard	02/25/2008	"Generally well tolerated when used in accordance with prescribing information. Most side effects were mild to moderate."	TEVA
ENDO-CHI_LIT-00551655 Opana Tactical Plan	11/4/2015	"Opana ER is the single, effective, responsible solution to treat moderate to severe chronic pain, based on true 12 hour efficacy and no CYP450 DDIs, thereby decreasing the worries associated with opioid therapy."	Endo
ENDO-CHI LIT-00084164 Understanding Your Pain Brochure	10/18/2010	"The medical term for "slowed breathing" is "respiratory depression." This is very rare when oral opioids are used appropriately for pain relief."	Endo
ALLERGAN_MDL_02173994 A Steady Pace Wins the Race		 Q. Can I become addicted to morphine? A. Morphine is one of a class of drugs known as "opioids" (OH peeoyds), and with all opioids, the potential for addiction does exist. But when taken for pain management according to your doctor's prescription, there is little risk of addiction. Morphine is one of the best understood, most widely prescribed pain medications.	Allergan

H. Addiction less than 1% or low or rare.

Bates	Date	Contents	Defendant
TEVA_MDL_A_00025942	04/2007	"Addiction rarely occurs when you take medicine under your doctor's supervision." P.36	TEVA
TEVA_MDL_A_03913582		"The majority of legitimate pain patients do not abuse their analgesic medication."	TEVA

JAN-MS-00653426 Chronic Pain: Prevalence and Impact Slide Set		"Iatrogenic addiction from opioid analgesia in patients experiencing pain is exquisitely rare."	Janssen
JAN-MS-01192118 Memo on Addiction to Sales Force	9/18/2001	"Iatrogenic addiction following opioid administration is relatively rare. Physicians should not let concerns of physical dependence deter them from using adequate amounts of opioids in the management of severe pain when such use is indicated."	Janssen
JAN-MS-02268552 Nursing 2008 Pain Mangement Survey Report	1/31/2011	"What percentage of patients who receive opioids for short term treatment of acute pain (1-3 days) will become addicted? Less than 1%."	Janssen
JAN-MS-00310473 Speakers Notes, Assessing The Risk for Substance Abuse	2002	"Given the relatively decreased potential of misuse of long-acting (e.g., methadone) and sustained-release opioids (e.g., transdermal fentanyl) in chronic pain patients, these may be preferred over short-acting opioids."	Janssen
JAN-MS-00653403 Optimizing Chronic Pain Management with Duragesic	12/14/2001	"In 10 years of use, low and stable reported rate of abuse" p.32	Janssen
JAN-MS-00302787 Duragesic Pain Specialist Overview	2002	"The abuse levels for each of the analgesics studied were less than 1% of the total DAWN mentions and declined during the study period despite substantial increases in medical use. The investigators concluded that the trend of increasing medical use of opioid analgesics to treat pain does not appear to contribute to increases in the health consequences of opioid use."p.51	Janssen

I. Patients can be easily tapered off opioids.

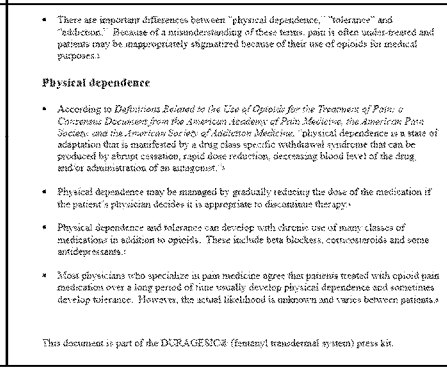
Bates	Date	Contents	Defendant
ALLERGAN_MDL_01610522 July 2010, Actavis Elizabeth LLC	7/1/2010	"*Development of Tolerance and Physical Dependence* is a major reason some clinicians feel opioid therapy should be limited for patients with CBP. Most clinicians do not consider this a major issue, however. Although tolerance and dependence do occur	Allergan

Kadian Learning System (take-home study aid for sales reps)		with long-term use of opioids, many studies have shown that tolerance is limited in most patients with CPC [sic]. Physical dependence simply requires a tapered withdrawal should the opioid medication no longer be needed." "Physical withdrawal generally, but not always, resolves within 5 to 8 days and is not considered life-threatening. Nonetheless, these withdrawal symptoms are uncomfortable and unpleasant, and management of the symptoms is desirable. Medically, treatment of withdrawal symptoms is a straightforward process that can usually be accomplished with minimal difficulty. Detoxification is usually performed by reducing the opioid dosage by 10% to 20% each day, with the entire process requiring 5 to 10 days for completion. Almost any opioid can be used for detoxification because they all have some degree of cross-tolerance."	
ALLERGAN_MDL_00145639 Oxymorphone Prescribing Information	7/8/2011	"When the patient no longer requires therapy with oxymorphone hydrochloride extended-release tablets, gradually taper doses to prevent signs and symptoms of withdrawal in the physically dependent patient."	Allergan
JAN-MS-00653426 Opioidphobia		"Opioids can be discontinued in dependent patients without withdrawal difficulties by simply tapering them over about a week."	Janssen
JAN-MS-00236017 Nucynta Dosing and Administration Guide	6/16/2009	"Generally, tolerance and or withdrawal are more likely to occur the longer a patient is on continuous opioid therapy. Withdrawal symptoms may be reduced by tapering NUCYNTA™"	Janssen

J. Dependence is not a significant concern - only physical and easily reversed.

Bates	Date	Contents	Defendant
ALLERGAN_MDL_01610520 (Cover email) and ALLERGAN_MDL_01610522 Kadian Learning System (take-home study aid for sales reps)	7/1/2010	"It is important to recognize that tolerance and dependence (discussed above) do not indicate addiction. Rather, they are an expected consequence of taking opioids in moderate to high doses for a significant length of time." "*Development of Tolerance and Physical Dependence* is a major reason some clinicians	Allergan

		feel opioid therapy should be limited for patients with CBP. Most clinicians do not consider this a major issue, however. Although tolerance and dependence do occur with long-term use of opioids, many studies have shown that tolerance is limited in most patients with CPB [sic]. Physical dependence simply requires a tapered withdrawal should the opioid medication no longer be needed." "Substance dependence is defined as opioid use that is associated with tolerance to the substances' effect or withdrawal symptoms if the substance is discontinued. Care should be taken to differentiate physical withdrawal symptoms from substance craving. Craving is extremely strong psychological desire to use the substance, but is not a physical symptom."	
ALLERGAN_MDL_00145639 Oxymorphone Prescribing Information	7/8/2011	"Physical dependence is not the same as drug addiction. Your healthcare provider can tell you more about the difference between physical dependence and drug addiction."	Allergan
Acquired_Actavis_01405682 Morphine Sulfate ER Prescribing Information	6/12/2013	"Abuse and addiction are separate and distinct from physical dependence and tolerance. Physicians should be aware that addiction may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts. In addition, abuse of opioids can occur in the absence of true addiction."	Allergan
Acquired_Actavis_01406678 Fentanyl Transdermal System Prescribing Information	7/12/2012	"Abuse and addiction are separate and distinct from physical dependence and tolerance. Physicians should be aware that addiction may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts. In addition, abuse of opioids can occur in the absence of true addiction and is characterized by misuse for non-medical purposes, often in combination with other psychoactive substances."	Allergan
TEVA_MDL_A_03913582		"Physical Dependence…Does not independently cause or define addiction. Abstinence Syndrome can be avoided with careful tapering and monitoring for the withdrawal symptoms." Slide 14	TEVA

		"Tolerance to analgesia is seldom a clinical problem – Tolerance rarely 'drives' dose escalation – Tolerance does not cause addiction." Slide 15	
ENDO-OPIOID_MDL-02472794 Opioid Analgesics A Treatment Primer		"Addiction to opioids in the context of pain treatment is rare in those with no history of addictive disorders." "The occurrence of addiction as a result of opioid use for pain relief is extremely rare. Several studies have concluded that the risk is far less than 1%."	Endo
ENDO-OPIOID_MDL-05654763 Oxymorphone Learning System	2006	"Patients treated with prolonged opioid therapy do not usually develop addictive disorders, though the actual risk is unknown and likely varies with genetic disposition, among other factors."	Endo
JAN-MS-00303825 Duragesic Press Kit			Janssen

- There are important differences between "physical dependence," "tolerance" and "addiction." Because of a misunderstanding of these terms, pain is often under-treated and patients may be inappropriately stigmatized because of their use of opioids for medical purposes.1

Physical dependence

- According to *Definitions Related to the Use of Opioids for the Treatment of Pain: a Consensus Document from the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine*, "physical dependence is a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist."1
- Physical dependence may be managed by gradually reducing the dose of the medication if the patient's physician decides it is appropriate to discontinue therapy.1
- Physical dependence and tolerance can develop with chronic use of many classes of medications in addition to opioids. These include beta blockers, corticosteroids and some antidepressants.1
- Most physicians who specialize in pain medicine agree that patients treated with opioid pain medication over a long period of time usually develop physical dependence and sometimes develop tolerance. However, the actual likelihood is unknown and varies between patients.2

This document is part of the DURAGESIC® (fentanyl transdermal system) press kit.

K. Drug abusers and potential addicts can be easily identified and therefore not prescribed opioids, or prescribed opioids and monitored closely.

Bates	Date	Contents	Defendant
ALLERGAN_MDL_01610520 (Cover email) and ALLERGAN_MDL_01610522 Kadian Learning System (take-home study aid for sales reps)	7/1/2010	"Those patients with past histories or strong family histories of substance abuse and psychiatric illness are more likely to suffer from the disease of addiction. Similarly, a social history of personal and familial dysfunction or personality disorder is associated with a high incidence of substance abuse." "Note that persons who are not themselves opioid abusers but who obtain prescriptions for illicit resale are keenly aware of which clinicians in any area are willing to prescribe medications with a high street value. Often	Allergan

		these persons appear to be model patients, answering every question in a manner that will ensure their continued supply. Random drug screens are the most effective tool for detecting such individuals, because an appropriately chosen screening panel will be negative for the opioid that is being prescribed." "Consistent signs associated with substance abuse include changes in mental status, recent accidents or trauma, a history of poor impulse control (legal difficulties, gambling, losing jobs), and a history of poor or unpredictable responses to standard pain therapies. Patients with a past history or strong family history of substance abuse (including alcohol abuse) are far more likely to have a substance abuse problem than others are."	
ENDO-OR-CID-01299015 Letter to Opana sales team regarding abuse	2011	"As mentioned in the boxed warning of the Opana ER PI, proper patient selection along with proper education on the limitations of use and potential of abuse is imperative when considering Opana ER therapy.	Endo
JAN-MS-02328366 Correlation of opioid tolerance with physical dependence and addiction Article	1/17/2001	"Although early studies supported the notion that chronic opioid therapy leads to addiction, [ ] more recent data indicate that this risk is very low in patients with no history of drug abuse."	Janssen

L. Even patients at high risk of addiction can be safely prescribed opioids by using risk-mitigation strategies such as pain contracts.

Bates	Date	Contents	Defendant
Acquired_Actavis_00188875 Oxymorphone HCL Riskmap	4/20/2011	...Actavis South Atlantic will stress the requirement for coverage of risk management strategies and would require that education about the following elements be included in all opioid-related educational programs: ... Identification and ongoing monitoring of patients at higher risk for abuse and	Allergan

		diversion, and management tools for pain patients considered for long-term opioid therapy -Screening tools (e.g. the Screener and Opioid Assessment for Patients with Pain-Revised [SOAPP-R] and the Current Opioid Misuse Measure [COMM]) -Opioid agreement -Plan for follow-up -Role of other modalities such as urine drug screening, pill counts, etc. to assist in monitoring compliance	
TEVA_MDL_A_03913582 From speakers notes of Opioid Abuse Addiction and Diversion slide set		"Opioid Agreement – Advantages Patients at high risk for opioid abuse can receive opioids for pain management with a well planned agreement in place. Agreements may also facilitate the early diagnosis of the disease of addiction and the diagnosis of substance abuse relapse." Slide 35	
ENDO-CHI_LIT-00053284 Oxymorphone Learning System, Module 3, Oxymorphone Risk Management Program	2006	"Physical dependence and tolerance are related phenomena that occur with chronic use of many types of drugs, including many that are not associated with addiction or abuse (such as beta blockers for high blood pressure). Both result from changes in the body as it adapts to the constant presence of the drug. Physical dependence is due to adaptive changes that cause the body to depend on the drug's actions to drive a process." p.14	
ENDO-CHI_LIT-00084174	10/18/2010	Sample Pain Contract	Endo

M. Pain should be treated with opioids.

Bates	Date	Contents	Defendant
ALLERGAN_MDL_01787026 Kadian Copay Materials		"Why is pain management important? Pain management is a large part of your overall health	Allergan

Co-pay brochure cited in DDMAC Warning Letter		care plan. Many Americans suffer from chronic or ongoing pain… Managing your pain the right way begins by talking to your healthcare provider. Discover the cause of your pain by taking note of what makes your pain start and what makes it worse." What is chronic pain? Chronic pain is ongoing and can last longer than 6 months. Chronic pain can be mild or severe…" How can I treat my chronic pain? To help manage your pain, your healthcare provider will determine what level of pain control you need. Depending on what kind of pain you have and how it affects your life, your healthcare provider will choose a drug that works just for you."	
ALLERGAN_MDL_01234652_Image.pdf Kadian, Less Pain, More Options		"World Health Organization (WHO) guidelines recommend treating chronic pain with a long-acting opioid."	Allergan
JAN-MS-00653403 Optimizing Chronic Pain Management with Duragesic	12/14/2001	"Consider as first-line for patients with moderate-to-severe chronic pain who require continuous opioid analgesia: Degenerative joint disease –Chronic back pain - Cancer pain -Has been shown to be effective in certain cases of chronic neuropathic pain." p.34	Janssen
ENDO_FLAG-00241129 ENDOSell Coaching Report for Michelle Glass	05/26/2007	"Position: Opana as the FIRST line agent"	ENDO

N. Undertreated pain should be treated with opioids.

Bates	Date	Contents	Defendant
ALLERGAN_MDL_01610520 (Cover email) and ALLERGAN_MDL_01610522	7/1/2010	"Chronic pain is frequently untreated, undertreated, or incorrectly treated." Many patients receive inadequate pain relief	Allergan

Kadian Learning System (take-home study aid for sales reps)		because doctors are unwilling to manage chronic pain or do not have sufficient knowledge to treat it properly."	
TEVA_MDL_A_03913582 Opioid Abuse Addiction and Diversion slide set		"Undertreatment of pain is a serious problem. Effective pain management is an integral and important aspect of quality medical care. Pain should be treated aggressively. For many patients, opioids are the most effective treatment – using established management guidelines – often the only option that provides significant relief."	TEVA
JAN-MS-00827726 Tapentadol IR PriCara Field Sales Leadership Meeting	12/3/2008	"Medical unmet need in Pain Management. Pain management today is suboptimal. Side effects fuel under-treatment. Need better treatments: Comprehensive dual pathway pain management with improved side effect profile."	Janssen
ENDO-OPIOID_MDL-00585976 Opana ER Scientific Slide Kit	8/17/2012	"Despite its prevalence, chronic pain is undertreated. Even when patients are prescribed analgesics, pain may persist or worsen due to lack of efficacy. When the initial opioid trial fails, it is important to offer patients a switch in opioid medication in a timely fashion to prevent the development or worsening of chronic pain" "Addition of OPANA ER to the analgesic armamentarium can help address the high incidence and undertreatment of chronic pain"	Endo

O. There is more risk of leaving pain untreated than using opioids to treat pain.

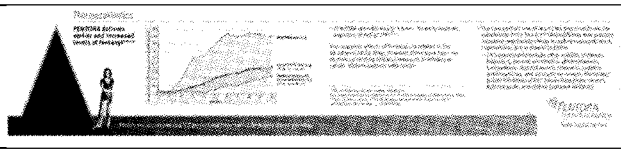
Bates	Date	Contents	Defendant
Acquired_Actavis_00943445 Managing Chronic Pain and the Importance of Customizing Opioid Treatment		"Chronic Pain is Undertreated. The undertreatment of chronic pain is a serious public health issue that results in enormous social cost and reduces patients' functional status and quality of life."	Allergan

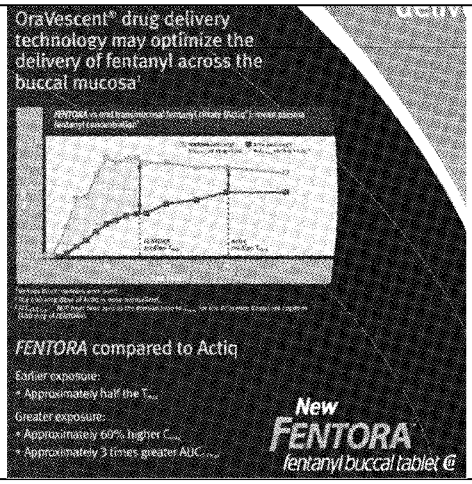
ALLERGAN_MDL_01610520 (Cover email) and ALLERGAN_MDL_01610522 Kadian Learning System (take-home study aid for sales reps)	7/1/2010	"Under-treatment of pain results in patients with a very poor quality of life and may lead to feelings of hopelessness and despondency."	Allergan
END00366720 Pain Management Slide Set by Dr. Ira Kornbluth	5/5/2009	"Chronic pain disables more people than cancer or heart disease and cost the American people more than both combined. The annual cost of chronic pain in the US, including healthcare expenses, lost income, and lost productivity is estimated to be $100 million."	Endo
Kadian Copay Assistance Program. Balzanti Exhibit 3	12/2009	"Many Americans suffer from chronic or ongoing pain. It can cause you to miss work and can even keep you from enjoying life. If left untreated, pain can place stress on your body and your mental health."	Allergan
ALLERGAN_MDL_01466349 Kadian Conversion Guide	2009	"Nearly 86 million people in the United States are affected by chronic pain. 76% of Americans with chronic pain experience pain daily, including 48% who say it is constant. Chronic pain is responsible for the loss of approximately $90 billion annually in reduced work productivity, sick time and direct medical costs, among others."	Allergan
TEVA_MDL_A_00025496 FENTORA – Overview of Chronic Pain	06/01/2006	"Breakthrough pain has been shown to predict poor medical outcomes. Breakthrough pain is associated with significant – Patient morbidity – Decreased functioning – Disrupting sleep – Increased levels of anxiety and depression. In a recent study of cancer outpatients, total annual healthcare costs per patient were 5 times higher for breakthrough pain patients ($12,000/yr) than for non-breakthrough pain patients ($2,400/yr)."	TEVA
TEVA_MDL_A_03274427 ACTIQ Managed Care Slide Set	Attached to an email dated 4/26/2005	"Unrelieved pain including breakthrough pain profoundly impairs quality of life. Patients suffer physical consequences (reduced physical functioning, poorer overall health), Psychological	TEVA

Attached to an email titling these slides as "MCO Speaker Slides and Supplemental Slides"		consequences (frustration, fear, anxiety and depression), Undertreatment of pain continues, clinical evidence suggests that effective pain management improves quality of life. "Inadequately managed pain burdens the healthcare system: Excessive health care expenditures, Lost productivity, Needless suffering. Guideline-based care improves outcomes in cancer patients with only small increase in cost. Poorly managed pain causes high pain related expenses, Optimal pain management benefits patients and the healthcare system overall."	
TEVA_MDL_A_03913570 ACTIQ Speakers Bureau Slide Set Economic Impact of Pain	09/02/2005	This entire slide set discusses the economic impact of pain in the United States and the importance of treating this pain.	TEVA
END00433069 Complete Opana Slide Set "Opana Brand of Products"	02/05/2010	"The results of the National Pain Survey conducted in 1999 found that 1 in 4 Americans suffers from chronic pain, and only 1 in 10 Americans take prescriptions medication to manage this pain. Annual costs of pain-related healthcare, litigations and compensation in the U.S. is estimated at > $100 billion. Pain is: responsible for > 50 million lost workdays annually. The second most common medical cause of work absenteeism. The leading cause of disability among individuals of working age."	ENDO

P. Opioids offer more effective pain control and are safer than alternatives.

Bates	Date	Contents	Defendant
ALLERGAN_MDL_01741588	10/27/2009	"Maintenance therapy with opioids can be safer than the long-term use of other analgesics, such as COX-s inhibitors, nonselective NSAIDS, or acetaminophen"	Allergan
ALLERGAN_MDL_00001525	02/2013	"Kadian contains morphine as its active ingredient and has a long history of safety and efficacy when	Allergan

Kadian Sales Training Presentation		used as indicated.'' In response to why should I switch my patients to Kadian objection.	
ALLERGAN_MDL_01145475 Managing Chronic Pain and the Importance of Customizing Opioid Therapy		"maintenance therapy with opioids can be safer than the long-term use of other analgesics, such as cyclooxygenase type 2 inhibitors, nonselective nonsteroidal anti-inflammatory drugs, or acetaminophen, in older persons."	Allergan
ENDO-OPIOID_MDL-02489844 EndoSell Objection Handling Workshop	11/1/2006	"For example, ENDO is only calling on experienced opioid prescribers like yourself and our goals are based on replacement of competitors with the durable efficacy and dosing advantages that OPANA® ER offers versus expansion of the class."	ENDO
ALLERGAN_MDL_00026848 Kadian Marketing Overview Sales Representative Training	10/2011	"KADIAN contains morphine as its active ingredient and has a long history of safety and efficacy when used as indicated."	Allergan
ALLERGAN_MDL_01466379 Kadian Less Pain, More Options	10/2009	"Oral morphine formulations give benefits that other opioids might not. The gold standard in pain control- reliable, with proven efficacy and safety when taken appropriately."	Allergan
Acquired_Actavis_00369838 Kadian Regional Meetings	11/2011	"Now you can prescribe the same KADIAN® with its long history of safety and efficacy at a generic price"	Allergan
ALLERGAN_MDL_00449946 Managing Chronic Pain and the Importance of Customizing Treatment Slide set		"Opioids can be used with minimal risk in chronic pain patients without a history of abuse or addiction."	Allergan
ALLERGAN_MDL_00449946 Managing Chronic Pain and the Importance of Customizing Treatment Slide set		"Maintenance therapy with opioids can be safer than the long-term use of other analgesics, such as COX-2 inhibitors, nonselective NSAIDs, or acetaminophen, in older persons."	Allergan
TEVA_MDL_A_00029984	05/26/2011		Teva

TEVA_MDL_A_00025378	10/2006			

Q. Defendants' opioids will make your life better without risk.

Bates	Date	Contents	Defendant
ALLERGAN_MDL_01610520 (Cover email) and ALLERGAN_MDL_01610522 Kadian Learning System (take-home study aid for sales reps)	7/1/2010	"Although the effect of the therapy in reducing the patient's pain is of primary importance, the improvement in the patient's ability to function is considered the gold standard of chronic pain treatment. Being able to perform more household tasks, walk longer distances, or even return to work are usually considered the key measurements in treating CBP. It is also important to confirm improvement with family members. Too often, a patient reports that their treatment relieves their pain quite effectively, but a spouse complains that the patient is sedated or even intoxicated from their medication. There remains no question that opioids effectively reduce the severity of most types of CBP."	Allergan
JAN-MS-00890573 Information About Duragesic® (fentanyl transdermal system) CII	7/16/2002	"Duragesic helps patients return to activities of daily living. In a twelve-month open-label study, Duragesic significantly improved both physical and social functioning (activities such as returning to work and participating in family life). In a crossover comparison with sustained release oral morphine, patients using Duragesic had significantly better measures of social functioning, vitality, mental health and reduced pain."	Janssen

JAN-MS-02324033	2001	Duragesic Refined Positioning Statement: DURAGESIC significantly improves physical and social functioning by providing the only chronic pain relief that is consistent and effective for 72 hours.	Janssen

R. No maximum dose - if you are in pain more opioids could be given without additional risk (i.e., "titrate to effect" concept from cancer/palliative care should be used with chronic pain).

Bates	Date	Contents	Defendant
ALLERGAN_MDL_01745342	1/28/2011	"KADIAN does not have a ceiling or recommended maximal dose, especially in patients with chronic pain of malignancy. In such cases the total dose of KADIAN should be advanced until the desired therapeutic endpoint is reached or clinically-significant opioid-related adverse reactions intervene." "KADIAN doses can be titrated up every other day."	Allergan
JAN-MS-00306410		"Game, uninterrupted. Chronic pain relief that supports functionality."	Janssen
ALLERGAN_MDL_01466349	2009	"Avoid Limitations of other opioid therapies. No ceiling dose – no fumaric acid, acetaminophen, or ibuprofen."	Allergan
ALLERGAN_MDL_00026848	10/2011	"Kadian does not have a ceiling or recommended maximal dose, especially in patients with chronic pain of malignancy. In such cases the total dose of KADIAN should be advanced until the desired therapeutic endpoint is reached or clinically-significant opioid-related adverse reactions intervene."	Allergan
TEVA_MDL_A_01150240	2009	"Titration: From starting dose, titrate to a dosage strength of FENTORA that provides adequate analgesia with tolerable side effects."	Teva
TEVA_MDL_A_02416207	11/1/2002	"Luncheon with Drs. Tsang, Brereton, Baikadi, SanFilippo and staff on Actiq for the management of btcp., titration to effect via coupons, risk management program and benefeatures were presented and discussed."	Teva

ALLERGAN_MDL_01745342_ Image.pdf	1/28/2011	"KADIAN does not have a ceiling or recommended maximal dose, especially in patients with chronic pain of malignancy. In such cases the total dose of KADIAN should be advanced until the desired therapeutic endpoint is reached or clinically-significant opioid-related adverse reactions intervene."	Allergan
ALLERGAN_MDL_00449946_ IMAGE.PDF		"Start low and titrate until patient reports adequate analgesia. Set dose levels on basis of patient need, not on predetermined maximal dose." "No ceiling dose or acetaminophen toxicity."	Allergan
TEVA_MDL_A_00026098 Triple i Prescriptions Sponsored by: Fentora Fentanyl buccal tablet		"The initial dose of FENTORA is 100 mcg. From initial dose, titrate to effect. Maintain patient on dose that provides adequate analgesia with minimal side effects."	TEVA
END00000105		"The dose of OPANA ER can be gradually adjusted, at increments of 10 mg every 12 hours every 3-7 days, until adequate pain relief and acceptable side effects have been achieved."	Endo
END00000119		"This may be just a beginning dose for your patient so you may need to titrate by 10 mg every 12 hours every 3-7 days until adequate pain relief and acceptable side effects have been achieved."	Endo
ENDO-CA-00110112	1/31/2008	"I most recently observed this with Dr. Helms where you got him to see that he was too conservative in dosing Opana in the past and to agree to try Opana again on a patient he was seeing that very week."	Endo

S. Opioids can be prescribed for any pain condition without risk.

Bates	Date	Contents	Defendant
ENDO-CHI_LIT-00545908 Opana Tactical Plan	9/22/2006	"So why Opana? Wide range of patients. Opioid experienced and opioid naïve. Acute and chronic pain."	Endo
END00018819	April 2007	"Bill Profile: 'Doctor, OPANA®ER offers you and your patients unique dosing advantages. OPANA®ER has been proven	Endo

New Sales Tools: Patient Profiles		effective in multiple patient types including opioid naïve and opioid experienced patients with low back pain. Doctor, let's review a patient profile. Do you have patients like Bill in your practice who could benefit from around the clock treatment for the moderate to severe pain?"	

T. Opioids can be prescribed to any age group without risk.

Bates	Date	Contents	Defendant
ALLERGAN_MDL_01610520 (Cover email) and ALLERGAN_MDL_01610522 Kadian Learning System (take-home study aid for sales reps)	7/1/2010	"**Special Populations**... Pediatric: Infants under 1 month of age have a prolonged elimination half-life and decreased clearance relative to older infants and pediatric patients. The clearance of morphine and its elimination half-life begin to approach adult values by the second month of life. Pediatric patients old enough to take capsules should have pharmacokinetic parameters similar to adults, dosed on a per kilogram basis."	Allergan

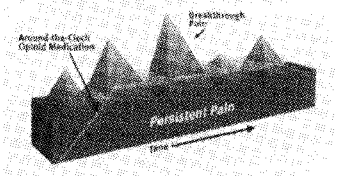
U. "Round the clock" dosing should be used for chronic pain rather than "as needed" dosing.

Bates	Date	Contents	Defendant
Acquired_Actavis_00943445 Managing Chronic Pain and the Importance of Customizing Opioid Treatment		"Longer-acting agents are more effective than short-acting agents for chronic pain; 'around-the-clock' dosing for 'around-the-clock' pain."	Allergan
ALLERGAN_MDL_01610520 (Cover email) and ALLERGAN_MDL_01610522 Kadian Learning System (take-home study aid for sales reps)	7/1/2010	"When patients have constant or nearly constant pain, analgesics should be given "ATC" (around the clock), not "PRN" (when necessary). Fixed, regular dosing intervals are allowed, but frequent episodes of breakthrough pain indicate that regular "around the clock" dosing should be increased."	Allergan
ALLERGAN_MDL_01466379 Kadian Less Pain, More Options sales aid	10/2009	"Switching from a short-acting opioid to long (acting)morphine can improve efficacy and tolerability."	Allergan

ALLERGAN_MDL_00449946 Managing Chronic Pain and the Importance of Customizing Opioid Treatment		"Longer-acting agents are more effective than short-acting agents for chronic pain; 'around-the-clock' dosing for 'around-the-clock' pain."	Allergan
ALLERGAN_MDL_01741588 Managing Chronic Pain and the Importance of Customizing Opioid Treatment	10/27/2009	Longer-acting agents are more effective than short-acting agents for chronic pain; "around-the-clock" dosing for "around-the-clock pain" p.9	Allergan

V. "Breakthrough pain" applies to chronic pain, not just cancer pain, and short-acting opioids should be used to supplement long-acting opioids for that reason.

Bates	Date	Contents	Defendant
TEVA_MDL_A_01496786 Fentora Marketing Plan 2008	7/27/2007	"Promote ROO subclass as ideal treatment option for BTP."	Teva
ALLERGAN_MDL_01610520 (Cover email) and ALLERGAN_MDL_01610522 Kadian Learning System (take-home study aid for sales reps)	7/1/2010	"As with cancer pain, opioids for CBP are used 'by the clock' on a scheduled basis, with breakthrough medication sometimes (but not always) made available."	Allergan
ALLERGAN_MDL_01234652 Kadian Less Pain, More Options Sales Aid		"Jim G. Car accident left him with chronic back and neck pain. Taking 5 mg of short-acting hydrocodone tablets 6 times a day for 3 months. Side effects are too extreme, pain relief is inadequate. Recommendation: Prescribe him 20 mg KADIAN® once a day or 10 mg twice a day, and titrate upwards. Keep short acting opioid on hand to treat breakthrough pain until proper analgesic level is reached."	Allergan
JAN-MS-02387022 Nucynta ER/Nucynta 2014 Business Plan	8/9/2013	"Moderate to severe acute pain – SAO of choice for appropriate patients such as … on an opioid (CIII) but require additional analgesia."	Janssen

TEVA_MDL_A_00027170 Fentora Patient Starter Kit	5/5/2008	Chronic pain (pain that lasts for more than 3 months) often has 2 parts, and doctors often treat each part with a different medicine. For pain that lasts all day long, called *persistent* or *constant pain*, a doctor can give *around-the-clock opioid pain medicine*. This is medicine that may work for 8 hours or more. However, even if the around-the-clock opioid pain medicine controls persistent pain most of the time, a patient can still experience sudden flares of moderate-to-severe pain. This is called *breakthrough pain*—pain that "breaks through" the around-the-clock opioid medicine.  Breakthrough pain is commonly associated with sudden onset and in most cases does not last for more than 2 hours.	

CURRICULUM VITAE
MATTHEW PERRI III

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ACADEMIC RANK AND APPOINTMENTS

2021- present	Professor Emeritus, Clinical and Administrative Pharmacy
2017 – 2020	Program Director, PharmD / MBA Dual Degree Program
2015 – 2019	Associate Head, Clinical and Administrative Pharmacy
1985 - present	Graduate Faculty, University of Georgia Graduate School
1985 – 2020	Adjunct Professor, College of Public Health, University of Georgia Institute of Gerontology.
1996 – 2020	Professor of Pharmacy, University of Georgia College of Pharmacy
2012 - 2015	Director, Pharmacy Care Administration Graduate Program
1996 - 2006	Associate Head, Department of Clinical and Administrative Sciences, College of Pharmacy
1981- 2007	Pharmacist, Community Practice
2001 - 2006	Clinical Pharmacist, Athens Primary Care Pharmacy Care Clinic
1990 - 1996	Associate Professor of Pharmacy, University of Georgia College of Pharmacy
1990 - 1996	Director of Graduate Studies, University of Georgia College of Pharmacy
1985 - 1990	Assistant Professor of Pharmacy
1981 - 1990	Consultant Pharmacist The Lowman Home for the Aged and Infirm, White Rock SC
1981 -1985	Consultant Pharmacist, The Babcock Centers ICF MR and Teaching and Research Assistant, University of South Carolina

EDUCATION

1985 Ph.D., University of South Carolina, Columbia, SC.
1981 B.S. Pharmacy, Temple University School of Pharmacy, Philadelphia, PA.

ACHIEVMENTS AND POSTGRADUATE TRAINING

2011- 2020	Board Member, Association for Marketing and Health Care Research
2019	Nominee, UGA Creative Research Award
2011, 2012, 2019	College of Pharmacy Nominee for the Josiah Meigs Distinguished Teaching Professorship
2001 – 12, 2018-present	Board Member, Georgia Department of Community Health Drug Utilization Review Board
2004 - 2010	Chair, Georgia Department of Community Health Drug Utilization Review Board
2009-2010	Phi Delta Chi Faculty of the Year
2008	Sloan Foundation Award for Excellence in Graduate Education
2004	University of Georgia Student Government Teaching Award
2002	Immunization Provider Certification, American Pharmaceutical Association
2001	Business Leadership Program, University of Georgia Terry College of Business
2001	Invited Member of the University of Georgia Teaching Academy
2000-01	Mentor, Lilly Teaching Fellows Program
1999-04	Board Member, Medical College of GA, Blue Cross Center for Health Care Improvement
1998	Mentor, University of Georgia Teaching Improvement Program
1995-96	University of Georgia College of Pharmacy Teacher of the Year
1989	Title III Advisory Board Member, Athens Community Council on Aging
1988-89	Mentor, University of Georgia Teaching Improvement Program
1986-87	Lilly Teaching Fellow, University of Georgia
1985	Recipient of 1985 J.M. Smith Computers in Pharmacy Award University of SC
1984	Rho Chi Pharmacy Honor Society

GRANTS / CONTRACTS AND GIFTS

GA Department of Community Health (Medicaid)
Neuropsychiatric EEG-Based ADHD Assessment Aid (NEBA) Monitoring Study
2017-2019 $25,000
Principle Investigator

UGA SBIRT Interprofessional Training Program.
Grant No: 1H79T1026457-01
2016-2019; $851,016
Department of Health and Human Services
Co-Investigator

Opioid Prescribing n Medicaid: Healthcare Utilization and Deaths from Overdose.
Grant No: 1R01DA039930-01A1
2016-2019; $675,000
National Institutes of Health, NIDA
Principal Investigator (Co PI J. Jayawardhana)

Prescriber Education
US Attorney General Consumer and Prescriber Grant Program
2006-2008; $396,000
Principal Investigator (Co PI R. Tackett)

Perri M, Walthour A. American Foundation for Pharmaceutical Education, $5,000, 2007-08.

Perri M, Walthour A. American Foundation for Pharmaceutical Education, $6,000, 2007-08.

Perri M, Rollins B. American Foundation for Pharmaceutical Education, $6000, 2007-08.

Perri M, Rollins B. American Foundation for Pharmaceutical Education, $6,000, 2006.

Perri M. Roger Green and Associates Graduate Student Training in Marketing Research, 2000-2006; $181,500.

Griffin S, Aull L, Herist K, and Perri M, Insulin Resistance Clinical Trial; Co-investigator, 2006-2008, $42,486.

Perri M and Deshpande A. Drug Information Association, Communicating Benefit and Risk Information in Direct-to-Consumer Advertising, 2004-05, $23,000.

Perri M and Shindes SB. Antecedents of Drug Requesting Behavior, Sankyo Pharma, 2003, $10,000.

Perri M and Johnson T. Long Term Care Intervention Team: Implications for Outcomes and Public Policy, Department of Community Health, State of GA, 2002, $115,000.

Perri M and Cook C. Patient Satisfaction with Managed Care Pharmacy Services, UpJohn, 1997, $5,000.

Perri M and Kamath AR. R&D Productivity in the Pharmaceutical Industry, Elan Corporation, 1996, $3,097.

Neel A, Pittman J, Marasco R, Pritchard L, Perri M., Reese L., Morton M., "A Tacrine HCL Outcomes Research Project in a Long Term Care Facility, Warner Lambert Park- Davis, 1995, $315,000 (consultant only).

Pritchard L and Perri M. "Examining the Quality of Service of Two Different Pharmacy Designs: The Patients Perspective", Wal-Mart Inc., 1995, $11,598.

Perri M and Martin B. "Improving Medication Compliance: A Practical Intervention", The West Company, 1993, $26,600.

Perri M and Pritchard FL. "OBRA 90: A BluePrint for Quality Pharmaceutical Care", Glaxo, Inc., 1993, $15,000.

Perri M, Kotzan JA, Francisco G and Pritchard F. "The Impact of OBRA 90 on the Practice of Pharmacy in the State of Georgia", Georgia Department of Medical Assistance, one year, 1992, $33,265.

Francisco G and Perri M. "Developing a Curriculum to Train Pharmacists to Provide Pharmaceutical Care in the Community Chain Pharmacy Setting", American Association of Colleges of Pharmacy, 1992, $32,412.

Perri M and Wolfgang AP. "Hospital Pharmacy Salary Survey 1991", $1,000; "Hospital Pharmacy Salary Survey 1990", $1,000; "Hospital Pharmacy Salary Survey 1989", $750; "Hospital Pharmacy Salary Survey, 1988", $750; "Hospital Pharmacy Salary Survey, 1987", Georgia Society of Hospital Pharmacists, $750. (Annual Survey)

Park, D.C. and Morrell, R., "Intervention Strategies to Improve Drug Compliance in Community Dwelling Older Adults", AARP Andrus Foundation, M. Perri (project consultant) July 1989, $76,842.

Perri M and Kotzan JA. "An Analysis of Consulting Pharmacist Effectiveness for Medicaid Patients in Nursing Homes", Georgia Department of Medical Assistance, July 1989, $5,775.

Kotzan JA and Perri M. "An Analysis for Potential Savings Earned from a Starter Dose Program for Anti-arthritic Drug Products for Medicaid Recipients", State of Georgia, Department of Medical Assistance, Atlanta, GA, 1989 $3,613.

Perri M, Wolfgang AP, Park D and Carroll NV. "Older Adults and Generic Medications: Intervention Strategies to Enhance Usage", The American Association of Retired Persons (AARP) Andrus Foundation, April 1988, $65,769.

Perri M. "Health Care Information Through Public Advertising", Faculty Research Grants, Office of Vice President for Research, July 1986, $2,500.

Perri M. "Development of a Case Study Teaching a Method in Pharmacy Management", The Lilly Foundation, through Office of Instructional Development, May 1986, $3,000.

Perri M. "An Interactive Computer Learning Center", Instructional Services Grants, University of Georgia Office of Instructional Development, March 1986, $1,000.

Kotzan JA, Perri M, Carroll NV, and Wolfgang AP. "Pharmacy Management Studies", Eckerd Foundation, 1985, $40,000.

Continuing Education Grants and Contracts Funded

Perri M, Cooper JW, Ozburn WE, (1993-1997) "Alzheimers Disease Counseling Guidebook", Post-graduate continuing education contract, through Warner Lambert Parke Davis, $15,740.

Perri M and Ozburn W, (1994) Pharmacist Training Program, Post-graduate continuing education contract, through Promotions Unlimited, $3,000.

Perri M, Pritchard FL, Ozburn WE and Gammil C. (1993) "OBRA 90 a Blueprint for Quality Pharmaceutical Care", Post-graduate continuing education contract, through Glaxo Inc, $10,580.

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1. Wang Yang Perri M. Patient, Physician and Organizational Influences in Physician Prescribing Behavior. Submitted.

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Huang M, Rollins B and Perri M. Consumer Preferences for Attributes of Alzheimer's Disease Predictive Genetic Tests. Assoc Marketing and Health Care Research. Park City Utah, March 1, 2012.

Rollins B, Ramakrishnan S, Perri M. An Experimental Examination of Consumer Attitudes, Behavioral intentions and Information Search Behavior after Viewing a Predictive Genetic Test DTC Ad. Assoc Marketing and Health Care Research. Park City Utah, March 2, 2012.

Rollins, B., Ramakrishnan, S. and Perri M. Direct to Consumer Advertising of Predictive Genetic Tests: A Health Belief Model Based Examination. American Academy of Advertising, Annual Meeting, March 15-18 2012.

Huang, M., Rollins B and Perri M. Public Awareness of the Genetic Information Non-discrimination Act (GINA) of 2008, International Society for Quality of Life Research, Denver CO, October 2011.

Huang, M. and Perri M. Public Preferences for the Predictive Genetic Test for Alzheimer's Disease in the United States. ISPOR 14th Annual European Congress. Poster presentation. Sunday November 6, 2011, Madrid Spain.

*,+ Perri M. Pharmaceutical Marketing: Extreme Couponing or Just Good Business. Rx Ohio Collaborative, Express Scripts, Ohio State University. June 30, 2011.

Rollins B and Perri M. To Brand or Not to Brand. Association for Marketing and Health Care Research. Steamboat Springs, CO February 27 2011.

Ramakrishnan S, Rollins B and Perri M. Consumer Response to DTC Advertising of Predictive Genetic Tests. Association for Marketing and Health Care Research. Steamboat Springs, CO February 27 2011.

+ Walthour A and Perri M. Utilization of Health Care Services Following GA Medicaid 2004 Policy Change for Atypical Antipsychotic Agents. APHA, November 6-10, 2010. Denver CO.

+ Bhutada N, Menon A, and Perri M. Impact of Celebrity Endorsements in Prescription Drug Advertising on Consumers Attitudes and Behaviors. Association for Marketing and Health Care Research, February 26th, 2010, Tahoe City, CA.

+ Bhutada N, Deshpande A, and Perri M. Consumers' evaluation of the information in print direct-to-consumer advertising: Does format of the brief summary matter? Am Public Health Assoc, November 7-11, 2009, Philadelphia, PA.

+ Perri M and Bhutada N. Do Coupons in Print Direct-To-Consumer Advertising Influence on Consumers?" 2009 Association for Marketing in Health Care Research, Jackson Hole WY, February 26th 2009.

Merrill Norton, Robin L Southwood, Matthew Perri III, Henry Cobb, and Nilesh S. Bhutada, "*Impact of attending educational symposium upon first year pharmacy student attitude towards providing pharmaceutical care to mentally ill patients*" at the American College of Clinical Pharmacy (ACCP) 2007 Annual Meeting, October 14–17, 2007, Denver, CO.

Robin L. Southwood, Merrill Norton, Matthew Perri III, Henry Cobb, and Nilesh S. Bhutada, *"Impact of attending educational symposium upon third year pharmacy student attitude towards providing pharmaceutical care to mentally ill patients*" at the 42nd ASHP Midyear Clinical Meeting and Exhibition, December 2-6, 2007, Las Vegas, NV.

+ Dubberly J, Perri M, Smith L, Walthour A. Case Study: Cost Control in Mental Health. ISPOR 12th Annual International Meeting, May 20, 2007.

+ Jaing J,, Fu Z, Perri M. Prevalence of Potentially Inappropriate Medication Use in the Elderly. ISPOR 10th Annual International Meeting, *Poster Award Finalist*, May 16, 2005.

Provost M, Galen RS, DiPiro JT, Watson R, Zinkhan G, Martin B and Perri M. The impact of e-Health Information an Patients' Medication Adherence, Knowledge and Attitudes: a Randomized Controlled Trial. 7th Annual Meeting of the Canadian Society of Tele-health, Qubec City, October 5th, 2004.

Herist, K., McElhannon, M., Aull, L, Cook., C, Cobb, H., Hart, M., Johnson, T., Perri, M. Development and Implementation of a Financial Business Plan in the Formation of a University-Affiliated Pharmacy Care Clinic within a Physician's Office. AACP Annual Meeting, Salt Lake City, UT; July 2004

McElhannon, M., Herist, K., Cook, C., Aull, L., Johnson, T., Cobb, H., Hart, M., Perri, M. Development of Policies and Procedures in the Formation of a University-Affiliated Pharmacy Care Clinic within a Physician's Office. AACP Annual Meeting, Salt Lake City, UT; July 2004.

+ Cook, C., McElhannon, M., Herist, K., Cobb, H., Aull, L., Johnson, T., Hart, M., Perri, M. Assessing Student Perceptions of Proposed Curricular Changes Prior to Implementation. AACP Annual Meeting, Salt Lake City, UT; July 2004.

Perri M, Menon A and Deshpande A. "Update on DTC Advertising Research from UGA" Drug Information Association Annual Meeting, June 14, 2004, Washington DC.

+ Menon A, Perri M and Kotzan J. "Using HEDIS Measures to Evaluate Health Plan Performance in the Treatment of Major Depression" Drug Information Association Annual Meeting, June 14, 2004 Washington DC.

+ Deshpande A, Menon A, Perri M. "Adverse Outcomes Associated with Inappropriate Medication Use in Nursing Home Patients. Drug Information Association Annual Meeting, June 14, 2004 Washington DC.

+ Aull L, Johnson JT, Herist K, Cook C, Perri M, Phillips J and Duke L. Evolution of clinical experiences for third year students: Increasing the application of clinical knowledge. Am College of Clinical Pharmacy Annual Meeting, Atlanta GA November 2003.

+ Provost M, Perri M, and Galen R. Teaching Tele-monitoring and the Use of High The Tools for Disease Management in Pharmacy Practice. AACP Annual Meeting, Minneapolis MN, July 18, 2003.

+ Cook C and Perri M. Correlations between a stage of change measure and four validated measures of medication compliance. Int Soc of Pharmacoeconomics and Outcomes Research (ISPOR), International Meeting, FR, May 2003.

+ Cook C, Perri M. "Comparison of Four Compliance Measures". American Pharm Assoc Annual Meeting, New Orleans, March 28, 2003.

Deshpande AD, Menon AM, Perri III, Matthew, and Zinkhan GM. "The Perceived Usefulness of Direct-to-Consumer Prescription Drug Advertising for Consumer Decision-making". Association for Health Care Research Annual Meeting, March 19-22, 2003, Jackson Hole, WY.

Melanie Provost, Matthew Perri , Vincent Baujard[a], Celia Boyer.[a] Opinions and e-Health Behaviours of Patients and Health Professionals in the U.S.A. and Europe. [a] The Health On the Net Foundation, Switzerland, www.hon.ch, U.S.A. Medical Informatics Europe (MIE). Annual Meeting MIE-2003, Podium Presentation, St-Malo, France, May 4-7th, 2003. URL: http://www.med.univ-rennes1.fr/mie2003/

+ Deshpande AD, Menon AM, Perri M. "Consumers Search for Prescription Drug Information on the World Wide Web", Drug Information Association, Chicago IL, June, 2002.

+ Menon AM, Cantrell R, Dong D, and Perri M. "Consumer Attitudes towards Direct To Consumer Advertising and its Effect on Information Search Behavior", Drug Information Assoc, Chicago IL, June 2002.

+ Menon AM, Deshpande AD, Perri M, and Zinkhan G. "The Perceived Value of Risk Disclosures in Direct to Consumer Prescription Drug Advertisements", Marketing and Public Policy Conference, Atlanta GA, May 2002

+ Deshpande AD, Menon AM, Perri M, and Zinkhan G. "The Utility of Direct to Consumer Advertising for Health Care Decision Making: A Consumer Perspective", Am Pharmaceutical Assoc, Philadelphia PA, March 2002.

+ Menon AM, Deshpande AD, Perri M, and Zinkhan G. "Consumers Trust in Prescription Drug Information: The Internet and its Effect on Information Search Behavior", Am Pharm Assoc, Philadelphia PA, March 2002.

+ Shinde, S Knut A, Slaughter E and Perri M. "Modeling the Mediation of Consumer Involvement Between DTC Ads and Consumer Attitudes", Business and Health Administration Association, Chicago IL, February 2002.

+ Deshpande AD, Menon AM, Slaughter E, and Perri M. "Consumers Benefit Perception in A Direct to Consumer Prescription Drug Advertisement and its Effect on Drug Inquiry Behavior", Am Assoc Pharm Scientists, Denver CO, October 2001.

+ Menon AM, Deshpande AD, and Perri M. "Medication Taking Behavior after Exposure to a Direct -to-Consumer Prescription Drug Advertisement", Am Assoc Pharm Scientists, Denver CO, October 2001.

+ Menon AM, Deshpande AD, Slaughter E, and Perri M. "Consumers Risk Perception in a Direct -to-Consumer Prescription Drug Advertisement and its Effect on Drug Inquiry Behavior", Drug Information Association, Denver CO, July 2001.

+ Deshpande AD, Menon AM, Slaughter E, and Perri M. "Consumers Drug Request Behavior After Exposure to a Direct to Consumer Prescription Drug Advertisement and its Effect on Drug Inquiry Behavior" Drug Information Association, Denver CO, July 2001.

+ Shinde SB, Fox, R., Slaughter, E, and Perri M. "The Influence of Direct-to-Consumer Advertising on Consumers Recall, Knowledge of Indication and Interaction with Doctors: An Exploratory Study", American Pharmaceutical Association, March 16-20, 2001, San Francisco CA.

+ Shinde SB, Zinkhan GM, Slaughter, E, and Perri M. "Factors Influencing Clarity of Direct-to-Consumer Advertisements: A Regression Analysis," Association for Health Care Research , March 21-24, San Antonio TX.

*,+ Perri M, "The Present and Future of Direct-to-consumer Advertising Practice and Research", Special Session at American Marketing Association Summer Educational Conference, San Francisco CA, August 10, 1999, with Ross MA, Clark MJ, Pinto MB, Shimp TA, Slaughter E and Zinkhan G,

Perri M, Misra SM. "Patient Satisfaction as an Outcome of an Over-the-counter Medication Counseling Algorithm", American College of Clinical Pharmacy, International Congress of Clinical Pharmacy, Orlando FL, April 12, 1999.

+ Perri M, Poirier S. "Developing Skills to Enhance Patient Compliance: The Pharmacy Care Pathway", Academy of Managed Care Pharmacy, at the 1996 Educational Conference, "Pharmaceutical Care: Tools for a New Generation", October 31 - November 3, 1996, Orlando FL.

Kotzan JA and Perri M. "Pharmacy Care in the Community Setting: Results of a National Survey", Pharmaceutical Care Outcomes Research Conference: Linking Research to Practice", September 26, 1996, Athens GA.

Kamath A and Perri M. "Research Productivity In Pharmaceutical Companies", McMasters International Business Conference, Innovation Research Center, McMasters University, Hamilton, Ontario, January 23-25, 1996.

+ Kotzan JA, Martin BC and Perri M. "A Market Share Analysis for Prior Authorized Medicaid Prescriptions", AAPS, November 1995.

+ Tackett RL, Rubin JW, Zumbro LG, Perri M, Barber DA. "Reduced Endothelium-Dependent Vasodilation in Postmenopausal Black Females", American Heart Association, November 1995.

+ Tackett RL, Zhao l, Ricci A, Zumbro LG, Rubin JW, Perri M, Barber DA, "Racial Differences in the response to Verapamil But Not Nifedipine and Diltiazem, American Heart Association, November 1995.

+ Kamath A and Perri M. "Status of Research in the Pharmaceutical Industry" AAPS, November 1995.

+ Kamath A and Perri M. "Organizational Determinants of R&D Productivity in Pharmaceutical Companies: An Interpretative Model", AAPS, November 1995.

Kamath A, Perri M. "Organizational Considerations in Research and Development in Pharmaceutical Companies: Conceptual and Measurement Issues", Third Annual Interdisciplinary Students of Organizations Conference, University of North Carolina, Chapel Hill NC, Sept 15-17, 1995.

Kamath A and Perri M. "Input-Output Relationships in Pharmaceutical R&D", at European Doctoral Summer School in

Technology Management, Manchester Business School, Manchester England, August 14-25th 1995 (Aug 19).

+ Kotzan JA, Martin BC and Perri M, "Prescription Utilization for Medicaid Patients", American Pharmaceutical Association Annual Meeting, Orlando, FL, March 19, 1995

+ Tackett RL, Rubin JW, Zumbro GL, Shoemaker K, Perri M, Barber DA, "Impaired Vasodilation in Saphenous Veins in Females Undergoing Coronary Artery Bypass", Experimental Biology Meeting, April 13, 1995, Atlanta GA, FASEB Journal 9 A5084 1995.

+ Tackett RL, Rubin JW, Zumbro GL, Perri M, Barber DA, "Saphenous Veins in Black and White Females Exhibit Impaired Vasodilatory Mechanisms", American Heart Association Conference on the Functional and Structural Aspects of the Vascular Wall, Snowbird Utah, February 95.

+ Perri M, Martin BC and Kotzan JA, "Care Seeking Behavior and the Role of the Pharmacist", American Pharmaceutical Association Annual Meeting, Orlando, FL, March 20, 1995 .

+ Kotzan JA, Perri M, and Martin BC, "Prescription Utilization for Medicaid Patients", Am Pharm Assoc Annual Meeting, Orlando, FL, March 20, 1995

* Perri M. "Reimbursement for Cognitive Services", National Conference on Mental Health and Substance Abuse, Georgia Center for Continuing Education, University of Georgia, Athens, GA Jan 31, 1995.

+ Pritchard FL and Perri M. "Quality of Service in the Retail Drug Setting: An Examination of Expectations and Perceptions", Association for Health Services Research, San Diego, CA, June 1994.

* Perri M. "Family Considerations: Communicating with the Diabetes Patient", NARD Management Institute, Diabetes Education Program, NARD Rx Expo 94, Nashville, TN, April 26, 1994.

* Perri M. "Effective Use of the Managers Time", NARD Pharmacy Ownership Training Program, Memphis, TN, March 4-9 1994.

* Perri M. "Family Considerations: Communicating with the Diabetes Patient", NARD Management Institute, Diabetes Education Program, NARD Annual Meeting, Indianapolis, Indiana, October 25, 1993.

* Perri M. "Challenges in Implementing OBRA 90", American College of Apothecaries Midyear Meeting, Orlando, Florida, May 28, 1993.

* Perri M. "Pharmacy Location Analysis" NARD Rx Expo 93, Walt Disney World, Florida, May 27, 1993.

* Perri M. "Family Considerations: Communicating with the Diabetes Patient", NARD Management Institute, Diabetes Education Program, Orlando, Florida, May 25, 1993.

* Perri M. "Selecting a Location For Success", NARD Pharmacy Ownership Training Program, Memphis, TN, March 28, 1993.

* Perri M and Fincham, J.E., "The Pharmacists Role in Smoking Cessation: Clinical and Reimbursement Issues", American Pharmaceutical Association Annual Meeting, Dallas, Texas, March 23, 1993.

Perri M, Pritchard L, Fink J., and Francisco G, "OBRA 90: A Blueprint for Quality Pharmaceutical Care", a national television broadcast from the Georgia Center for Continuing Education, February 23 and 25, 1993.

* Perri M and Pritchard L. "The Challenge of The Omnibus Budget Reconciliation Act of 1990", Drug Emporium National Franchise Association Meeting, Las Vegas, Nevada, December 17, 1992.

+ Kotzan JA, Perri M, Crosby J, "An Economic Assessment of Implementing an Investment Based Medicaid Reimbursement Policy" American Association of Pharmaceutical Scientists, San Antonio, TX, November 15, 1992.

* Perri M. "Developing Marketing Strategies to Improve Profitability", NARD Pharmacy Expo '92, New Orleans, LA, May 29, 1992.

* Perri M and De Nicola T. "Niche Marketing Your Pharmacy for Increased Profitability", NARD Annual Meeting, Baltimore, MD, October 29, 1991.

+ Perri M. "Consumer Recall and Awareness of a Multimedia Campaign On Generic Prescription Medications", National Council on Patient Information and Education, 8th Annual Meeting, Washington, DC, April 22, 1991.

+ Wolfgang AP, Perri M, and Kotzan JA. "Consumer Experience with the Rx OTC Switch: A Comparison of 1985 and 1989", American Pharmaceutical Association, New Orleans, LA, March 10, 1991.

* Lamy P, Beardsley R, Park D, Morrow D, Willis, Perri M and Siegler I. "Facilitating Medication Compliance", a symposium, American Psychological Association, New Orleans, LA, August 12, 1989.

+ Kotzan JA and Perri M. "A Statewide Medicaid Prescription Program for Nursing Homes", American Association of Pharmaceutical Scientists, Las Vegas, Nevada, November 5, 1990.

+ Perri M and Wolfgang AP. "Generic Medications: Educational Intervention Strategies", American Pharmaceutical Association, Washington, DC, March 11, 1990.

+ Wolfgang AP and Perri M. "Older Consumers' Attitudes Toward the Use and Advertising of Generic Drugs", American Pharmaceutical Association, Washington, DC, March 10, 1990.

+ Ortmeier B and Perri M. "An Alternative to Demographic Segmentation: The List of Values Psychographic Measure", American Pharmaceutical Association, Washington, DC, March 10, 1990.

+ Perri M and Wolfgang AP. "An Educational Module: Informing Older Consumers About Generic Medications", American Association of Colleges of Pharmacy, Portland, Oregon, July 11, 1989.

*,+ Perri M, Wolfgang AP, Park D, Morrell R, and Brown H. "Medication Usage in the Elderly: A Research Perspective", Southern Gerontological Society Annual Meeting, Charleston, S.C., April 26, 1989. (Symposium)

+ Perri M and Wolfgang AP. "An Educational Module to Inform Older Consumers About Generic Prescription Medications", Southern Gerontological Society Annual Meeting, Charleston, S.C., April 26, 1989.

+ Wolfgang AP and Perri M. "Attitudes Toward the Use and Advertising of Generic Drugs", 10th Annual Meeting of the Southern Gerontological Society, Charleston, S.C., April 26, 1989.

+ Wolfgang AP and Perri M. "Prescriptions and Consumer Cost Sensitivity", American Pharmaceutical Association annual meeting, Anaheim, CA, April 1989.

+ Kotzan JA, Wolfgang AP, and Perri M. "Physician Newsletter for Prescription Price Information", American Association of Pharmaceutical Scientists, Orlando, Florida, October 1988.

* Perri M. "The Risks and Rewards of Opening Your Own Pharmacy" and "Using the Right Advertising and Publicity to Open a Pharmacy"; "Finding the Right Site for a Pharmacy"; "Purchasing the Right Inventory"; and "Selecting, Training & Motivating Employees", National Association of Retail Druggists, Management Program, Georgia Center for Continuing Education, Athens, GA, September 1988.

+ Perri M. "Health Information Through Public Advertising", American Pharmaceutical Association, Atlanta, GA, March 1988.

+ Wolfgang AP, Perri M, Kotzan JA, and Carroll NV, "Consumer Perceptions of Prescription Prices", American Pharmaceutical Association, Atlanta, GA, March 1988.

+ Carroll NV, Wolfgang AP, Kotzan JA, and Perri M., "Consumer Attitudes and Actions Toward Generic Drugs", American Pharmaceutical Association, Atlanta, GA, March 1988.

+ Perri M. "Pharmacy Management by the Case Method", American Association of Colleges of Pharmacy, Charleston, S.C., July 1987.

+ Perri M and Duke K. "Innovations in Pharmacy Education - Pharmacy Career Simulator", American Association of Colleges of Pharmacy, Charleston, S.C., July 1987.

+ Glascock J. DiPiro J, Cadwallader D, and Perri M. "Stability of Terbutaline Sulfate Repackaged in Disposable Plastic Syringes", American Society of Hospital Pharmacists Annual Meeting, Atlanta, GA, December 1987

+ Perri M. "Consumer Views of Physician Dispensing", American Association of Pharmaceutical Scientists, Washington, D.C., November 1986.

+ Kotzan JA, Carroll NV, and Perri M. "Economic and Demographic Analysis of Medicaid Prescription Consumption", American Association of Pharmaceutical Scientists, Washington, D.C., November 1986.

+ Carroll NV, Perri M, Kotzan J.A, and Fincham JE. "Consumers Perceptions of Pharmacy Patronage Issues", American Association of Pharmaceutical Scientists, Washington, D.C., November 1986.

+ Perri M and Dickson WM. "Direct To Consumer Advertising of Prescription Medications: Influence on Consumer Behavior", American Pharmaceutical Association, San Francisco, CA, March 1986.

+ Perri M, Kotzan JA, Fincham JE, and Carroll NV. "The Rx to OTC Switch: Factors in Product Selection", American Pharmaceutical Association, San Francisco, CA, March 1986.

+ Perri M and Nelson AA. "A Preliminary Study of Direct To Consumer Advertising", American Pharmaceutical Association, Montreal, Canada, April 1984.

REGIONAL PRESENTATIONS

(* denotes invited presentation, + denotes abstract published)

Perri M. Keynote Address, Emory School of Medicine Geriatrics Conference, Callaway Gardens, GA July 2018. "Dealing w with Direct-to-Consumer Ads.

* Perri M. Communication Skills for the Busy Practitioner. RC Wilson Pharmacy Association Meeting. January 16 2013

Perri M. "Follow up on Atypical Antipsychotic Utilization in Georgia Medicaid: Psychiatric Office Visits and Utilization Trends" Georgia Department of Community Health, December 13, 2011.

Perri M. "Essential Communication Skills for Pharmacy Practitioners" at Mercer Southern School of Pharmacy, Phi Delta Chi Founders Day, November 5, 2011.

Perri M. "Balancing Academic Interests" September 1, 2011, South College, Knoxville TN.

Perri M. Time series modeling of changes in health care services utilization for atypical antipsychotics. Department of Public Administration and Policy, UGA School of Public Information and International Affairs, April 26, 2011.

Perri M. Changes in Health Care Services Utilization for Atypical Antipsychotic Agents, Georgia Department of Community Health, Atlanta GA, March 17, 2011.

* Perri M. "Overview of the US Pharmaceutical Industry" UGA School of Public Health, November 18, 2007, Athens, GA

Perri M. "Refining Communication Skills in Pharmacy Practice", Nontraditional Pharm D Program, Mercer / UGA, August 16, 2005, Athens, GA

Perri M. "Refining Communication Skills in Pharmacy Practice", Nontraditional Pharm D Program, Mercer / UGA, August 14, 2004, Athens, GA

Perri M. "Patient Counseling and Communication Skills in Substance Abuse", UGA Center for Continuing Education, Athens, GA, October 19, 2003.

Perri M 'Refining Communication Skills in Pharmacy Practice", Nontraditional Pharm D Program, Mercer / UGA, August 22, 2003, Athens, GA

Perri M. "Patient Counseling and Communication Skills in Substance Abuse", UGA Finale Symposium, Tifton GA, December 15, 2002.

Perri M. "Short Course on Physical Assessment", Psychology Certification Program, May 17-19, 2002.

Perri M. "Refining Communication Skills in Pharmacy Practice", Nontraditional Pharm D Program, Mercer / UGA, August 24, 2001, Athens, GA

* Perri M. "Innovative Pharmacy Services", Georgia Pharmacy Association Annual Continuing Education Seminar, Macon GA, March 10, 2001.

* Perri M. "Developing an Innovative Pharmacy Service', Georgia Pharmacy Association Annual Meeting, Jacksonville Beach Florida, June 16, 2001.

* Perri M. "Counseling for the Pharmacologic Treatment of Schizophrenia", University of Georgia Center for Continuing Education, GSAMS Workshop on Schizophrenia, School of Social Work, May 11, 2001.

Perri M. "Counseling Your Patients", Workshop on Substances of Abuse, University of Georgia College of Pharmacy Office of Postgraduate Continuing Education, October 22 at the Georgia Center for Continuing Education and December 4, 2000 at the Rural Development Center, Tifton GA.

Perri M. "Pharmacologic Treatment of Schizophrenia", Gwinett Tech, Georgia Psychology Association, June 4, 1999.

Perri M. "Schizophrenia: The New Treatment Options", at Schizophrenia from the inside out: Understanding Mental Illness and Best Practice, University of Georgia School of Social Work, Athens GA, January 15, 1999.

Misra S and Perri M. "Consumer Attitudes on Rx-OTC-Switches", Southern Pharmacy Administration Conference, University of Mississippi, Oxford MS, June 1, 1996.

Perri M. "Surviving the 90's: The Future of Hospital Pharmacy Practice", Southeastern Society of Hospital Pharmacists, Georgia Center for Continuing Education, April 18, 1996 Athens, GA.

Perri M. "Strategies for Improving Patient Compliance", Proctor and Gamble Pharmaceuticals, Cincinnati Ohio, October 17, 1995.

Perri M. "Pharmacoeconomics in Practice", Anderson Area Medical Association, Anderson SC, January 9, 1996.

* Perri M. "Medication Compliance and Disease State Management", The West Co., Lionville, PA September 7, 1995.

+ Zhao L, Ricci AM, Rubin JW, Zumbro L, Perri M, Barber D, Tackett RL, " Racial Differences in the Response to Calcium Channel Antagonists in Human Saphenous Vein", Southeastern Pharmacology Society, September 20, 1995, abstract published in Proc Soc Exp Bio (in press).

Kamath A and Perri M. "An Interpretive Model of R&D Productivity", International Students of Organizations Conference, University of North Carolina, Chapel Hill, NC, September 16, 1995.

Kamath A and Perri M. "Determinants of R&D Productivity in Pharmaceutical Companies", Graduate Research Day, University of Georgia College of Pharmacy, Georgia Center for Continuing Education, June 11, 1995.

+ Kamath A and Perri M. "Innovations in the Pharmaceutical Industry: Organizational Considerations", First Annual Graduate Student Forum for Promoting Interdisciplinary Interaction, Athens, GA, May 11, 1995.

Perri M. "Managing Pharmaceutical Care", Georgia Pharmacy Association Annual Meeting, Panama City Beach Florida, June 17, 1995.

Pritchard L, and Perri M. "OBRA 90 Update: Where are we now?", Georgia Pharmacy Association Annual Meeting, Panama City Beach Florida, June 18, 1995.

Perri M. "Efficient and Effective Time Management", Publix Pharmacies Annual Meeting, Atlanta GA, March 21, 28, 1995.

Perri M. "Patient Communication and Interviewing", Publix Pharmacies Annual Meeting, Atlanta GA March 21, 28 1995.

Perri M. "Effectively Handling Problem Employees", Publix Pharmacies Annual Meeting, Atlanta GA March 21, 28 1995.

* Perri M., "Managing Time in the Community Pharmacy", RC Wilson Pharmaceutical Association, Athens, GA, Feb 15, 1995.

Perri M. "Reimbursement for Cognitive Services", at Implications of Managed Care on Community Pharmacy Practice, Post Graduate Continuing Education Fall Seminar, College of Pharmacy, University of Georgia, Athens, GA October 9, 1994.

* Perri M. "Improved Packaging and Improving Medication Compliance", Bristol Myers Squibb Company, New Brunswick, NJ, September 25, 1994.

Perri M. "The Organized Pharmacy Manager: Effective Time Management", Promotions Unlimited, Racine WI, July 19, August 9, 1994.

Perri M and Gourley D. "Pharmacist-Patient Consultation Program - Unit 2", Pfizer, National Healthcare Operations, National Association of Boards of Pharmacy / American Association of Colleges of Pharmacy Regional Meeting, St. Simons Island, GA, August 8, 1994.

Perri M. "Pharmacist-Patient Consultation Program - Unit 2", Pfizer, National Healthcare Operations, Los Angeles, CA August 2,3 1994.

Perri M. "Pharmacist-Patient Consultation Program - Unit 2", Pfizer, National Healthcare Operations, Dayton OH, June 28, 29, 1994.

* Perri M. "Improving Medication Compliance", Merck Co., West Point, PA, June 10, 1994.

Perri M. "Patient Communications: Getting Your Message Across", Promotions Unlimited, Racine WI, June 14, 1994.

+ Kamath A and Perri M. "Pharmaceutical Marketing Practices", AACP Southeast Regional Meeting, Pharmacy

Administration, Gainesville, FL, June 2-4, 1994.

Perri M. "Patient Communications: Getting Your Message Across", Promotions Unlimited, Racine WI, May 3, 1994.

Perri M. "Patient Communications: Getting Your Message Across", Promotions Unlimited, Racine WI, April 12, 1994.

* Perri M. "Communications - Getting Your Message Across", Georgia Society of Hospital Pharmacists, Midyear Meeting, February 18 & 19, 1994, Atlanta, GA.

* Perri M. "Counseling Patients in Challenging Situations", Drug Emporium Regional Meeting, February 9, 10, 1994, Atlanta, GA.

Perri M and Martin BC. "Improving Medication Compliance: A Practical Intervention", Sterling Rice Consultants, February 7, 1994 Boulder, CO.

Perri M. "The Challenge of Mandatory Patient Counseling: Hospitals Too!", Georgia Mental Health Conference, Georgia Center for Continuing Education, February 2, 1994, Athens, GA.

Perri M. "Ten Steps to Improved Productivity", University of Georgia Finale Symposium, ABAC, January 23, 1994, Tifton, GA.

* Perri M. "Efficiency in the Workplace: Effective Time Management", West Virginia Society of Hospital Pharmacists, October 20, 1993, Caanan Valley, WV.

* Perri M. "Pharmacist Patient Consultation Program - 2: Counseling Patients in Challenging Situations", Annual Kroger Seminar, October 25 and 28, 1993, Atlanta, GA.

* Perri M. "How to get customers to remember your business", Empire Pharmaceutical Association, New York, New York, July 14-15, 1993.

* Perri M. "Locating for Success", Georgia Pharmacy Association Annual Meeting, Ashville, NC June 16, 1993.

Perri M. "Patient Counseling" in Current Concepts in the Management of Hepatitis and Oncology, Atlanta, Georgia, May 22, 1993.

* Perri M. "The Emerging Role of the Community Practitioner", Lambda Kappa Sigma Hygiea Day, Athens, Georgia, March 2, 1993.

* Perri M. "The Future of Pharmacy Practice: OBRA 96", West Virginia Society of Hospital Pharmacists, Charleston WV, February 18, 1993.

* Perri M. "Pharmacy Practice for the 1990's", Augusta Area Pharmaceutical Association, Augusta, Georgia, February 16, 1993.

* Perri M. "OBRA 90", The Mckesson Consulting Group, Atlanta, Georgia, January 16, 1993.

Perri M. and Pritchard, L. "OBRA 90: Responding to the Challenge of Mandatory Patient Counseling", University of Georgia Finale 1992 Continuing Education Program, Tifton GA, December 12, 1992.

* Perri M. "Patient Counseling and Conflict Management", continuing education for pharmacy practitioners, funded by an educational grant from Pfizer and the Kroger Company, December 7, 8, 9, 10, 14, Atlanta GA, 1992.

Perri M. "The Impact of OBRA 90 on Pharmacy Practice", Middle GA Pharmaceutical Association, Macon GA, October 22, 1992.

Perri M. Pritchard L. "Quality Patient Counseling Under OBRA 90" , Pharmacy Continuing Education, October 14, 15 Los Angeles, CA, November 11, 12, Washington DC, November 17, 18, Philadelphia PA, 1992.

Perri M and Pritchard L. "Quality of Service: the New Horizon", A conference for professional development presented for practicing pharmacists September 15, 16, Atlanta, GA, 1992.

Perri M. "Marketing Pharmaceutical Care" University of Georgia Annual Fall Seminar, College of Pharmacy, Athens, GA, September 27, 1992.

* Perri M. "Advertising and Promotion that Work: Creating Customer Awareness", Georgia Pharmaceutical Association Annual Meeting, Savannah, GA, June 17, 1992.

* Perri M. "Employee Development in Practice", Associated Pharmacies Annual Meeting, Sandestin, FL, April 26, 1992.

* Perri M. "Niche Marketing that Works", Associated Pharmacies Annual Meeting, Sandestin, FL, April 25, 1992.

Perri M. "Designing a Pharmacy to Meet the Needs of Your Disabled Customers" Floyd County Pharmaceutical Association, Rome, GA, March 17, 1992.

* Perri M. "Statistical Power Analysis", Department of Pharmacology and Toxicology, University of Georgia, Athens, GA, February 1992.

* Perri M. (1991) "Third Party Prescription Program Analysis", Georgia Pharmaceutical Association Annual Meeting, Panama City, FL, June 19.

* Perri M. (1991) "Advertising and Promotion: Building Consumer Awareness", Samford University School of Pharmacy, Birmingham, AL, March 3.

Perri M. "Consumer Behavior in Pharmacy Marketing", West Georgia College, Carrollton, GA, November 17, 1991.

Perri M. "Personnel Training for the Americans with Disabilities Act of 1990" and "Niche Marketing and the Americans with Disabilities Act of 1990", at Making the Americans with Disabilities Act Work For You, University of Georgia Annual Fall Seminar, College of Pharmacy, Athens, GA, October 13, 1991.

Perri M. "Understanding Buyer Behavior", West Georgia College, Carrollton, GA, March 10, 1991.

Perri M. "Can You Afford to Fill Third Party Prescriptions?", West Georgia College, Carrollton, GA, January 13, 1991.

* Perri M. "Be A One Minute Manager", Georgia Educational Advancement Council, Berry College, Rome, GA, July 20, 1990.

* Perri M. "Professional Advertising and Promotion for Pharmacists", Harris County Pharmaceutical Association, Houston, TX, May 24, 1990.

* Perri M. "Strategic Planning for a Dynamic Business", "Marketing Advertising and Promotional Strategies for a Busy Professional", and "An Exercise in Decision Making" at Temple University / NARD Program, "Taking Control of Your Pharmacy Management Needs", Philadelphia, PA, March 15, 1990.

* Perri M. "Effective Management: The One Minute Manager", Georgia Society of Hospital Pharmacists, Annual Meeting, Georgia Center for Continuing Education, Athens, GA, October 28 & 29, 1990.

Perri M. "Third Party Payment Programs", University of Georgia College of Pharmacy, Athens, GA, September 29, 1990 and West Georgia College, Carrollton, GA, September 30, 1990.

Perri M. and Pritchard, L., "Effective Employee Development", Postgraduate Continuing Education Seminar, College of Pharmacy, University of Georgia, College of Pharmacy, February 18, 1990.

Perri M. "Managed Care: An Employers Perspective", at Third-Party Issues: Managed Health Care and the Medicare Catastrophic Health Care Bill, 41st Annual Postgraduate Pharmacy Seminar, University of Georgia, College of Pharmacy, Athens, GA, April 23, 1989.

+ Perri M, Wolfgang AP, Park D, Morrell R, and Brown H, "Medication Usage in the Elderly: A Research Perspective", 10th Annual Meeting of the Southern Gerontological Society Annual Meeting, Charleston, S.C., April 26, 1989.

+ Perri M and Wolfgang AP. "An Educational Module to Inform Older Consumers About Generic Prescription Medications", 10th Annual Meeting of the Southern Gerontological Society Annual Meeting, Charleston, S.C., April 26, 1989.

+ Wolfgang AP and Perri M. "Attitudes Toward the Use and Advertising of Generic Drugs", 10th Annual Meeting of the Southern Gerontological Society, Charleston, S.C., April 26, 1989.

* Perri M. "Advertising and Promotion Methods for a New Pharmacy", Opening Your Own Pharmacy, Texas Pharmaceutical Association, Austin, TX, May 6, 1989.

* Perri M. "What Do I Need to Know About Pharmacy Computers", Opening Your Own Pharmacy, Texas Pharmaceutical Association, Austin, TX, May 6, 1989.

* Perri M. "Finding the Right Site for a New Retail Pharmacy", Opening A New Pharmacy, Texas Pharmaceutical Association, Austin, TX, May 5, 1989.

* Perri M. "Attitudes and Actions: Generic Medications", Psychology Colloquium, The University of Georgia Department of Psychology, Athens, GA, Feb. 17, 1989.

* Perri M, Diehl PF and Arias I. "The Characteristics of a Good Teacher", Fall Colloquium on Teaching, University of Georgia, Athens, GA, September 14-15, 1989.

* Perri M, Wolfgang AP, and Park D. "Older Adults and Generic Medications: Intervention Strategies to Enhance Usage", University System Advances in Geriatrics: Creative Energies for Now and Tomorrow, University of Georgia, Athens, GA, March 2, 1988.

* Perri M. "The Direct Approach to Prescription Drug Advertising", Northeastern University, Boston, MA, July, 1988.

Perri M. "Marketing Strategies for Home Diagnostic Products", 40th Annual Postgraduate Pharmacy Seminar, University of Georgia College of Pharmacy, Athens, GA, April 24, 1988.

Perri M and Wolfgang AP. "Competition, Dollars and Sense", West Georgia College, Carrollton, GA, November 4, 1987.

Perri M. "Financial Management for Community Pharmacists: Break-even Analysis", University of Georgia College of Pharmacy, Athens, GA, October 1987.

Perri M. "Financial Management for Community Pharmacists: Cash Budgeting and Inventory Control", University of Georgia College of Pharmacy, Athens, GA, October 1987.

Perri M. "Financial Management for Retail Pharmacies: Break-even Analysis", and "Financial Management for Retail Pharmacies: Working Capital Management", Brunswick Pharmaceutical Association, Jekyll Island, GA, August 1987.

Perri M. "From the Four P's to the Five R's", West Georgia College, Carrollton, GA, March 1987.

Perri M. "Personnel Management", Fall Postgraduate Pharmacy Seminar, University of Georgia College of Pharmacy,

Athens, GA, October 1986.

Perri M. "Effective OTC Marketing", Annual Spring Postgraduate Pharmacy Seminar, University of Georgia College of Pharmacy, Athens, GA, April 1986.

Perri M. "Graduate Programs at the University of South Carolina College of Pharmacy", American Association of Colleges of Pharmacy Regional Pharmacy Administration Section meeting, Chapel Hill, NC, May 1985.

MAJOR PROFESSOR FOR GRADUATE STUDENTS
(N=42 Students Trained)

[redacted]	Degree Program	Topic	Year of Graduation
	Ph.D.	Pharmaceutical Marketing	2018
	Ph.D.	Inappropriate Medication Use	2015
	Ph.D.	Drug Distribution in Disaster Scenarios	2013
	Ph.D.	Policy Implications of Marketing Decisions	December 2011
	Ph.D.	DTC advertising of Predictive Genetic Tests	December 2010
	Ph.D	Prior Authorization for Atypical Antipsychotic Agents	December 2009
	Ph.D.	Branded and non-Branded Direct to Consumer Prescription Drug Advertising	May 2009
	Ph.D.	The effect of coupons on DTC advertising	December 2008
	MS	Cost of Inappropriate Medication Use in Ambulatory Elderly	May 2005
	Ph.D.	e-Health Information / Compliance	August 2004
	Ph.D.	Source credibility and DTC advertising	August 2004
	Ph.D.	Effectiveness of DTC information	August 2004
	M.S.	Medication Use in the Elderly	August 2003
	Ph.D.	Antecedents of Drug Requesting Behavior in DTC Advertising	August 2003
	Ph.D.	Application of the Trans-Theoretical Model in Compliance Behavior.	August 2002
	M.S.	Impact of DTC Advertising on Physicians	May 2001
	Ph.D.	Evaluation of a Pharmacy Care Pathway	May 1997
	Ph.D	Organizational Determinants of R&D Productivity in the Pharmaceutical Industry	June 1996
	M.S.	Job Satisfaction of Community Pharmacy Technicians	August 1995
	Ph.D.	Quality of Service in the Retail Drug Setting: Expectations and Perceptions	March 1993
	Ph.D.	A Study of M Medication Taking Behavior and Health Related Quality of Life.	December 1990
	M.S.	Computerization and Clinical Pharmacy Services	May 1987
	M.S.	Initial Drug Therapy Defaulting in a Veterans Administration Hospital Pharmacy	December 1996

GRADUATE STUDENT COMMITTEES:

	Degree Program	Area of Concentration	Year of Graduation
	Ph.D	Policy	
	Ph.D.	Mixed Methods, Pharmacoeconomics	
	Ph.D.	Pharmacoeconomics and marketing	
	Ph.D.	Policy	2017
	Ph.D.	Pharmacoeconomics	2017
	Ph.D.	Substance Abuse	2015
	Ph.D.	Prostate Cancer	2013
	Ph.D.	Family and Consumer Sciences; Food insecurity and medication adherence.	2013
	Ph.D.	Media and Diabetes Education	2010
	M.S	Cost of Illness	May 2006
	Ph.D.	Antioxidant Effects of St. John's Wort	2001
	Ph.D.	Modeling Drug Recalls	1994
	M.S	Pharm Care Admin	1995
	Ph.D.	Pharmacology	1994
	Ph.D.	Pharmacology	1994
	Ph.D.	Health Economics	1993
	Ph.D.	Pharmacology and Toxicology	1993
	Ph.D.	Pharmacy Care Administration	1992
	Ph.D.	Health Economics	1989
	Ph.D.	Pharmacology	1989
	M.D.	Health Economics	1987
	M.S.	Hospital Pharmacy Practice	1987

GRADUATE / RESIDENT INSTRUCTION

Course	Years Taught
Graduate Pharmacy Seminar	1985-2020 (Course responsibility varies)
Health Care Marketing (PHRM 8660)	2013, 2015, 2017, 2019
Pharmaceutical Marketing: Directed Study	2004, 2006, 2008 – 2020
Pharmaceutical Marketing	1986- 1995
Research Methods in Pharmacy	1990, 1997, 1999-2020
Problems in Pharmacy Management	1988, 1989
Health Care Systems	1992, 1999, 2000
Special Topics in Research Methods	1991-2020
Masters Thesis Research	1986-2020
Doctoral Thesis Research	1986-2020
Community Practice Residency (Preceptor)	2002-2007

UNDERGRADUATE INSTRUCTION

Course	Years Taught
Essentials of Pharmacy Practice (Course Coordinator, lecturer, laboratory instructor)	2015
Pharmacy Communications PHRM3900, Coordinator	1994-2020
Pharmacy Management (5650): Marketing lecture series	2001-2020
Literature Evaluation & Statistics (PHRM 4650)	2008-2020
Physical Assessment Laboratory (4100)	1996-2008
Pharmacy Care Skills Laboratories	1996-2020
Pharmacy Management (396)	1986-1996

Problem Based Learning (362)	1996-1999
Third Year Experiential Learning: 5140-5150 Practice site: Athens Primary Care Medical Clinic	1999-2006
Clinical Seminar	1999 – 2020
UGA Freshman Odyssey Seminar: Strong Medicine / Your Pharmacist is a Rockstar	2011-2020

ELECTIVE COURSES TAUGHT

Course	Years Taught
Pharmaceutical and Health Care Marketing (2012)	2012 - 2020
Pharmacy Marketing	1992-1994
Undergraduate Research	1991 to 2020
Entrepreneurship	1992, 1993
Communications Skills in Pharmacy Practice	1993-1997

INVITED LECTURES TAUGHT

Course	Years Taught
Pharmaceutical and Health Care Marketing, UGA School of Public Health, Drs. Fertig, Abraham and Jayawardhana	2009, 2010, 2013, 2014
Over the counter medication use and public education, College of Education, Dr. Getch, UGA College of Education.	2002, 2003, 2004, 2005, 2008

JOURNAL REFEREE / REVIEW BOARD (Selected)

Drugs and Aging
Currents in Pharmacy Teaching and Learning
International Journal of Pharmaceutical and Health Care Marketing
Annals of Pharmacotherapy
Medical Care
Health Marketing Quarterly
JAGS (Jour American Gerontological Society)
Journal of Pharmaceutical Health Services Research
Clinical Therapeutics
American Journal of Pharmaceutical Education
Journal of Pharmacoepidemiology
Journal of Pharmaceutical Marketing & Management
American Journal of Hospital Pharmacy
Journal of Geriatric Drug Therapy
America's Pharmacist
ISPOR Annual Meeting 2009 Abstract/Presentation Reviewer
Book Reviews: Haworth Press, Oxford Press
Journal of Pharmaceutical Care (1995- 2000) Editorial Review Board
Journal of Pharmacy Technology
Journal of the Academy of Marketing Science
Sensors
Patient Care (focus on family medicine, a publication of Medical Economics))
Expert Reviews

INTERNATIONAL, NATIONAL AND STATE COMMITTEES

2010 to 2017	Board Member, International Association for Marketing and Health Care Research
2010 to 2013	Board Member, GA Drug Utilization Review Board, Georgia Department of Community Health
2004 to 2010	Chair, Drug Utilization Review Board, Georgia Department of Community Health
2005	GA Senate Ad Hoc Committee on State Funded Health Plans
2001 to 2004	Board Member, GA Drug Utilization Review Board
1997	Georgia State Board of Pharmacy Task Force on Pharmacy Workloads
1988	Georgia Delegate to the American Pharmaceutical Association Annual Meeting
1987	American Association of Colleges of Pharmacy, Faculty Delegate

UNIVERSITY COMMITTEES

2014 – 2017	Promotion and Tenure Area Review Committee
2009 – 2011	Presidents Faculty Advisory Council
2004 - 2005	Graduate Council Area Committee on Appointment and Reappointment of Graduate Faculty
2001 - 2004	University of Georgia Promotion and Tenure Area Review Committee
2002	Selection Committee, Lilly Teaching Fellows Program
2001- 2002	Chair, University of Georgia Administrative Review Committee for Gerontology
1999 – 2001	University of Georgia SACHS Accreditation Self Study Logistics Committee
1998 – 2000	University of Georgia Program Review Committee
1997 – 1998	University of Georgia Faculty Symposium on Technology in Higher Education, Steering Committee
1996 – 1999	College of Pharmacy Representative to the Graduate Council
1994 – 1995	Chair, Program Review Committee, Small Business Development Center
1989 – 1990	Self Study Committee on Faculty/Staff, University of Georgia

COLLEGE OF PHARMACY COMMITTEES

2014 to 2019	Executive Committee and Administrative Committee
2012 to 2015	Admissions Committee
2005 – present	College of Pharmacy Promotion and Tenure Committee
2012	Rite Aid Professorship Selection Committee
2011-2013	Kroger Professorship Search Committee
2013	CAP Promotion and Tenure Committee
2008 – 2010	Chair, Admissions Committee
2007 – 2008	Admissions Committee
2005 - 2007	Chair, Faculty Awards Committee
2005 – 2006	Clinical Service Supplement Plan Committee
2005	Department Head Search Committee; Clinical Track Search Committee
2004 - 2009	Graduate Education Committee
1997 to 2006	Executive Committee
1995 to 2006	Clinical and Administrative Pharmacy Graduate Education Committee
2002 – 2004	Chair, Academic Committee
2001	Academic Committee
1997 – 2001	Administrative Committee
1996 – 1997	Chair, Task Force for College Reorganization
1998, 2003	Post Tenure Review Committee
1996-1998	Faculty Affairs Committee
1992 -1998	Curriculum Committee
1992 – 1997	Promotion and Tenure Committee
1988 - 1995	Pharmacy Ethics Court Advisor

1990 – 1995	Chair, Committee on Research and Graduate Studies
1989 – 1993	Deans Executive Committee
1991	Search Committee, Dean, College of Pharmacy
1989 – 1991	Assistantships and Graduate Faculty Reappointment
1989 – 1992	Educational Planning Committee
1989 – 1990	Graduate / Research Advisory Committee
1987	Chair, College of Pharmacy, Associate Dean Search Committee
1985 – 1987	Library and Instructional Aids Committee
1985 -1989	Curriculum Committee

Other Committee Duties on a rotating basis: Facilities and Safety Committee, Admissions Committee, Graduate Education Committee, Ad Hoc Committees.

CURRENT STATE PHARMACY LICENSES

South Carolina
Georgia

CONSULTANTSHIPS

National opioid litigation, various, 2016-2020
StoneTurn (2019)
US Department of Justice (2007-2015)
Finch McCrainy (2016- present)
Wood Law Firm (2015 – present)
Shoemaker Loop and Kendrick 2014 - present
Attorney General, State of Alabama 2012-2014
Breckenridge Pharmaceuticals Inc. 2012
Attorney General, State of Texas 2006- 2012
Fish & Richardson Law Firm 2006- 2012
Ven-A-Care of the Florida Keys & The Breen Law Firm, 2006-2011
Attorney General, State of California, 2008 - 2011
United States Department of Justice, 2006- 2011
State of Georgia, Senate Committee on Health Care Costs 2005
Roger Green Associates, 2003 to 2007
Astra Zeneca, 2004
Pfizer, Inc. 2004
MPE Communications 1990 - 2000
A & D Associates, New York, 1992- 1995
The Merck Company, October 1992 - 1995
National Healthcare Operations, U.S. Pharmaceuticals Group, Pfizer, November 1992 - 1995
The West Co., Lionville PA. 1993- 1995
NARD Management Institute 1993- 1995
Promotions Unlimited Corporation, 1993 - 1995
Senetics, Inc., November 1993 - 1994
Walsh PDS, Marketing Research, Summer 1991.
The Lowman Home for the Aged, June 1981 to May 1990 (Consultant Pharmacist)
Wyeth-Ayerst Laboratories, Radnor, PA
Athens Primary Care Medical Practice 1988
Carolina Pharmacy Network, June 1986
The Babcock Centers, Inc., 1981 - 1985 (Consultant Pharmacist)

SELECTED PUBLIC SERVICE ACTIVITIES AND PRESENTATIONS

- Coach, Oconee County Wresting Program (2017-present)
- WUGA Radio: Prescription Opioids, Abuse Misuse and Deaths, Aired March 2017
- WUGA Radio: Direct-to-consumer Prescription Drug Advertsing, Aired March 2017
- Volunteer Pharmacist, Mercy Health Clinic, 2004-2007, 2012 – present. Mercy is a not-for-profit, complete health clinic for those who are uninsured or cannot afford other forms of health care.
- Coach, Cedar Shoals High School Varsity Wrestling, 1999 – 2006
- Elder, First Presbyterian Church, Athens, GA 1994-1997, Chair of Personnel Division.
- Volunteer for the Clarke County Home Delivered Meals Program, 1986-1991
- Elected Member of the Title III Advisory Board, Athens Community Council on Aging (1987-1989)
- "Bicycle Fun and Safety", at Whit Davis Elementary School, Athens-Clarke County School District, Athens, GA, March 1991.
- "Medication Use in Children and Potential Effects on Classroom Behavior", First Presbyterian Weekday School, Athens, Georgia, February 10, 1993.
- "Good Drugs, Bad Drugs", at Whit Davis Elementary School, Athens Clarke County School District, Athens, GA April and October 1994.
- "Prescription Medications" for Mended Hearts (coronary bypass surgery rehabilitation/support group) at Athens Regional Medical Center, February 12, 1996.
- "Good Drugs and Bad Drugs" for various groups in Clarke County Public Schools, 1995- 1996.
- "How to get the most from your prescription medications", Kiwanis Club, Athens GA, June 25, 1996. "How Important Are Your Prescription Medications" for the Dick Mendenhal Radio Talk Show, AM 1340, August 9, 1996.
- "Drug Free Kids," Oconee County Elem. School, December 4, 1997 (8 presentations to 3RD grade classrooms)
- Rho Chi Pharmacy Honor Society Initiation Banquet, invited keynote speaker Ride Fast, Hog the Road and Act Like Traffic, December 10, 1997.

Schedule 2: Perri Prior Testimony and Depositions

2017-Present (Last 4 Years)

Year	Case	Venue	Report – Deposition – Trial / Issues in the Case
2018	BCBS et al. v GSK	USDC – Eastern District of Pennsylvania Civil Action No. 13-cv-4663-JS	Deposition / Manufacture and marketing of prescription medications
2019	National Prescription Opioid Litigation	United States District Court for the Northern District of Ohio Eastern Division Case No. 17-MD-2804.	Deposition / Pharmaceutical marketing, opioid marketing
2019	Opioid Litigation: State of Washington; State of Utah; State of Montana	Various	Expert reports for Utah and Washington, disclosure for Montana / Pharmaceutical marketing, opioid marketing
2019	Villarreal v. Taro Pharmaceuticals	USDC – Southern District of Texas McAllen Division	Deposition / Pharmaceutical marketing, amiodarone marketing
2020	Tucson Medical Center v. Purdue Pharma L.P., et al.	Case No. C20184991	Expert report / Pharmaceutical marketing, opioid marketing
2020	Her Majesty the Queen in Right of the Province of British Columbia v. Apotex Inc, Apotex Pharmaceutical Holdings, Inc., Bristol-Myers Squibb Canada, et al.	Vancouver Registry No. S 189395	Affidavit and expert report / Pharmaceutical marketing, opioid marketing
2021	California Opioid Litigation, People v. Purdue Pharma et al.	Superior Court of the State of California, In and For the County of Orange, Case No. 30-2014-00725287 CU-BT-CXC	Expert report, deposition, trial testimony / Pharmaceutical marketing, opioid marketing
2021	New Hampshire Opioid Litigation	Docket Number 217-2018-CV-00678	Expert Report, Deposition, Opioid Marketing
2021	Rhode Island Opioid Litigation	Case No. 2018-CA_001438	Expert Report, Opioid Marketing

Bates
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TEVA_MDL_A_07241241
TEVA_MDL_A_07241244
TEVA_MDL_A_07241248
TEVA_MDL_A_07241332
TEVA_MDL_A_07241336
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TEVA_MDL_A_07242961
TEVA_MDL_A_07242962
TEVA_MDL_A_07243008
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WAGMDL00095854
WAGMDL00100080
WAGMDL00303018
WAGMDL00303209
WAGMDL00524763

Schedule 4: Perri's Document Search Terms

Initial Marketing Search Terms

Marketing, marketing plan, marketing action plan, monthly plan, business plan, action plan, sales plan, regional/territory sales plan, ride-along, home office, scheme	Marketing goals, mission, objectives, strategy tactics, implementation, long range, short range (other than documents found in the marketing and business planning documents)	Marketing / sales metrics, market share, TRx, NRx, sales, sales growth	Marketing initiative, marketing activity, marketing events, marketing strategy
Selling, MD selling, physician selling, hospital selling, grand rounds, providers, trainer, educator, facilitator, in-service, teaching, education, presentations, seminars, detailing, MSL	Promotional strategy, advertising strategy, advertising, promotion Promotional,	Organizational chart, marketing organization, marketing organizational chart	Performance evaluation, incentives, staffing
Marketing decision, marketing decision makers	Customers, decision makers, key customers, opinion leaders, KOL, advisory board, speaker, speaker bureaus, writer, ghost writer, article, journal, publication(s)	Marketing Communications, Marketing Messages, flyers, slicks, promotional pieces, power-points (customer based)	Marketing research, market intelligence, competitive intelligence
Competition, competitive analysis,	Customer orientation, understanding customer needs, needs assessment, customer perceptions, customer surveys	Target market, segmentation, market segment, market segment	Product/Service positioning, positioning, image, brand image,
Marketing management, marketing administration	SWOT, SWOT analysis, strengths, weaknesses, opportunities, threats	Sales goals, sales training, incentives, compensation, sales compensation	Sales call, call records, sales planning, sales meeting, sales training, call log, weekly call log, sales report, sales log
Marketing metrics, admission, census, length of stay, information system	Promotional pieces, flyers, sales flyers, sales aids, marketing materials, corporate marketing materials,	Pricing, reimbursement, Medicaid, Medicare, out of pocket, private pay, coding, billing codes, insurance, insurance coverage; CAP; Medicare CAP, eligibility	Service, services, value added
External market environment, PHRMA, public relations, media, FDA, policy, guidelines, regulations,	CIA, Compliance	Price, price reporting, AWP, AMP, WAC, etc.	Product, service, features, benefits, patient centered care; excellence in care; customer satisfaction; shared decision making, comparative effectiveness
Product, production, supply chain, distributors, contracting, source program	Marketing and manufacturing overlap of terms, marketing, and regulatory overlap	Direct-to-consumer, branded/unbranded advertising, campaign, promotions	Market, sell, research, develop, test, evaluate, promote, educate, inform (Product Development and Marketing)
Patient advocacy, advocacy groups, non-profit, consumer representative, patient representative	Personal selling, face-to-face, in person, physician interaction	Product life cycle, product extension, patent extension	Distribution, distributor, contracting, account manager, wholesaler, wholesaler agreements, source program, wholesaler services

Bates Begin	Document Date	Document Description
	12/20/2019	Rhode Island -- Second Amended Complaint
	4/21/2020	Responses and Objections of Defendant Watson Laboratories et al. to Plaintiff's First Set of Interrogatories in Rhode Island v. Purdue
	8/9/2018	Amended Responses and Objections of Defendants Teva Pharmaceuticals USA, Inc. and Cephalon Inc. to Plaintiff's First Set of Interrogatories in Rhode Island v. Purdue
	9/30/2019	Responses and Objections of Defendant Watson Laboratories et al. to Plaintiff's Second Set of Interrogatories in Rhode Island v. Purdue
	4/28/2020	Responses to Plaintiff's Fourth and Second Set of Set of Interrogatories in Rhode Island v. Purdue
	6/8/2020	Teva Defendants' Responses and Objections to Plaintiff's First Requests for Admission in Rhode Island v. Purdue
	9/9/2020	Teva Defendants' Responses and Objections to Plaintiff's Fifth and Third Interrogatories in Rhode Island v. Purdue
	6/4/2019	Teva Defendants' Responses and Objections to Plaintiff's First Set of Interrogatories in Rhode Island v. Purdue
	9/10/2020	Michael Collins deposition transcript and exhibits in Rhode Island v. Purdue et al
	9/14/2020	Tim Sweeny deposition transcript and exhibits in Rhode Island v. Purdue et al
	9/9/2020	Timothy McMahon deposition transcript and exhibits in Rhode Island v. Purdue et al
		Fentora Targeting Report (James Mara CA deposition, Exh. 018)
	2/20/2019	Deposition of Paul Pyfer, In Re National Prescription Opiate Litigation
	1/11/2019	Deposition of Terrence Terifay In Re: National Prescription Opiate Litigation
	1/26/2021	Deposition of Paula Williams in City of Chicago v. Purdue Pharma, transcript and exhibits
	3/4/2021	Deposition of Robert Roche in City of Chicago v. Purdue; State of Ohio v Purdue; State of NM v. Purdue; Jared Effler v. Purdue; Mobile county Board of Health v. Sackler -- transcript and exhibits
Acquired_Actavis_00369839	11/00/2011	Regional Meetings November 2011 Generic KADIAN Sales Team Training
Acquired_Actavis_02283431	8/2/2011	Email from Ara Aprahamian to Hepp, Shepherd, Killion and McClanahan re: Oxymorphone ER 7.5mg and 15mg Follow Up

Acquired_Actavis_02283432	7/00/2011	Introduction of Oxymorphone Hydrochloride Extended-Release Tablets, CII; Sales Training Class
ACTAVIS0238310	2/18/2010	FDA Warning Letter re: NDA #20-616 Kadian (morphine extended-release) Capsules, CII
ACTAVIS0321896	2/00/2012	Realizing our vision, Building a Global Leader in Generic Pharmaceuticals
ACTAVIS0335952	11/17/2011	Email from Mark Killion to Nathalie Leitch re: T3 Bonus
ACTAVIS0357903	7/18/2011	Email from Mark Killion to Jennifer Altier and Nathalie Leitch re: Compliance presentation
ACTAVIS0357904	7/25/2011	Compliance Update, July 25, 2011, Presented by Mark Killion and Scott Miller
ACTAVIS0361608	6/28/2011	Email from Nathalie Leitch to jaltier2001@yahoo.com re: 10-38 Kadian Final Report.pttx
ACTAVIS0361609		Kadian LAO Decision-Making Process, Qualitative Research Interviews
ACTAVIS0413235	7/10/2012	Email from Mark Killion to Jennifer Altieri attaching Kadian Training Manual (Altieri Ex. 013)
ACTAVIS0578145		slideshow re Generics marketplace
ACTAVIS0799203	2/18/2010	FDA Warning Letter re: NDA #20-616 Kadian (morphine extended-release) Capsules, CII
ACTAVIS0815204	8/26/2011	Email from Nathalie Leitch to Jennifer Altier re: Weekly Update
ACTAVIS0816997	8/10/2011	Email from Christopher Hepp to Patrick McClanahan re: A347 Oxymorphone Training Materials
ACTAVIS0969302	7/20/2011	Email from Christopher Hepp to Michael Shepherd, Nathalie Leitch, Mark Killion, Patrick McClanahan re: A347 Oxymorphone Training Materials
ALLERGAN_CA_00021905	7/11/2018	Letter from FDA to Nicola Walters, Allergan Sales re NDA 020616
ALLERGAN_CA_00034597		spreadhseet with call information, 2002-2016
ALLERGAN_CA_00092503	10/4/2017	Email from Janet Pientka to Tara Brolly re: Info about ERLA shared REMS - from Carla to Lauren/Carla's departure
ALLERGAN_CA_00093277	10/13/2017	Email from Bernadette Oades to Janet Pientka re: Kadian details - email I spoke of and RPC Slides
ALLERGAN_MDL_00003124	8/1/2013	CA Call Notes - Actavis Monthly Call Report, 8/1/2012 to 8/1/2013
ALLERGAN_MDL_00011232	1/8/2013	Email from Jennifer Altier to Bill Reggio re: KADIAN Training Module; attaching: KADIAN LEARNING SYSTEM 07 01 2010.pdf; Kadian_LMS_TEST_NoCompetitverProducts.doc
ALLERGAN_MDL_00011234	7/1/2010	Kadian Learning System
ALLERGAN_MDL_00156509	11/7/2011	Email from Michael Perfetto to Doug Booth and Terrence Fullem re: oxymorphone Rx
ALLERGAN_MDL_00182779		spreadsheet with regional KOL data
ALLERGAN_MDL_00182780		spreadsheet with regional KOL data

ALLERGAN_MDL_00419788	10/00/2011	Actavis and Kadian, Pilot ABM Training, October, 2011
ALLERGAN_MDL_00439499		Kadian Learning System
ALLERGAN_MDL_00449945	5/7/2009	Email from Mike Hilton to Nathalie Leitch attaching: Kadian_Slides_for_Speaker_Training_with_MLRcmts_2_22.ppt
ALLERGAN_MDL_00449946		Managing Chronic Pain and the Importance of Customizing Opioid Treatment
ALLERGAN_MDL_00451338	3/7/2011	Email from Christopher Hepp to Robin Hagy re: Field contact Report 03/01-02/2011
ALLERGAN_MDL_00451339	3/00/2011	Field contact Form, Chris Hepp
ALLERGAN_MDL_00508576	8/26/2011	Email from David Myers to Michael Perfetto re Oxymorphone Promotion and chargeback results to date (Myers Ex. 020)
ALLERGAN_MDL_00684866	8/26/2011	E-mail from Jinping McCormick to John Hansen, Wendy Winter, Aubrey Sambrano cc: Ara Aprahamian, Michael Perfetto Re: Follow-up discussion re: Actavis Oxymorphone campaign
ALLERGAN_MDL_00684867	06/00/2011	Generic Now Available from Actavis
ALLERGAN_MDL_00684896		Presentation - Introduction of Oxymorphone Hydrochloride Extended-Release Tablets, CII
ALLERGAN_MDL_00950093	4/00/2011	A Proposal for an Accredited Education Program to Improve the Knowledge, Attitudes, and Practice Patterns of Physicians on the Topic of Opioids and Related REMS Guidelines, April 2011
ALLERGAN_MDL_01001415	10/24/2012	Email from Jennifer Altier to Dinorah Suriel re: Actavis eConnection proof for the Campaign Kadian
ALLERGAN_MDL_01051068	6/11/2010	Email from Nathalie Leitch to Tipp Nelson and Terrence Fullem re: Actavis
ALLERGAN_MDL_01107612	4/21/2010	Email from Nathalie Leitch to Tom Johnson re: Hi - and Kadian; attaching: 108 redacted kadian 2008 Brand Plan Part 1.zip
ALLERGAN_MDL_01107617	2008	Kadian 2008 Brand Plan
ALLERGAN_MDL_01108658	6/24/2010	Email from Nathalie Leitch to Lorraine Petrovsky attaching: Kadian Learning System 5.09.pdf
ALLERGAN_MDL_01108659		Kadian Learning System
ALLERGAN_MDL_01114172	2007	2007 KADIAN Speakers Bureau_03-
ALLERGAN_MDL_01114173		Kadian Speakers 1
ALLERGAN_MDL_01116174	11/1/2010	Email from Christopher Hepp to Debbie Webb re: Field Contact Form
ALLERGAN_MDL_01116175	10/26/2010	Field contact Form, Chris Hepp
ALLERGAN_MDL_01126762	10/00/2012	Kadian Dosing Guide
ALLERGAN_MDL_01199791	1/26/2011	Email from Christopher Hepp to Richard Askew re: Field contact Form
ALLERGAN_MDL_01199792	1/20/2011	Field contact Form, Chris Hepp
ALLERGAN_MDL_01234649	12/14/2009	Email from David Myers to Elisabet Hjaltadottir re: Actavis Bran Project update; attaching: kadian.pdf
ALLERGAN_MDL_01234652		Kadian, less pain more options

ALLERGAN_MDL_01338506	2/22/2016	Email from Christine Maolo to Alexis Evolga and Michael Dorsey re: WAGs MORPHINE SULFER - KADIAN
ALLERGAN_MDL_01399181	2010	CA Call Notes - Actavis Field Status Report, Aug, Sept, Oct 2010
ALLERGAN_MDL_01399182	2010	CA Call Notes - Actavis Field Status Report, Aug, Sept, Oct 2010
ALLERGAN_MDL_01451249	6/28/2011	Email from Nathalie Leitch to Beth Zelmick-Kaufman and Arnetha Wharton re: 2010 KADIAN Expenses; attaching: Kadian Exp 2010 Actuals.xls; image001.gif
ALLERGAN_MDL_01451251	2010	Kadian 2010 Expenses Budget
ALLERGAN_MDL_01466309	11/6/2009	Submission from Lucy Gary (Actavis) to FDA Re: NDA #20-616 Kadian (morphine sulfate extended-release) capsules
ALLERGAN_MDL_01466324	2/16/2009	Submission from Lucy Gary (Actavis) to FDA Re: NDA #20-616 Kadian (morphine sulfate extended-release) capsules
ALLERGAN_MDL_01466348	10/20/2009	Submission from Lucy Gary (Actavis) to FDA Re: NDA #20-616 Kadian (morphine sulfate extended-release) capsules
ALLERGAN_MDL_01540065		CA Call Notes, 2005 - 2008
ALLERGAN_MDL_01610520	1/15/2013	Email from Jennifer Altieri attaching Kadian Training Manual (Altieri Ex. 002)
ALLERGAN_MDL_01614093		CA Call Notes -Kadian HCP database
ALLERGAN_MDL_01692522	1/27/2010	Email from Nathalie Leitch to James Burt and Terrence Fullem re: urgent; attaching: NSM Presentation Jan 2010.ppt
ALLERGAN_MDL_01741588	10/27/2009	Managing Chronic Pain and the Importance of Customizing Opioid Treatment
ALLERGAN_MDL_01745342	1/28/2011	Email from Nathalie Leitch to Ivailo Georgiev re: Kadian; attaching 2011 Goals and Priorities FINAL.pdf; Marketing Presentation FINAL.pptx; 2010 Results FINAL.pptx
ALLERGAN_MDL_01745345	2011	"Putting It All Together" 2011 KADIAN National Sales Meeting
ALLERGAN_MDL_01745376	2011	"Putting It All Together" 2011 KADIAN National Sales Meeting
ALLERGAN_MDL_01745417	2011	"Putting It All Together" 2011 KADIAN National Sales Meeting
ALLERGAN_MDL_01746794	2011	CA Call Notes - TMSUpdate
ALLERGAN_MDL_01870026	2010	CA Call Notes - Actavis Field Status Report, Aug, Sept, Oct 2010
ALLERGAN_MDL_01890663		CA Call Notes - Actavis Call Activity, 2009 - 2012
ALLERGAN_MDL_02104539	1/10/2011	Submission from Charlene Salmorin to FDA Re: NDA #20-616 Kadian (morphine sulfate extended-release) capsules

ALLERGAN_MDL_02104585	10/14/2010	Submission from Charlene Salmorin to FDA Re: NDA #20-616 Kadian (morphine sulfate extended-release) capsules
ALLERGAN_MDL_02104760	9/2/2010	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
ALLERGAN_MDL_02104775	9/2/2010	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
ALLERGAN_MDL_02104857	10/29/2009	Submission from Lucy Gary (Actavis) to FDA Re: NDA #20-616 Kadian (morphine sulfate extended-release) capsules
ALLERGAN_MDL_02104934	2008	Kadian prescriber information
ALLERGAN_MDL_02104948	2008	Kadian promotional material
ALLERGAN_MDL_02105236	01/00/2012	Kadian Dosing Guide
ALLERGAN_MDL_02105256	3/2/2012	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
ALLERGAN_MDL_02105271	12/12/2011	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
ALLERGAN_MDL_02105286	11/18/2011	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
ALLERGAN_MDL_02105564	6/16/2011	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
ALLERGAN_MDL_02105628	4/20/2011	Submission from Charlene Salmorin to FDA Re: NDA #20-616 Kadian (morphine sulfate extended-release) capsules
ALLERGAN_MDL_02105658	3/30/2011	Submission from Charlene Salmorin to FDA Re: NDA #20-616 Kadian (morphine sulfate extended-release) capsules
ALLERGAN_MDL_02105779	2/23/2011	Submission from Charlene Salmorin to FDA Re: NDA #20-616 Kadian (morphine sulfate extended-release) capsules
ALLERGAN_MDL_02105796	2/23/2011	Submission from Charlene Salmorin to FDA Re: NDA #20-616 Kadian (morphine sulfate extended-release) capsules
ALLERGAN_MDL_02107016	10/00/2010	Kadian Dosing Guide
ALLERGAN_MDL_02107030	09/00/2010	Kadian Dosing Guide
ALLERGAN_MDL_02107034	2012	Kadian Dosing Guide
ALLERGAN_MDL_02169261	03/00/2007	Kadian Precise Relief. Personalized pain relief. Learn more about customized pain control with KADIAN.
ALLERGAN_MDL_02186009	8/11/2017	Email from IR-Medcom to Risha Patel re: FW New Customer: Stacie Noetzelmann
ALLERGAN_MDL_02449320	3/16/2014	03.16.14 Authorized Speakers; Master Screening File; RandomSpeakerList
ALLERGAN_MDL_02513100	4/25/2006	KADIAN Advocacy Development; Brainstorming Meeting, April 25, 2008
ALLERGAN_MDL_03223455	2010	CA Call Notes - 2010 Calls

ALLERGAN_MDL_03684488	6/20/2011	Email from David Myers to Michael Perfetto and others re: Oxymorphone Launch Preparation with attachment(Myers Ex. 014)
CA-2236.0001		Endo Payments to NIPC, 2003-2012
CHI_000324959	2/11/2011	email from Samantha Libby-Cap to APF Staff re Special Announcement to HCP member: Live dinner Dialogues on responsible Opioid Prescribing in the Era of REMS
CHI_000432477		Finding Help for Your Pain, A Pain Resource Guide, American Pain Foundation
CHI_000435580	2000	Reading this could help ease your pain, Pain Action Guide, American Pain Foundation
CHI_000466610		spreadsheet
CHI_000872159	2/8/2012	Email from Lisa Ward to Allstaff re: URL: Live Dinner Dialogues on Responsible Opioid Prescribing
CHI_001216652	12/20/2011	NIPC, APF Educational Grant Request for the National Initiative on Pain Control
CHI_002389086	10/7/2007	Email from Chris Handler to Greg Panico re: AAPM Day Three and Four Summary (Sept. 29-30)
DCAG_0000458		The Diversion of Controlled Pharmaceuticals
END00033272		APF-NIPC Dinner Dialogues Series: Responsible Opioid Prescribing in the Era of REMS
END00065654		Registration form for Responsible Opioid Prescribing in the Era of REMS
END00350906	2009	Educational Grant Request Form for program title, "2009 Proposal for Moderate-to-Severe Chronic Pain Collateral Activities: Addressing and Closing Practice Gaps in the Appropriate Use of Opioid Analgesia"
END00350909	2/26/2009	2009 Proposal for Moderate-to-Severe Chronic Pain Collateral Activities: Addressing and Closing Practice Gaps in the Appropriate Use of Opioid Analgesia
END00442647	4/7/2011	Email from Linda Kitlinski to Samantha Libby-Cap re NIPC Status Update and more...
END00446251	2/17/2011	email from Samantha Libby-Cap Kitlinksi, Reese re: NIPC Status Update
END00446252	2/17/2011	National intitiative on Pain Control as of February 17, 2011
END00446260	2011	Responsible Opioid Perscribing in the Era of REMS Dinner Dialogues Series Registration Counts
END00448666	2011	Educational Grants Decision Report 2011
END00692522	2013	PER Number Assignment 2013
END00733192	2012	CA Call Notes - Pain and Other Products Reps, 1/1/2012 - 9/25/2012; Endo Urology Reps, 1/1/2012 - 9/25/2012; Endo Sales Rep Report, 1/1/2012 - 9/25/2012
END00735355	2006	PER Number Assignments
END00735356	2007	PER Number Assignment 2007

END00735357	2008	PER Number Assignment 2008
END00735359	2010	PER Number Assignment 2010
END00735360	2011	PER Number Assignment 2011
ENDO-CA-00000001		CA Call Notes, 2007 - 2016
ENDO-CA-00003155	2009	CA Call Notes - Call Detail Printout from Endo's Sales Force Automation (SFA) Trex System
ENDO-CA-00006454	6/16/2009	ENDOSell Coaching Report - Marciela Chaldez
ENDO-CA-00006464	7/15/2009	ENDOSell Coaching Report - Chris Pastor
ENDO-CA-00006467	7/27/2009	ENDOSell Coaching Report - Erin Carlson
ENDO-CA-00039141	7/27/2009	ENDOSell Coaching Report - Erin Carlson
ENDO-CA-00164784		re HCP meal expenses, 2007-2012
ENDO-CA-00164785		re HCP meal expenses, 2012-2015
ENDO-CA-00168859		CA Call Notes - Endo International plc Compliance Year 2 Records Review Monitoring, Records Review Issues Tracker, 2/21/2015 - 2/20/2016
ENDO-CA-00169808	7/00/2016	CA Call Notes
ENDO-CA-00170995	7/20/2009	ENDOSell Coaching Report - Tyler Case
ENDO-CA-00170998	7/27/2009	ENDOSell Coaching Report - Erin Carlson
ENDO-CA-00256652	7/17/2009	Email from Kelvin Chung to Donna Rickman, Ruth Njuguna, Lynnel Anderson and Chris Patterson re: ECR for 7-15 and 7-16
ENDO-CA-00256653	7/15/2009	ENDOSell Coaching Report - Kelvin Chung
ENDO-CA-DATA-00000006		spreadsheet with Opana IR call data, 2008 and 2009
ENDO-CHI_LIT-00023394	6/00/2009	Opana ER - Situation Analysis, Marketing Science "Insights to Impact", Cassie Mapp, June 2009
ENDO-CHI_LIT-00024370	8/28/2008	Opana Brand Quarterly Review
ENDO-CHI_LIT-00043048	1/15/2010	Email from Toja Riley to Simon, Wyse, Bingol re: 2010 Opana ER Promotional Slide Decks ("Attached are the Approved Opana ER Promotional Slide Decks for 2010")
ENDO-CHI_LIT-00043049		The Role of Opana ER in the Management of Moderate to Severe Chronic Pain
ENDO-CHI_LIT-00043054		Opana ER; For the Management of Moderate to Severe Chronic Osteoarthritis (OA) Pain
ENDO-CHI_LIT-00043059		Opana ER; For the Management of Moderate to Severe Chronic Low Back Pain
ENDO-CHI_LIT-00053284	2006	Oxymorphone Learning System, Module 3, Oxymorphone Risk Management Program
ENDO-CHI_LIT-00079368		Count Down to National Sales Meeting, Presented by Joanne Manidis
ENDO-CHI_LIT-00084048	10/15/2010	Email from Ellen Keane to Treca Adams and others re: FW Opana ER Resources
ENDO-CHI_LIT-00154563	2008	Opana Meeting Budgets by Region
ENDO-CHI_LIT-00167089	8/13/2008	Email from Tara Piotrowski to Demir Bingol re: Opana Master Lists - Cancellation Summary Updated
ENDO-CHI_LIT-00167091	06/00/2008	Speakers information
ENDO-CHI_LIT-00184665	2009	Vendor Program Reports, Opana Programs

ENDO-CHI_LIT-00210473	2/00/2007	Memo to Endo Sales Team from The OPANA Brand Team re: OPANA ER Call Plan Document: Message and Support Materials
ENDO-CHI_LIT-00280922	12/5/2012	Confirmed Opana ER Programs
ENDO-CHI_LIT-00280923	2012	Opana ER Speaker Bureau Confirmed Programs
ENDO-CHI_LIT-00283553	3/7/2013	Email from Alicia Logan to Rhianna Trice re: Speaker Program Stuff
ENDO-CHI_LIT-00283571	2012	Opana ER; with INTAC Technology; 2012 Faculty Forum Speaker Training
ENDO-CHI_LIT-00329674	8/8/2011	email from Gregory Pyszczymuka to Matthew Wieman re; Slides
ENDO-CHI_LIT-00329675	7/00/2011	Opana ER; Extended-Release Tablets, Challenges of Treating Moderate to Severe Chronic Pain
ENDO-CHI_LIT-00395461	1/3/2011	Email from Phyllis Enfanto to Gregory Pyszczymuka re Speaker programs
ENDO-CHI_LIT-00395462	2010	Opana Allocation Summary
ENDO-CHI_LIT-00403782	9/8/2011	email from Gregory Pyszczymuka to Cochran, Gilbert, Price, Mendez, Keane, Jackson re FW Weekly Client Status Call - 9/8/11
ENDO-CHI_LIT-00403784	2011	speakers information
ENDO-CHI_LIT-00466249	12/12/2012	Email from Kristin Vitanza to Alicia logan re: Old Opana ER slide decks
ENDO-CHI_LIT-00466250		Opioid Treatment Options for the continuum of Care in Pain Management, Supplemental Slides
ENDO-CHI_LIT-00466251		Opioid Treatment Options for the continuum of Care in Pain Management
ENDO-CHI_LIT-00466252		Opana ER Case Studies
ENDO-CHI_LIT-00466253		Opioid Treatment Options for Chronic Pain Management: considerations for Primary Care Physicians
ENDO-CHI_LIT-00466254		Understanding the CYP450 System in Moderate to Severe Chronic Pain Patients Treated with Opioids
ENDO-CHI_LIT-00466255		Opioid Treatment Options for the Continuum of Care in Pain Management
ENDO-CHI_LIT-00466256		Managing Chronic Pain in the Opioid-Naïve and Opioid-Experienced Patients
ENDO-CHI_LIT-00466257		conversion and dosing Strategies for Opana and Opana ER: How, Why, and When
ENDO-CHI_LIT-00473077	5/13/2013	Email from Julie Sykes to Rhianna Trice re: Confirmed Opana ER program report
ENDO-CHI_LIT-00473078	2013	ENDO Speaker Bureau Confirmed Programs
ENDO-CHI_LIT-00551009	5/26/2006	Email from Peter Lankau to John Buckingham and others re FW Penwest DRAFT Manufacturing & Marketing Plan 2
ENDO-CHI_LIT-00551010		Powerpoint: Oxymorphone ER Marketing Plan Post-Launch, Amy Romero

ENDO-OPIOID_MDL-00298948		Letter from FDA to Endo Pharmaceuticals re NDA dataed December 19, 2002
ENDO-OPIOID_MDL-00483947	2012	Opana ER Speaker Bureau Confirmed Programs
ENDO-OPIOID_MDL-00567270	2010	Scientific Affairs Patient Advocacy Activity/National & State Initiatives
ENDO-OPIOID_MDL-00567280	10/8/2010	State pain Initiatives Q3 2010 Summary of Scientific Affairs & CAM Activities/Support, October 8, 2010
ENDO-OPIOID_MDL-00644449	6/24/2012	Email from Larry Romaine to Kenneth Price re: Opana ER speaker porgram update - Midwest Region
ENDO-OPIOID_MDL-00673955	12/28/2009	Email from Toja Riley to Anderson, Jackson, Price, Bingol, Cochran, Keane re: 2009 Speaker Programs to be completed
ENDO-OPIOID_MDL-00673957	2009	Speakers information
ENDO-OPIOID_MDL-00780308	4/2/2008	Email from Ronald Jackson to various re FW: OPANA Speaker Program Status - Important Action Items!
ENDO-OPIOID_MDL-00780314	2008	2008 Opana Faculty Forum Speaker Roster
ENDO-OPIOID_MDL-00786302	11/15/2008	Email from Ronald Jackson to Sarah Francis re FW reports
ENDO-OPIOID_MDL-00786304	2008	Vendor program reports
ENDO-OPIOID_MDL-00795064	10/14/2009	Email from Chad Simon to Robert Lee re: Opana
ENDO-OPIOID_MDL-00795066	2008	Opioid Treatment Options for the continuum of Care in Pain Management
ENDO-OPIOID_MDL-00795090	2008	Management of Chronic Pain in the Opioid-Naïve and Opioid-Experienced Patients
ENDO-OPIOID_MDL-00795118	2008	Opioid Treatment Options for Chronic Pain Management: Considerations for Primary Care Phsycians
ENDO-OPIOID_MDL-00866675	6/27/2007	Email from Kristin Vitanza to Cochran, Jackson, Keane, Kampfl, Brassil, Ferstler, Ciullo re: OPANA ER Speaker Program Weekly Status Report - 3 attachments
ENDO-OPIOID_MDL-00866677	6/25/2007	OPANA Dinner Meeting Master List
ENDO-OPIOID_MDL-01053500	12/21/2006	Email from Kristin Vitanza to various re UPDATED: OPANA ER Dinner Meeting Status Report - 2006 and 2007
ENDO-OPIOID_MDL-01053502	12/19/2006	OPANA Dinner Meeting Master List
ENDO-OPIOID_MDL-01292653	6/11/2012	Email from Larry Romaine to Kathleen Crenshaw re FW: Official Launch of Opana ER Bran Liasion Program - Next Steps and Final Assignments
ENDO-OPIOID_MDL-01463855		Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain, Evidence Review, The American Pain Society in Conjunction with The American academy of Pain Medicine
ENDO-OPIOID_MDL-01605952	2001	Opioid Analgesics in Nonmalignant Pain. Hewitt, D. J. 2001. Pain Management Today. Vol 1.
ENDO-OPIOID_MDL-01607905	2009	PER Number Assignment 2009

ENDO-OPIOID_MDL-01664131		Understanding the Dynamics of Treating Moderate-to-Severe Chronic Pain
ENDO-OPIOID_MDL-01726376	9/9/2008	Email from Demir Bingol to Catherine Loughead
ENDO-OPIOID_MDL-01726379	9/8/2008	OPANA Dinner Meeting Master List
ENDO-OPIOID_MDL-01861224	8/10/2006	email from J.P. Brassil to Jackson, Kampft, McLaughlin re "htursday Lunch Topics"
ENDO-OPIOID_MDL-02152345		New Opana; New Opana ER; New Opioid Treatment Options for the Continuum of Care in Pain Managment
ENDO-OPIOID_MDL-02192656		Speakers information
ENDO-OPIOID_MDL-02344002	2000	CD&E: The Critical Connection for Success in 2000 and Beyond
ENDO-OPIOID_MDL-02472180	10/31/2016	Email from Colleen Lindell to Vin Tormo re: Documentation
ENDO-OPIOID_MDL-02472193	9/00/2016	Speakers information
ENDO-OPIOID_MDL-02818218	2010	CA Call Notes
ENDO-OPIOID_MDL-03458088	2/00/2006	RiskMAP Update for Oxycodone Extended Release Tablets (10 mg, 20mg, 40mg, 80mg)
ENDO-OPIOID_MDL-04095507	3/25/2002	Email from Kristin Livingston to Dorothy Brady and others re: Risk Management Presentation
ENDO-OPIOID_MDL-04095508		powerpoint: Endo Risk Management Strategy
ENDO-OPIOID_MDL-04283892	2010	CA Call Notes
ENDO-OPIOID_MDL-05967764	1998	Clinical Development & Education 1998 Mid-Year Update on Goals & Objectives, Linda A Kitlinski
ENDO-OPIOID_MDL-06234663		Note from Clinical Development & Education (CD&E) regarding: PER #11018 - American Pain Society (Kitlinksi exhibit 004)
ENDO-OR-CID-00772464		Letter from Frank Casty to Julie Suko re: Reformulated Opana ER
EPI000005372	6/14/2012	Memo from Greg to Mary re 2012 SOW for Media Campaign (inVentiv Communications and Opana ER)
EPI000309119		CA Call Notes, 2009 - 2010
EPI000596338	2008	Opana Faculty Forum Speaker Roster
EPI000799695	3/8/2004	ENDO Pharmaceuticals Inc. Oxymorphone Extended Release (ER)Tablets EN3202 Risk Management Plan for Oxymorphone Extended Relaese (ER) Tablets
JAN00012142	6/6/2011	Nucynta ER Launch Plan; NSD-RBD Meeting, June 6th, 2011
JAN00012389	2012	2012 Business Plan Forecast: Nucynta & Nucynta ER
JAN00013583	11/00/2010	Nucynta ER Launch Visual Aid Testing (Part One)
JAN00015164	9/28/2010	PSI Pharmastrat, Inc.; Nucynta ER: Physician Assessment of Patient Cost/Co-Pay & Willingness to Pay
JAN00019054	2012	spreadsheet: 2012 Brand Investment Summary
JAN00021291		Nucynta BIOMM Visualization Phase II
JAN00021393	12/20/2012	Nucynta 2013 BP Review

JAN-0006-0001860		spreadsheet with Speaker data, including honorarium, expenses, topics and projects
JAN-0006-0001861	2010	spreadsheet with Speaker data, including meeting dates, locations, honorarium, expenses, topics and projects, 2010
JAN-0006-0001862		spreadsheet with Speaker data, including honorarium, expenses, topics and projects
JAN-0006-0001863	2011	spreadsheet with Speaker data, including meeting dates, locations, honorarium, expenses, topics and projects, 2011
JAN-0006-0001864	2012	spreadsheet with Speaker data, including meeting dates, locations, honorarium, expenses, topics and projects, 2012
JAN00124243		Nucynta ER Frequently Asked Questions (FAQs)
JAN00222151	4/10/2006	Duragesic website
JAN00222296		Patient Booklet Answers to your Questions
JAN-CA-00000004		CA Call Notes 2006, 2008
JAN-CA-00000005		CA Call Notes, 1992 - 1999
JAN-CA-00000006		CA Call Notes, 1996 - 2002
JAN-CA-00000007		CA Call Notes 2013, 2015
JAN-CA-00000008		CA Call Notes 2013, 2015
JAN-CA-00000009		CA Call Notes, 2002 - 2005
JAN-CA-00000010		CA Call Notes, 2002 - 2006
JAN-CA-00000011		CA Call Notes, 2005 - 2007
JAN-CA-00000012		CA Call Notes, 2006 - 2008
JAN-CA-00000349	10/00/2011	NUCYNTA ER, New Perspectives in the Management of Moderate to Severe Chronic Pain
JAN-CA-00001179		CA Call Notes, 2010 - 2013
JAN-CA-00001180		CA Call Notes, 2009 - 2010
JAN-CA-00001181		CA Call Notes, 2013 - 2015
JAN-CA-00001182		CA Call Notes, 2013 - 2015
JAN-CA-00001183		CA Call Notes, 2009 - 2012
JAN-CA-00001184		CA Call Notes, 2009 - 2013
JAN-CA-00002096	2015	Johnson & Johnson Code of Business Conduct: Live Our Credo, Know Our Code
JAN-CA-00057477	7/26/2005	Key Strategic Drivers of our Vision
JAN-CA-00103177	2010	PriCara PAIN Pre-Work Business Analytics Workshop, 2010 Cycle 1
JAN-CA-00103206	8/30/2010	Email from Russell Stough to Denise Arredondo and others re FW Anthem / WellPoint Nucynta Targets
JAN-CA-00103208		spreadsheet re WellPoint Targets
JAN-CA-00103209	12/9/2010	Email from Russell Stough to Craig Abraham re FW Nucynta Wolters Kluwer Data
JAN-CA-00103211		spreadsheet with data re MCO (health plans) claims and co-pays for Nucytna in 2010
JAN-CA-00103522		spreadsheet with data re regional pain summaries

JAN-CA-00103825	2/26/2010	Email from Molly Chassey to Kristine Kennedy re Business Plan
JAN-CA-00103826		spreadhsheet with data including Orange County SWOT, 2009 budgets, critical issues and tactics, core physicians, scorecards, top prescribers, hospitals, pharmacies and speaker programs
JAN-CA-00103864	3/9/2010	Email from Tea Damavandi to Molly Chassey re: detail suggestion, please do not forward
JAN-CA-00103880	3/12/2010	Email from Molly Chassey to Kristine Kennedy re: Opportunity
JAN-CA-00105074	11/24/2009	Email from Tea Damavandi to Karen Martin re: Updated Savings Card data
JAN-CA-00105123	5/28/2010	Email from Karen Martin to Cynthia Baker re: FW Call Frequency to Rx Converter
JAN-CA-00105124		spreadsheet: Nucynta call frequency to Rx converter
JAN-CA-00116577	10/15/2009	Email from will Fitzpatrick to Tammi Acord and others re: FW 28 Nucynta S-Program attendance vs. Scripts Wk 10-2-09.xls
JAN-CA-00116578		spreadsheet: PriCara Pain - Weekly Summary Report
JAN-MD-00009089	7/19/2012	Email from Elan Abutbou to Scott Brunton re FW: District Meeting Follow Up
JAN-MD-00009092	7/17/2012	powerpoint: "It's on Like Donkey Kong"
JAN-MD-00136498		PriCara Northeast Pain Region memorandum to Mary Bradley, Dave Luby, Seth Moskos, Kim Chappelle, Lisa Carlista, Donna Nicolosi, James Glover, Meshia Grierson, Sal Como, Rachel Sassi RE: EAGLE CAMP follow-up - sales force training program (Nicolosi Ex. 17) (State of NH v. Johnson & Johnson)
JAN-MD-00203098		Tapentadol ER DM Pull-Through Guide (M. Mosseau Ex. 3) (State of NH v. Johnson & Johnson)
JAN-MS-00007119	8/8/2008	Letstalkpain.org site architecture
JAN-MS-00016322		Management of Pain, Modul 1: Diagnosis of Pain
JAN-MS-00023677		Nucynta and Nucynta ER Cycle 1 Meeting
JAN-MS-00027525		Nucynta ER Messaging Evolution Full Report
JAN-MS-00068759		Chronic Pain Management Message Platform
JAN-MS-00230364	11/12/2010	Letter from FDA to Roxanne McGregor-Beck re NDA # 022304
JAN-MS-00235949	5/00/2010	Nucynta: An Advance in Multimodal Analgesic Therapy
JAN-MS-00236075	6/00/2009	Nucynta: An Advance in Multimodal Analgesic Therapy
JAN-MS-00236189	3/00/2011	Nucynta: A New Perspective for Moderate to Severe Acute Pain Relief: A Focus on the Balance of Efficacy and Tolerability
JAN-MS-00259643	1/19/2010	Correspondence from Lisa Ferguson to Matthew Mosseau RE: Meeting with Injured Workers Pharmacy, Cycle Meeting, OZ Principle presentation

JAN-MS-00271169		APS Activities
JAN-MS-00272800	2/00/2010	Flyer for Nucynta virtual speaker program
JAN-MS-00274566		INROADS Web Conference Par 1: Navigating the Maze of Pain Medication
JAN-MS-00288318	7/11/2013	Email chain from Patricia Yap to Dominic Lazzaro RE: K02TLE133008 RE: Direct Mail Shipment of PNMT Cards with Call Center Sticker
JAN-MS-00288433	9/9/2013	Email chain from Patricia Yap to Surekha Kakaraparthi, Dominic Lazzaro cc: David Weisel RE: BIOMM
JAN-MS-00289213	1/6/2012	Email From Paul Lowman to Patricia Yap - Calendar invite for Institutional Quality Initiative - Improving Pain Management in the Hospital
JAN-MS-00291349	5/12/2005	Letter from FDA to James K. Burrus, Johnson & Johnson
JAN-MS-00299212	3/00/2004	1,360 Loaves...And Counting
JAN-MS-00302787		Duragesic, Pain Specialist Overview
JAN-MS-00303825		Duragesic Information on Opioid Dependence, Tolerance and Addiction
JAN-MS-00306286	11/00/2002	"Now I have the freedom to worry less about my chronic pain"
JAN-MS-00309771	7/9/2002	Speaker Analysis Summery
JAN-MS-00310473		Assessing the Risk for Substance Abuse
JAN-MS-00312510	7/19/2002	spreadsheet with regional data re lectures including lecture titles and spending
JAN-MS-00312512	7/19/2002	spreadsheet with regional data re lectures including lecture titles and spending
JAN-MS-00312513	7/19/2002	spreadsheet with regional data re lectures including lecture titles and spending
JAN-MS-00314799	10/31/2003	Speaker Analysis Summary, Bureau: Duragesic Trained Speakers, Date Range: 01/01/2003 - 12/31/2003
JAN-MS-00315240	12/11/2003	Pain Council 2004; Steering Committee Conference Call, December 11, 2003 - 1:30 - 2:30 pm EST
JAN-MS-00324074	9/15/2010	Email from Carissa Bamrick to Michelle Wanat and Jeff LaVaute re: NUCYNTA IR Promotional Speaker Slide Deck
JAN-MS-00324076	5/00/2010	NUCYNTA, An Advance in Multimodal Analgesic Therapy
JAN-MS-00324259	8/28/2008	Email From Nithya Desikan to Kimberly Deem-Eschleman re FW: FYI - "Let's Talk Pain" coalition - launch press release
JAN-MS-00330383	6/17/2010	Email from Robyn Kohn to Kimberly Deem-Eshleman, Malcolm Monaghan and Brian Bastean re: RKDENUCYNTA ER Launch Governance Market Access61710.pptx

JAN-MS-00330384		powerpoint: Advocacy and Policy Key Launch Activities, A Vital Balancing Act: Recognizing Prescription Drug Abuse While Ensuring Patient Access
JAN-MS-00343034	10/18/2010	Email from Frank Demiro to Ciatlin Ryan, Sharon Szabo re: FW: National Webcast Invitations: Nov and Dec
JAN-MS-00343039	06/00/2010	Flyer for "An Advance in Multimodal Analgesic Therapy"
JAN-MS-00345033	4/25/2011	Email from Frank Demiro to Linda Hutchins and Hye Yoon Park re: WebEx Schedule
JAN-MS-00345036	4/00/2011	Pricara invite for, "A New Perspective for Moderate to Severe Acute Pain Relief: A Focus on the Balance of Efficacy and Tolerability"
JAN-MS-00352926	2010	PowerPoint presentation Northeast Pride 2Q10 Cycle Meeting
JAN-MS-00356925	6/4/2010	Email from Linda Blair-Cusumano to Lisa Ferguson RE: Region Main Tent Opening, attaching Region Main Tent Opening PowerPoint
JAN-MS-00358806	5/12/2009	Email from Cassie Hallberg to Lisa Ferguson RE: Notice of meeting cancelation - Advocacy/key stakeholders in New England, attaching Pain Stakeholders Strategy PowerPoint
JAN-MS-00358807		Pain Stakeholders Strategy PowerPoint presentation
JAN-MS-00359950	10/16/2009	Letter from Lisa Ferguson to Benny Reyes RE: meeting summary - launch trends and developing action plans
JAN-MS-00361477	5/1/2009	Email from Wil Rivera to Linda Blair-Cusumano RE: Updated KOL Spreadsheet, attaching New England Region Pain KOLs
JAN-MS-00361478		New England Region Pain KOLS spreadsheet
JAN-MS-00361841	6/24/2010	Email from Theresa Smith to Lou Pascarella, Deborah Henry, Lisa Ferguson RE: Community of Care Targeting 2H10, attaching 2H10 COC Product Specialist Update PowerPoint
JAN-MS-00361843	7/24/2010	Community of Care Product Specialist Targeting, June 24th, 2010 PowerPoint presentation
JAN-MS-00362270	5/1/2009	Email from Shane Scott to Timothy Ferencik and others RE: Ready...Set...EARN! Nucynta sales incentive program
JAN-MS-00362272		PowerPoint slide "Are you prepared to win big Northeast Region?" details launch contest, commend Lisa's 12K worth of Award Per Q's
JAN-MS-00362273		Blast Off to Making Pain History flyer detailing reward contest for TRx volume among targeted pain specialists

JAN-MS-00363973	2/14/2012	Email from Juliana Mastroserio to Lisa Ferguson, Kanitha Burns, Michael Hanlon RE: Nucynta ER User/Non-User Report, attaching WIDI Nucynta Users + Non-Users Report PowerPoint
JAN-MS-00363974		Nucynta ER Users & Non-Users Qualitative Research Summary Report PowerPoint
JAN-MS-00363975		Just Qual interview sheet for prescribers
JAN-MS-00403802	3/4/2011	Email from Robyn Kohn to John Hoffman RE pain Advocacy & Launch Development Deck attach NAD Update Advocacy PowerPoint slides
JAN-MS-00403803		Advocacy, Policy, Quality Launch Activities PowerPoint presentation
JAN-MS-00406401	5/27/2008	Email from Maureen Drexler to Robyn Kohn re: ASPN CA Chapter Invite
JAN-MS-00406402	2008	Invite: Inroads into pain Management: Improving Nursing Response for Optimal Analgesia and Drug Safety
JAN-MS-00408379	5/15/2008	Email from Ryan VanOrden to Robyn Kohn re: PDF: Invitation for San Francisco
JAN-MS-00408380	2008	Invite: Abuse, Addiction, and Pain Relief, Time for Change
JAN-MS-00408482	11/11/2008	Email from Jennifer Lerner to Robyn Kohn re: PM&R pdf
JAN-MS-00408484	2008	Flyer for: Adding Quality to Life, New Stategies to Break the Cycle of Acute and Chronic Pain in Rehabilitation, Thursday, November 20, 2008
JAN-MS-00408610		Opioid Risk Management: Dispelling the Myths and Integrating Clinical Strategies to Protect Your Practice
JAN-MS-00428395		Speaker List
JAN-MS-00430026	11/12/2014	Email from Surekha Kakaraparthi to Dominic Lazzaro cc: Ron Kuntz RE: Nucynta ER Digital Campaign Overview Follow UP
JAN-MS-00442057	6/29/2007	Email from Lynn Leonard to Haya Taitel re: Unbranded Tactical v1.ppt
JAN-MS-00442058		Non-Branded Promotion
JAN-MS-00447323		Tapentadol 2007 Strategic Overview
JAN-MS-00450006	5/4/2011	Email from Ron Kuntz to Colleen Zook re: 2011%20NUCYNTA%20_Speaker_Slide_Deck_FINAL.ppt
JAN-MS-00450007	3/00/2011	A New Perspective for Moderate to Severe Acute Pain Relief: A Focus on the Balance of Efficacy and Tolerability
JAN-MS-00458370		speaker information
JAN-MS-00476773	6/30/1905	Pain Finding Relief
JAN-MS-00476823	9/2/2008	Email from Cortney Baldwin to David Moore re: AAFP Product Theater

JAN-MS-00476824	2008	Invite for: Product Theater Lunch Presentation at the 2008 AAFP Scientific Assembly, San Diego, CA
JAN-MS-00476825	2008	Flyer for: 2008 American Academy of Family Physicians (AAFP)
JAN-MS-00483047	1/1/2007	Email From Haya Taitel to David J Hewitt, MD re Clinical Phase IV Trial - evaluation
JAN-MS-00588903	2004	Speaker Analysis Summary; Date Range 1/1/04 - 12/31/04
JAN-MS-00615973	9/23/2010	Email from Michelle Wanat to various re: Discuss story flow for Tap ER Speaker Slide Deck (attached)
JAN-MS-00641042	4/10/2007	Email from Robyn Kohn to various re: ASPAN CE Nurse Symposium Announcement
JAN-MS-00645974	7/8/2010	Advertising & Promotion Copy Review Submission Cover Sheet: NUCYNTA ER Speaker Slide Deck
JAN-MS-00653403		Optimizing Chronic Pain Management with Duragesic
JAN-MS-00653426		Perri add-ons
JAN-MS-00654707	12/8/2000	Email from Bruce Moskovitz to Gary Vorsanger re: JCAHO pain management, Jean Gillespie
JAN-MS-00654709	10/19/2000	Word draft document: JCAHO Pain Management Initiative Conference Call Minutes, Thursday October 19, 2000
JAN-MS-00654710		Word draft document re: Developing an educational monograph about pain management to support the implementation and adoption of JCAHO's pain management standards
JAN-MS-00654711	11/28/2000	Emal from Jeann Gillespie to bmoscovi@janus.jnj.com and others re: Update on the JCAHO pain management project
JAN-MS-00657665	4/29/2013	Email from Hana Saikali to Belma Popovic, Roger Lo, Michael Opait, Margaret Ngai, Dominic Lazzaro, Surekha Kakaraparthi RE: BIOMM weekly status report, attaching Nucynta_BIOMM_Project Status April 29
JAN-MS-00657666	4/29/2013	Nucynta Project Status Report - Biomm
JAN-MS-00658495	2/00/2013	powerpoint: Nucynta - Powerful Pain Management: Proven Across Multiple Acute and Chronic Pain Models
JAN-MS-00658637	6/3/2013	Email from Dominic Lazzaro to Patricia Yap, Ron Kuntz, David Lin, Kanitha Burns, David Weisel, Oliver Bock, Michael Hanson cc: James Rugg, Surekha Kakaraparthi, John Jacoppi, Patricia Ruddick, Elinor Riggs, Belma Popovic RE: BIOMM Visualization tool launch phase 1, attach BIOM User manual
JAN-MS-00658638		BIOMM Visualization Tool User Manual
JAN-MS-00658962	7/10/2013	Email from Carissa Wysocki to Patricia Yap re: IR and ER Live Decks I nYour Queue

JAN-MS-00658965	6/6/2013	Copy Review Submission Cover Sheet: 2013 NUCYNTA IR Speaker Deck - LIVE Programs
JAN-MS-00659608	10/23/2013	E-mail from Margaret Ngai to Dominic Lazzaro, Patricia Yap, John Kilkeary cc: Matthew Selvaggio, Hana Saikali, Ravi Viswanathan, Cathy Gray, Felix Hsieh RE: Nucynta Analytics Presentation, attach New PRM Writer List, Nucynta PRM Performance Analysis
JAN-MS-00659609	2013	New 2013 Writers Enrolled in PRM
JAN-MS-00659610	10/00/2013	Powerpoint - Nucynta PRM Performance Analysis, Results ending September 30, 2013
JAN-MS-00659949	10/16/2009	Email from Linda Blair-Cusumano to Ben Reyes, Susan Mangler, Lisa Ferguson attaching Reyes letter 10/12/09
JAN-MS-00660070	12/11/2013	Email from Dominic Lazzaro to Patricia Yap re: Discussion Guide Comments
JAN-MS-00660071		NUCYNTA ER, Clinical Exchange Roundtable Program Discussion Guide
JAN-MS-00660576	1/10/2013	E-mail from Belma Popovic to James Rugg, Satish Maduri, and others Re: BIOMM Status Meeting - Status Report, attaching Nucynta BIOMM Project Status
JAN-MS-00660577	1/10/2013	Nucynta Project Status Report - Biomm
JAN-MS-00661078	10/00/2012	CA Call Notes - Targets
JAN-MS-00662328	8/30/2013	E-mail from Patricia Yap to David Lin cc: Ken Jordan Re: JMLC Best Practices
JAN-MS-00664671	1/27/2012	Email from Keith Hofbeck to Michael Paulik & Paul Lowman re RE: Institutional Quality Campaign Initiative
JAN-MS-00664673	9/28/2010	Exhibit B - Work Order
JAN-MS-00665005	2011	2011 NucyntaER Speaker Training
JAN-MS-00665498	3/13/2012	Email from Kristen Colasurdo to Patricia Yap re: $2.9MM SOW
JAN-MS-00665499	7/4/1905	spreadsheet with brand budget and SOW data, 1/12/2012 to 12/21/2012
JAN-MS-00665997	11/1/2012	Email from Lisa Biancani to Patricia Yap re Fw: Nucynta PRM Framework Meeting for 11/01/2012@2PM
JAN-MS-00665999	11/1/2012	PRM Framework for 2013
JAN-MS-00747492	9/2/2004	Warning Letter to Ajit Shetty, Janssen from Thomas Abrams, FDA
JAN-MS-00748826	12/19/2012	E-mail from Lisa Biancani to Patricia Yap cc: Kanitha Burns RE: Can you please send the slides you used to make recommendations of what we should do bby target audience?, attaching BIOMM overview, CRM plan 2013

JAN-MS-00748827	2013	Excel spreadsheet - BIOMM: Cross Channel Communication Plan for 2013
JAN-MS-00748828		Powerpoint - Nucynta BIOMM program: Behavioral Insights to Optimize Marketing Mix
JAN-MS-00764718		CA Call Notes - List for boxes to ship
JAN-MS-00767407	11/20/2013	E-mail from Marie Hull to Kanitha Burns cc: Beth Bengtson RE: DFR 2013 for review, attaching digital footprint inventory - Nucynta 061013
JAN-MS-00767408	4/10/2013	Digital Footprint inventory - Nucynta 061013
JAN-MS-00767409	11/20/2013	E-mail from Marie Hull to Kanitha Burns RE: PPT, attaching Visualization Nucynta 071113 2017 powerpoint
JAN-MS-00767410	7/12/2013	PowerPoint - Nucynta Digital Footprint Report
JAN-MS-00768709	12/20/2012	PowerPoint - 2013 BP Review with Michael Yang
JAN-MS-00779345	9/2/2004	Facsimile from FDA to James Burrus, Johnson & Johnson re with Warning Letter re NDA # 19-813
JAN-MS-00824678	5/3/2011	Email from Tara Blackman to Sharon Szabo and Frank Demiro re: IM News this week
JAN-MS-00824684	4/00/2011	Invite: A New Perspective for Moderate to Severe Acute Pain Releif: A Focus on the Balance of Efficacy and Tolerability
JAN-MS-00830892	2012	NucyntaER Speakers Bureau
JAN-MS-00834504	4/4/2011	Email from Frank Demiro to Paul Lowman and Laura Flannery re: FW virtual Speaker Calendar for 2011
JAN-MS-00834505	3/00/2011	Invite: An Advance In Multimodal Analgesic Therapy
JAN-MS-00857283	4/14/2010	Email from Blair-Cusumano to Mary Bradley and others RE: Eagle Camp Follow-up attach Eagle Camp Follow-up
JAN-MS-00857284		PriCara Northeast Pain Region memorandum to Mary Bradley, Dave Luby, Seth Moskos, Kim Chappelle, Lisa Carlista, Donna Nicolosi, James Glover, Meshia Grierson, Sal Como, Rachel Sassi RE: EAGLE CAMP follow-up
JAN-MS-00857287		Network Selling PowerPoint
JAN-MS-00857288		Eagle Camp-Specialty Best Practices Recap
JAN-MS-00859228	2/16/2010	Email from Scott Sheffield to Matthew Mosseau and Lisa Ferguson RE: New Hampshire & Vermont TRx by Zip, attach NH VT TRx by Zip spreadsheet
JAN-MS-00859229	1/29/2010	New Hampshire & Vermont Nucynta TRx by Zip
JAN-MS-00867873	9/18/2010	Email from Roger Golden to Lisa Ferguson RE: New Hampshire Vermont Partnership Community of Care
JAN-MS-00890573		Chronic Pain: Prevalence and Impact
JAN-MS-00938063	10/6/2010	Email from Bruce Carroll to Robyn Kohn re: FW NUCYNTA Speaker Program
JAN-MS-00938065	9/00/2010	Invite: An Advance In Multimodal Analgesic Therapy
JAN-MS-00981895	2014	powerpoint: Nucynta ER Patient Assessment, Selection and Initiation of Therapy

JAN-MS-00997778	10/7/2014	Email from Dominc Lazzaro to Ron Kuntz re: FW Current NUCYNTA IR Deck
JAN-MS-00997779	2014	NUCYNTA ER Clinical Exchange Roundtable Program TRAINING GUIDE
JAN-MS-01050166	8/20/2012	Email from Bruce Colligen to Carol Allocco and others re: Pain Policy Resources (Allocco Exh. 21) (State of NH v. Johnson & Johnson)
JAN-MS-01050168	8/00/2012	Addressing Unmet Nees in Pain Management and Prescription Drug Abuse: Prescription Drug Monitoring Programs (Buckley Exh. 13) (State of NH v. Johnson & Johnson)
JAN-MS-01050171	8/00/2012	Chronic Pain & Prescription Drug Abuse (Allocco Exh. 26) (State of NH v. Johnson & Johnson)
JAN-MS-01050172	7/00/2012	Balance in Public Policy: Pain Treatment Access vx. Stemming Prescription Drug Abuse, Issue Summary (Buckley Exh. 12) (State of NH v. Johnson & Johnson)
JAN-MS-01050177	7/00/2012	Addressing Unmet Nees in Pain Management and Prescription Drug Abuse: Building Balance in Public Policy (Buckley Exh. 11) (State of NH v. Johnson & Johnson)
JAN-MS-01051151	2014	PowerPoint-CNS Staff Meeting
JAN-MS-01062329	7/30/2013	E-mail from Dominic Lazzaro to David Weisel, Jason Sapp, Asha Mahesh, James Rugg, Sanjay Chokra, Roger Lo, Oliver Bock, Elinor Riggs, Surekha kakaraparthi cc: Mona Morgan RE: Nucynta BIOMM Kick-off, attaching 2014 BIOMM Kickoff powerpoint
JAN-MS-01062330	7/31/2013	BIOMM Kickoff (Data Integration & Visualization)
JAN-MS-01063280	10/24/2013	E-mail from Dominic Lazzaro to Surekha Kakaraparthi RE: BIOMM Monthly Data Review
JAN-MS-01065773	4/21/2014	Email from Dominic Lazzaro to Amit patel re: FW current NUCYNTA ER/IR Decks
JAN-MS-01065774	2014	NUCYNTA ER Patient Assessment, Selection and Initiation of Therapy
JAN-MS-01067464	2/28/2014	E-mail from Dominic Lazzaro to Surekha Kakaraparthi RE: Benchmark Report for June Data
JAN-MS-01067678	9/22/2014	Email from Dominic Lazarro to Amit Patel re: FW For Your Review: Roundtable Training Guide
JAN-MS-01067679	2008	NUCYNTA ER Clinical Exchange Roundtable Program TRAINING GUIDE
JAN-MS-01080008	8/00/2011	powerpoint: Nucynta - New Perspectives in the Management of Moderate to Severe Chronic Pain
JAN-MS-01094381	3/13/2012	Email from Sandra Louro to Dominic Lazzaro re: Educational Dinner Posters, Raleigh-Durham, San Diego

JAN-MS-01098312	4/17/2013	E-mail from Michael Opait to Surekha Kakaraparthi, Roger Lo, James Rugg, Dominic Lazzaro cc: Belma Popovic, Hana Saikali, Ann Harrison, Margaret Ngai RE: BIOMM Impact Analysis Report for Profero Access Coverage
JAN-MS-01099325	9/27/2013	E-mail from James Rugg to Margaret Ngai cc: Dominic Lazzaro, Hana Saikali, Roger Lo, Surekha Kakaraparthi, Sanjay Chhokra, Patricia Ruddick RE: June/Plantrak data is now available in the following analyses, attaching BIOMM2a-OpenIssues
JAN-MS-01099421	10/30/2013	E-mail chain from Mark Chen to Surekha Kakaraparthi, Dominic Lazzaro cc: Rory Martin RE: confirming data elements
JAN-MS-010994323		CDR Classification spreadsheet
JAN-MS-01100057	1/23/2014	E-mail from Surekha Kakaraparthi to Dominic Lazzaro, James Rugg, Hana Sikali Roger Lo cc: Margaret Ngai, Ann Harrison, Sharon Nicholson, Patricia Ruddick RE: BIOMM Database - Ready for testing?
JAN-MS-01100061	11/00/2013	Spreadsheet - Montly Benchmark Report Nucynta/Nucynta ER
JAN-MS-01100867	6/3/2014	E-mail from Sharon Nicholson to Dominic Lazzaro cc: Hana Saikali RE: 2014 Mid Year Analysis Outline (BIOMM), attaching Nucynta Analytics Measurement Plan 3.6.2014 R1
JAN-MS-01100868	2014	Analysis Outline - 2014 Nucynta Mid-Year Analytics Review
JAN-MS-01124875	9/16/2008	Email from Christine Rauschkolb to Greg Panico re: for Review Draft tapentadol (IR) approval press release
JAN-MS-01192118	9/18/2001	Update Bulletin re: Abuse Potential of Opioids
JAN-MS-01242895	3/16/2007	Email from Greg Panico to Ron Kuntz re FW: Ketchum Tapentadol Presentation from 15 March
JAN-MS-01242896	3/15/2007	Tapentadol: Breaking Through Barriers to Treatment
JAN-MS-01498613		KOL information
JAN-MS-02109392	11/21/2001	Email from Adrienne Minecci to Taryn Sichta re: JCAHO-NPC monograph
JAN-MS-02118349	6/25/2001	Janssen Pain Franchise Review
JAN-MS-02241168	4/9/2010	Email from Lynda Mack to Gary Vorsanger re unbranded speaker deck
JAN-MS-02268552	2008	Nursing 2008 Pain
JAN-MS-02324033	7/30/2002	Duragesic 2003 Business Plan, July 30, 2002
JAN-MS-02336600	4/4/2001	Email from Gary Vorsanger to Jim Eckhardt re: FW Pain Mgmt. Monograph, Tables, & Outline
JAN-MS-02336601		Undated email to undisclosed recipient(s) fro Mary Gail Swenson, forwarding attachments from Jeann Gillespie re NPC-JCAHO pain management monograph one -- manuscript, tables and outline

JAN-MS-02336603		"Dear Colleague Letter" providing monograph
JAN-MS-02336673		"Dear Colleague Letter" outline
JAN-MS-02336678	4/4/2001	Email from Gary Vorsanger to Alan Baseman re FW Pain Mgmt. Monograph, Tables & Outline
JAN-MS-02336679		Undated email to undisclosed recipient(s) from Mary Gail Swenson, forwarding attachments from Jeann Gillespie re NPC-JCAHO pain management monograph one -- manuscript, tables and outline
JAN-MS-02336681		"Dear Colleague Letter" providing monograph
JAN-MS-02336751		"Dear Colleague Letter" outline
JAN-MS-02348617	1/7/2013	E-mail from Belma Popovic to David Weisel, Oliver Bock, Dominic Lazzaro cc: Michael Opait, James Rugg, Patricia Yap RE: BIOMM User Manual, attaching BIOMM User Manual_2013
JAN-MS-02348619		BIOMM Visualization Tool User Manual
JAN-MS-02350631	3/6/2013	Email from Patricia Yap to Michael Weingarten re CAPG Corporate Membership
JAN-MS-02359088	12/11/2009	Email from Michael Weingarten to Michele Cappel & Others re RE: CAPG 2010 funding request CA Maverick Team: Cappel SMD Los Angeles
JAN-MS-02359772	8/20/2009	Email from Jennifer Hunt to Patricia Yap re FW: Display Fee: California Assn of Physicians Groups - $2500 ($800 Nucynta; $800 Concerta; $800)
JAN-MS-02359773	7/30/2009	CAPG Request to IMJP re: Board meeting in Newport Beach
JAN-MS-02365141		Brand Presentation - CamPAINing for RELIEF
JAN-MS-02385628	12/16/2012	E-mail chain from Patricia Yap to Kanitha Burns cc: David Lin, Frank Demiro, Ron Kuntz, Johnette Johnson, Dominic Lazzaro RE: deck for M Yang review, attaching BIOMM overview 11.27.2012 MYANG
JAN-MS-02385630		PowerPoint slides - Nucynta BIOMM program: Behavioral Insights to Optimize Marketing Mix
JAN-MS-02404914	3/4/2010	Email from Samir Mody to various re: N-PAT
JAN-MS-02404928		Opioid Therapy...Current Challenges and Future Approaches
JAN-MS-02470285	5/28/2010	Email from Jean Nycz to Burt Ahlzadeh and others RE: Call Frequency to Rx Converter, attaching 2010-05 call vol & Frequency Analysis
JAN-MS-02470287		Nucynta call frequency to Rx converter
JAN-MS-02470317	7/29/2009	Email from Matthew Rowland to William Gagliard and others RE: How New Hampshire & Vermont Legislation Affects the Field Sales Data, attach Field Management Deidentified IMS data
JAN-MS-02470318		VT & NH Law - Prescriber De-identification PowerPoint slides
JAN-MS-02472395		CA Call Notes

JAN-MS-02474272	2009	Lisa Ferguson 2009 PDM Golas & Objectives, Action Plan and Performance
JAN-MS-02498982	10/31/2007	Email from Allison Bagin to Robyn Kohn re: Pain Management Save-the-Date (CA and VA)
JAN-MS-02498983	2008	Save the date for February 2, 2009 CME in Huntington Beach, CA, "Individualizing Analgesic Regimens: Strategies to Reduce Abuse and Diversion"
JAN-MS-02518126	2014	spreadsheet with data re MEDFORCE Speakers Bureau Budget Reconciliation with data including speaker, event type, topic, location, date, honorarium and expenses, 2014
JAN-MS-02522610	2008	Finding Relief Pain Management for Older Adults
JAN-MS-02533808	1/15/2007	Email from Haya Taitel to Gregory Imber re: FW Master KOL Listing; attachments: Market RX mkt res findings.xls, marketRx Duragesic KOL Mapping Final Report-021804ppt, Master Advocate Listing.xls
JAN-MS-02533811	2/18/2004	Duragesic KOL Mapping Analysis
JAN-MS-02533813		national KOL information
JAN-MS-02533814	2004	KOL information
JAN-MS-02557930	2013	spreadsheet with data re MEDFORCE Speakers Bureau Budget Reconciliation with data including speaker, event type, topic, location, date, honorarium and expenses, 2013
JAN-MS-02564213	2008	spreadsheet: attendee report 08 20 2009; data includes operating company, product, date, venue, attendee name/license state/ME number, etc., September - December 2008
JAN-MS-02564214	2009	spreadsheet with attendee data for events, including information re operating company, product, date, venue, attendee name and practice name, 2009
JAN-MS-02727829	1/17/2000	Email from Michelle Sheridan to Bockes and others re: Oxycontin Backgrounder Memo - chris Johnson Memorandum
JAN-MS-02727830		Oxycontin Backgrounder, Family Feud Questions
JAN-MS-02913539	1/11/2013	E-mail from Patricia Yap to Johnette Johnson re: Nucynta 2013B Tactics Review Myang final dec2012
JAN-MS-02913540	12/20/2012	PowerPoint slides - 2013 BP Review
JAN-MS-02914651	7/22/2013	Nucynta ER/Nucynta 2014 Business Plan, President Review #1, "Transforming minds, bringing hope for a meaningful life"
JAN-MS-02919167	05/00/2013	West Pain District 2013 Business Plan - Shari Dorff May 2013
JAN-MS-02970470	2001	DURAGESIC New Sales Hire Packet
JAN-MS-02971035		Glossary
JAN-MS-02973890	2012	powerpoint: 2012 Business Plan Forecast: Nucynta & Nucynta ER

JAN-MS-02975853	6/25/2012	Nucynta ER & Nucynta, 2012 NU / 2013 PBP - Working Deck
JAN-MS-02987848	6/25/2001	2001 Pain Franchise Review
JAN-MS-02987999	1/21/2004	Duragesic Business Update
JAN-MS-03010750		Suggest ULTRAM ER Verbiage
JAN-MS-03027760	10/8/2002	Powerpoint: Duragesic The Tipping Point, 2003 Tactical Plan, October 8, 2002
JAN-MS-03074517	2005	spreadsheet with attendee data for events, including information re operating company, product, date, venue, attendee name, 2005
JAN-MS-03076039	2005	Speaker Analysis Summary; Date Range 1/1/05 - 12/31/05
JAN-MS-03090610		Use of Opioids Analgesics in Pain Management. Candiotti, K. PrescribeResponsibly.com.
JAN-MS-03781395	2009	Invite: Lunch presentation in conjunction with AAPA: NEO Pathways, New directions in pain
JAN-MS-03862398	7/24/2003	spreadsheet with data re speaker events, including speaker name, lecture title, total attendance, event type and venue, funding
JAN-MS-03863720	6/10/2004	spreadsheet with data re speaker events, including speaker name, lecture title, total attendance, event type and venue, funding
JAN-MS-03871746	8/24/2010	Email from Frank Demiro to Dominic La Selva, David Lin, David Moore, Linda Hutchins, Darwin Gibson RE: Attendee NewsChannel Re-Launch, attach NUCYNTA08/24 NExGen PowerPoint, Pain News
JAN-MS-03871747	8/24/2010	Nucynta tapentadol PowerPoint
JAN-MS-03877616	9/22/2011	Email From Russell Stough to Darwin Gibson re Russell R Stough PDM Comments
JAN-MS-03877617	9/19/2011	Russell R Stough - 2011 PDM Comments
JAN-MS-04031238	2009	Flyer for 2009 California Association for Nurse Practitioners 32nd Annual Educational Conference
JAN-MS-04076304	2009	Invite: Dinner presentation at the California Association For Nurse Practitioners 32nd Annual educational Conference; NEO Pathways, New directions in pain
JAN-MS-04239129	10/00/2011	CA Call Notes
JAN-MS-05433110	2013	2013 Performance Planning and Review for Dominic Lazzaro
JAN-MS-05439358	6/1/2009	Email from Gary Vorsanger to Dr. David Biondi re: 6/6 San Diego Speaker Training Meeting
JAN-MS-05439360		J&J Pharmaceutical Research & Development - Tapentadol Acute Pain Clinical Trial Overview
JAN-MS-05439361	6/6/2009	agenda - NUCYNTA Speaker Training Meeting San Diego, CA June 6, 2009
JAN-MS-05439362	5/00/2009	NUCYNTA An Advance in Multimodal Analgesic Therapy

JAN-NH_00145637	12/8/2003	Email from Jennifer Furness to Laura Reynolds RE: Manager Final Reviews attaching 2002-2003 Summary Ratings for Barone, Granitski, Masi, Mosseau, Russo, Strout, Troeller
JANNH00038844		call log, 2009 - 2011
JANNH00038844_Confidential	2009-2011	Call logs re Nucynta Dosing & Admin Guide, Nucynta PNMT Savings cards, Nucynta 10 free pills voucher, 2009-2011
JANNH00132731		call log, 1992 - 1999
JANNH00132732		call log, 1996 - 2002
JANNH00132733		call log, 2002 - 2006
JANNH00132734		call log, 2002 - 2006 re product presentation and samples 2002-2006
JANNH00132735		call log, 2005 - 2007
JANNH00132736		call log, 2006 - 2007
JANNH00132788		call log
JANNH00132789		call log, 2013 - 2015
JANNH00132791		call log, 2009 - 2013
JANNH00132792		call log, 2009 - 2013
JAN-NH-00136854		powerpoint: NEO Pathways, Heading in new directions in pain management
JAN-NH-00145524	11/5/2003	Email from Robert Troeller to Laura Reynolds and Jenifer Furness RE: Finalized HR Reviews, attaching reviews for Bernstein, Cataldo, Garneau, Koopman, Lague, Nickels, Sidita and Sibley
JAN-NH-00145547	5/1/2000	Janssen Pharmaceutica 2003 340 Green Sales Representative Personnel Review of Caroline Lague
JAN-NH-00145637	12/8/2003	E-mail from Jennifer Furness to Laura Reynolds RE: Manager Final Reviews, attaching reviews for Barone, Granitski, Masi, Mosseau, Russo, Strout, and Troeller (C. Mosseau Ex. 6) (State of NH v. Johnson & Johnson)
JAN-NH-00145656	2003	Janssen Pharmaceutica 2003 Green District Manager Personnel Review
JAN-NH-00148038	3/17/2003	Email from Robert Troeller to Julie Bernstein and others RE: 2003 Voucher Commitment , attaching 2003 Voucher Commitment
JAN-NH-00148039	2003	Spreadsheet Manchester Duragesic Sample Voucher Commitment
JAN-NH-00148223	7/24/2003	Email from Robert Troeller to Jennifer Furness and Caroline Lague RE: Proposal - Maggie Mahomat - Nurses Ad Board Meeting - October, attach Proposal for the Attendance of Maggie Mahomat to the Nurses Ad Board Meeting
JAN-NH-00148224		Proposal for the Attendance of Maggie Mahomat to the Nurses Advisory Board Meeting

JAN-NH-00148514	11/5/2003	Email from Robert Troeller to Jennifer Furness RE: Speaker Programs - costs, honoraria fees for speakers Bernstein, Lague, Koopman, Nickels, Baker
JAN-NH-00148601	1/22/2004	Email from Robert Troeller to Joseph Kryzan, Nicole Barone, Jennifer Furness RE: Paint the Picture Workshop, attach Paint the Picture Workshop
JAN-NH-00148602		Painting the Picture: The Emotive Sell presentation by Nicole Barone, Joe Kryzan, Bob Troeller
JAN-NH-00149645	11/26/2012	Email from Matthew Mosseau to Robert Barrett, Kristin Ferragamo, Gregg Fowler, Donna Nicolosi, Mark Paulhamus, Lisa Rachlin, Tim Stanley, Tanya Wilson, Michael Genus RE: Q3 NUC Leaders (M. Mosseau 4) (State of NH v. Johnson & Johnson)
JAN-NH-00169728	10/2/2011	Email chain among Michael Genus, Brenda Pennels, Ben Reyes, Timothy Ferencik, William Masi, Mariel McKenny, Matthew Mosseau RE: 2H'11 Retail Incentive NUCYNTA ER Launch Plan Overview
JAN-NH-00169729	2011	Altitude: Reach New Heights - 2011 Incentive Compensation & Recognition Plan
JAN-NH-00179563	4/3/2014	Email from Kevin Buckley to Kevin Buckley re: Leg Update - ME, NH, MA and RI (Buckley Exh. 17) (State of NH v. Johnson & Johnson)
JAN-NH-00187056	2/11/2005	Email from Jason Smith to Jodie Sanborn, Erik Principe, Matthew Mosseau, William Masi RE: Review Guides attaching Duragesic Review Guide (M. Mosseau Ex.5) (State of NH v. Johnson & Johnson)
JAN-NH-00200000		Q1 and Q2 Sales results and goals for multiple sales personnel (M. Mosseau Ex. 13) (State of NH v. Johnson & Johnson)
JAN-NH-00204507	8/24/2012	Email from Kara Sabean to Brenda Pennels RE Sabean Calibration, thanks for recognition, attach Sabean Calibration Aug 2012
JAN-NH-00204508		Sales Performance Self evaluation of Kara Sabean
JAN-NH-00216327	10/19/2000	Email from Debbie Angeline to Meritt Phillips, Robert Troeller, Anthony Focella, Douglas Dickinson, Derek Hughes, Howard Johnson, Joseph Russo, Heather Thomson, attaching Duragesic Pain Management Slide kits
JAN-NH-00216328	1999	Pain Management Refined: New Approaches Volume III: Opioid Use in the Treatment of Chronic Pain presentation
JAN-NH-00217947	1/31/2003	Janssen Pharmaceutica Field Conference Report assessment of Caroline Lague (C. Mosseau 7) (State of NH v. Johnson & Johnson)
JAN-NH-00218183	7/29/2003	Email from Caroline Lague to Robert Troeller RE: Revised Business Plan, attaching business plan file (C. Mosseau 14) (State of NH v. Johnson & Johnson)

JAN-NH-00218184	2003	Caroline Lague Business Plan 2003 - Manchester 340 Green Haverhill Territory
JAN-NH-00218870		Grow and Defend - Manchester Style - sales team growth goals
JAN-NH-00222232	4/21/2003	Email from Weiyi Yang to Tom Murphy, Anthony Tautkus, Jennifer Furness, Robert Hutchinson, Michael Schmoyer, Edward McDonnell, Chris Matteson, Thom Middleton RE: New England Market Assessment presentation, attaching presentation
JAN-NH-00222233		Discussion on Short-term and Long Term Strategies and Tactics in the New England Market PowerPoint presentation
JAN-NH-00224848	10/28/2004	Email from Jennifer Furness to Jared Maley, Matthew Mosseau, Scott Granitszki, Jill Strout, Keith Willis, Nicole Barone, Robert Troeller, William Masi RE: Manager Meeting Presentations, attaching 2004 Duragesic Transition Plan, 2004 November Meeting, 2004 November Meeting Duragesic Presentation
JAN-NH-00224849	11/00/2004	Duragesic Transition Plan PowerPoint presentation
JAN-NH-00224858	11/00/2004	Duragesic Fentanyl Transdermal System, November 2004 Meetings
JAN-NH-00233957	2/26/2002	Email from Howard Johnson to Anne Donoghue, Bradley Krout, Lisa Lee, William Masi, Dannan Paolini, Kinsey Sharpe, Penelope Steward, Pamela Thomas, Synita Thomas-Butler, attaching Duragesic Coupon Leveraging Strategies, Duragesic Coupons KVB
JAN-NH-00233958	2/20/2002	Email chain among Diane Chapman to Nicole Barone and others RE: Duragesic Coupon Leveraging Strategies
JAN-NH-00233960		Duragesic Coupon Program
JAN-NH-00234445	1/23/2004	Email from Laura Reynolds to Nicole Barone, Scott Granitzski, Joseph Kryzan, William Masi, Matthew Mosseau, Jill Strout, Robert Troeller, Keith Willis RE: More 1st Cycle stuff, attaching Green Alignment Presentations, Retention presentation
JAN-NH-00234446	2004	Janssen presentation 370 Green Sales Force
JAN-NH-00235286	12/6/2004	Email chain among Jennifer Furness, Nicole Barone and others RE: Selling Skills CCV (Creating Customer Value) Initiative, attaching support and training materials (M. Mosseau Ex. 6) (State of NH v. Johnson & Johnson)
JAN-NH-00237218	1/15/2013	2012 Performance and Development Plan Summary for Caroline Mosseau
JAN-NH-00237636	5/22/2012	Email from Steven Castor to Sheila Conroy and others re: FW NE Update (Buckley Exh. 9) (State of NH v. Johnson & Johnson)

JAN-NH-00238013		Curriculum Vitae of Caroline A. Mosseau (C. Mosseau Ex. 3) (State of NH v. Johnson & Johnson)
JAN-NH-00241172	6/30/2002	Janssen Pharmaceutica Human Resources Development Log (C. Mosseau Ex. 5) (State of NH v. Johnson & Johnson)
JAN-NH-00241192	2002	Caroline Lague Business Plan 2002 - Manchester 340 Green Haverhill Territory
JAN-NH-00242668	5/19/2004	Green Primary Care Field Conference Report (M. Mosseau Ex. 9) (State of NH v. Johnson & Johnson)
JAN-NH-00242850	6/17/2005	JOM Primary Care Field Coaching Report (M. Mosseau Ex. 10) (State of NH v. Johnson & Johnson)
JAN-NH-00242902	1/26/2006	Field Coach Report Primary Care Pain (M. Mosseau Ex. 11) (State of NH v. Johnson & Johnson)
JAN-NH-00242978	8/3/2006	Field Coach Report Primary Care Pain (M. Mosseau Ex. 12) (State of NH v. Johnson & Johnson)
JAN-NH-00243938	11/5/2009	Email from Donna Nicolosi to Matthew Mosseau RE: Self Assessment, attach Nicolosi 2009 Representative Competency Self Assessment (Nicolosi Ex. 14) (State of NH v. Johnson & Johnson)
JAN-NH-00243939	2009	2009 Representative Competency Self Assessment of Donna Nicolosi
JAN-NH-00246414		One Page Performance Summary Document for Donna Nicolosi, Sr. Exec. Healthcare Community Specialist (Nicolosi Ex. 18) (State of NH v. Johnson & Johnson)
JAN-NH-00246654	2/19/2010	Email from Matthew Mosseau to Donna Nicolosi RE: Northeast Region FCR, attaching Northeast Region FCR (M. Mosseau Ex. 8) (State of NH v. Johnson & Johnson)
JAN-NH-00246739	11/17/2009	Email chain among Lisa Ferguson, William Gahara and others RE: Nov. 12 Nucynta dinner program
JAN-NH-00246984	9/4/2009	Email chain among Donna Nicolosi, William Gahara and others RE: PriCara Meeting - speaker confirmation, post-program feedback from William Gahara (Nicolosi Ex. 12) (State of NH v. Johnson & Johnson)
JAN-NH-00247011	8/24/2009	Email chain among Donna Nicolosi, Matthew Mosseau and others RE: Call Plan attainment (Nicolosi 11) (State of NH v. Johnson & Johnson)
JAN-NH-00247055	8/10/2009	Work session notes including Nucynta Speakers and Demonstrated Partnerships
JAN-NH-00247258	6/24/2009	Email from Matthew Mosseau to Donna Nicolosi, Linda Blair-Cusumano RE: Work Session Follow up - Donna Nicolosi, attaching Certification sheet NUCYNTA Donna Nicolosi (Nicolosi Ex. 8) (State of NH v. Johnson & Johnson)
JAN-NH-00247259		Donna Nicolosi NUCYNTA Certification Sheet

JAN-NH-00247358	4/27/2009	Email from Matthew Mosseau to Donna Nicolosi RE: FCR 4/9/09 Donna Nicolosi attach Field Coach Report v7R (Nicolosi Ex. 6) (State of NH v. Johnson & Johnson)
JAN-NH-00247365	4/19/2009	Email from Gary Prevost to Kathy Fleming, Donna Nicolosi, Lisa Carlista, Sandy Saunders, Vanessa Sciortino, Richard Fuller, Lisa Domitrovits, Mikyoung Kim-Perez, Matthew Mosseau RE: Resource for next 2 questions attach Top 5 Questions and Responses for Nucynta Launch (Nicolosi Ex. 7) (State of NH v. Johnson & Johnson)
JAN-NH-00247442	3/26/2009	Email from Matthew Mosseau to Donna Nicolosi, Linda Blair-Cusumano RE: FCR 3/5/09 Donna Nicolosi, attach Field Coach Report (Nicolosi Ex. 5) (State of NH v. Johnson & Johnson)
JAN-NH-00247502	11/18/2008	Email from Matthew Mosseau to Lisa Carlista and others RE: Finishing Strong - year end goals and practices related to NEO, Pharmacy and Expanding Ultram ER (Nicolosi Ex. 4) (State of NH v. Johnson & Johnson)
JAN-NH-00247523	9/28/2008	Email chain among Matthew Mosseau to Lisa Carlista and others RE: NEO Campaign Best Practice Discussion, attaching NEO Campaign Best Practice Discussion (Nicolosi Ex. 3) (State of NH v. Johnson & Johnson)
JAN-NH-00256169	6/11/2012	Email exchange among Brenda Pennels, Craig Thomas, Kara Sabean RE: Concord D-H Ohio - Nucynta prescriptions, voucher use resulting from sales lunch meetings
JAN-NH-00256472	2001	Janssen Pharmaceutica 2001 275 Sales Representative Personnel Review of Caroline Lague (C. Mosseau Ex. 4) (State of NH v. Johnson & Johnson)
JAN-NH-00256512	3/25/2002	Email from Jessica Garneau to Robert Troeller RE: Keith's Field Training Evaluations, attach Field training feedback, weeks 1 and 2
JAN-NH-00256513	3/22/2002	Keith Nickels Field Training Feedback - Week 1
JAN-NH-00256514	3/18/2002	Keith Nickels Field Training Feedback - Week 2
JAN-NY-00012030	10/15/2002	Email from Caroline Lague to Robert Troeller RE: Field Training Feedback Form - Julie Bernstein, attaching form (C. Mosseau 11) (State of NH v. Johnson & Johnson)
JAN-NY-00012031	10/5/2002	Julie Burnstein Field Training Feedback - Week 1
JAN-NY-00019159	7/27/2004	Email chain among Jennifer Furness, Nicole Barone and others RE: Sizzlin'' Summer - June Results attaching Sizzlin'' Summer Contest Activity Summary
JAN-NY-00019161		Blank slip-sheet -"Technical Exception"

JAN-NY-00069902	10/27/2009	Email from Kyle Spitzer to Caroline Mosseau, John Kerrane, Melanie Meseroll RE: CDR 10-19
JAN-NY-00069903	10/19/2009	Spreadsheet comparing quarterly sales numbers
JAN-NYDFS-00000714061	6/4/2010	Email from Jean Nycz to Coreen Kenny and others RE: Northeast Recommendations, attaching NH and VT Human Resource Recommendations
JAN-NYDFS-00000714062		NH and VT Human Resource Recommendations - how to rebuild market in pharma-hostile states, and identify opportunities to partner with organizations to grow blocks of business
JAN-NYDFS-00000735387	3/11/2011	Email chain among Lee Blevins, Kimberly Deem-Eschleman and others RE: Florida, Pain market information
JAN-NYDFS-00001364791	9/27/2013	E-mail from James Rugg to Margaret Ngai cc: Dominic Lazzaro, Hana Saikali, Roger Lo, Surekha Kakaraparthi, Sanjay Chhokra, Patricia Ruddick RE: June/Plantrak data is now available in the following analyses, attaching BIOMM2a-OpenIssues
JAN-NYDFS-00001364800	10/1/2013	E-mail from Maragret Ngai to James Rugg cc: Dominic Lazzaro, Margaret Ngai, Hana Saikali, Roger Lo, Surekha Kakaraparthi, Sanjay Chhokra, Patricia Ruddick RE: June/Plantrak data is now available in the following analyses
JAN-NYDFS-00001376198	6/17/2013	Nucynta Data Visualization Business Requirements Document (BRD)
JAN-NYDFS-00001376201		spreadsheet: Nucynta Data Discovery questions, Data Load Status-Tactics, Data Load Status-Others, List of Req Docs
JAN-NYDFS-00001376231		Spreadsheet - NY FOIL
JAN-NYDFS-00001376233		page excerpt from NY FOIL Confidential Treatment explaining index calculations
JAN-NYDFS-00001376452		Digital Plan by Lisa Biancani and Dominic Lazzaro
JAN-NYDFS-00001389773		Spreadsheet - Investment by Marketing Mix pie chart
JAN-NYDFS-00003799789	2012	Spreadsheet - 2012 Brand Inventory Summary
JAN-NYDFS-00003799790	12/20/2012	PowerPoint slides - 2013 BP Review with Michael Yang
JAN-OH-00011820	6/3/2010	Email chain among Lisa Ferguson, Coreen Kenny and Jean Nycz RE: Proposal, attaching NH-VT Human Resource Recommendation PowerPoint
JAN-OH-00011821		VT/NH Human Resource Recommendation - Northeast Region
JAN-OH-00104932		NH and VT Human Resource Recommendations - how to rebuild market in pharma-hostile states, and identify opportunities to partner with organizations to grow blocks of business
JAN-TX-00001492	2006	powerpoint: Direct-to-Consumer Overview

JAN-TX-00002318		powerpoint: NEO Pathways, Heading in new directions in pain management
JAN-TX-00013833	6/13/2011	Email From Mike W. Baker to William Lunsford re FW: Follow Up to TX, CA, and FL launch opportunity discussions
JAN-TX-00053505	8/24/2006	Email from Allison Kaelberer to Sean Wilmert and others re: UltramERrecap
JAN-TXMED-00005541	3/30/2012	Email from Russell Marshall to Craig Abraham and others re: FW McClure
KP360_OHIOMDL_000344240	2002	Advances in Opioid Analgesia: Maximizing Benefit, Minimizing Harm
KP360_OHIOMDL_000345871	1/4/2019	printout of slideshow: Clinical Evaluation of the Patient With Chronic Pain
KP360_OHIOMDL_000348775	2003	Opioid Analgesia: Practical Treatment of the Patient With Chronic Pain
KP360_OHIOMDL_000370439	2004	Opioid Analgesia: Practical Treatment of the Patient With Chronic Pain
MDL_KP360_000000002		NIPC grants information, 2003 - 2012
MNK-T1_0000529044		Opioids in Acute Pain Management
MNK-T1_0000626241		Welcome to Your Exalgo Patient Identifier
MNK-T1_0001279950		Covidien Train-the-Trainer, CARES Alliance Education Module, Steven Passik, PhD
MNK-T1_0001347664	6/29/2010	Synchrony Medical, Module 6: Opioid Treatment Landscape
NORAMCO-PA_001030113	4/18/2013	E-mail from David Lin to Bill Grubb attaching NUCYNTA 2013BP Tactics Review
NORAMCO-PA_001030114	12/20/2012	PowerPoint - 2013 BP Review
P-12079_00001	12/20/2012	2013 BP Review with Michael Yang (MDL Plaintiffs Trial Exhibit P-12079_00001)
PDD1503491667	6/00/2001	Dear Physician letter
PDD1503510199	7/7/1998	Purdue Marketing Tips memo: Model Guidelines for the Use of Controlled Substances For The Treatment of Pain, Adopted May 2, 1998 by The Federation Of State Medical Boards Of The United States, Inc.
PKY180117076	8/4/1998	Purdue Marketing Tips memo: Oxycontin Precise Letter Program Updates
PKY180231304	12/00/1999	Regional Manager Meeting, December 1999
PKY181696752		Oxycontin Reprint Review
PLTF_2804_000003808	12/14/2018	Email from S. Amy Spencer to Linda Singer re: External-Portenoy -- electronic copy of executed declaration
PLTF_2804_000003809	12/13/2018	Declaration of Russell K. Portenoy, M.D. (MDL)
PMT000442347	9/18/2016	Email from Elizabeth McElhinney to Alan Must and others re: Concord Monitor: Drugmakers fought state opioid limits amid crisis (Buckley Exh. 6) (State of NH v. Johnson & Johnson)
PPLP003409951		Oxycontin Marketing Mix

PPLP003477086	9/00/2007	packet of grant paperwork re $100,000 grant by Purdue to FSMB for "Responsible Opioid Prescribing - A Physician Guide" Project
PPLP003541889		Marketing Overview of OxyContin (oxycodone HCl extended release tablets) Level 100
PPLP004001344	9/13/2013	OxyContin growth opportunities, Phase I Final Report: Diagnostic, Sept 13, 2013
PPLP004492921	1/24/2019	Deposition of Russell Portenoy in State of Oklahoma v. Purdue
PPLPC013000315100	7/2/2012	Email from Elizabeth McElhinney to Alan Must and others re: NH Panelists discuss drug issue at forum (Buckley Exh. 5) (State of NH v. Johnson & Johnson)
PPLPC022000010938	6/28/2001	Purdue Memorandum to Darlene Fujimoto RE: JCAHO-Leadership Summit on Pain Management
PPLPC029000132250	7/30/2004	powerpoint: Sales Force Metrics, July 30, 2004
TEV_FE0002286		Prescription and decile counts for Fentora, 2006 and 2007
TEV_FE00037945	2009	Fentora 2009 Brand Plan
TEV_FE0008161	4/3/2010	2010 Fentora Targeting
TEV_FE00116840	2008	FDA letter to Cephalon re: NDA 21-947/S-005
TEVA_CAOC_00694155		grant request and payment information from 2012-2016
TEVA_CAOC_00696029	2006	Actiq speaker programs
TEVA_CAOC_00696030	2006	Fentora speaker programs
TEVA_CAOC_00736064		CA Call Notes - fentora final addtl metrics
TEVA_CAOC_00784527	5/15/2013	Email from John C. Jacobs to Daufenbach, Reedy, Day, "Opioid Clinical Summary8 24 11.pptx"
TEVA_CAOC_00784528	9/1/2011	Opioid Clinical Summary. Michael Toscani, Pharm.D., Christopher Neumann, Pharm.D.
TEVA_CAOC_01129106		CA Call Notes, 2006 - 2016
TEVA_CAOC_01196126		Regional Symposia information, 2001 - 2004
TEVA_CAOC_01577362		CA Call Notes
TEVA_CAOC_01903919		CA Call Notes, 2001 - 2005
TEVA_CAOC_02134227	2003	Actig Regional Meetings information, 2003
TEVA_CAOC_02232811	2/13/2012	Email from John C. Jacobs to Miller, Smith, Day, Khan, Foy, Daufenbach, "FW: Opioid Clinical Summary Presentation on Sept 1st"
TEVA_CAOC_02232814	9/1/2011	Opioid Clinical Summary. Michael Toscani, Pharm.D., Christopher Neumann, Pharm.D.
TEVA_CAOC_02771150		CA Call Notes
TEVA_CAOC_03723100	03/00/2004	Actiq National Consultant Meeting - Final Attendance Report - 4912, Ritz Carlton Half Moon Bay, CA, March 19 through March 21, 2004
TEVA_CAOC_03857402		US Sales Compliance Policy Playbook
TEVA_CAOC_04325615		CA Call Notes, 2001 - 2006

TEVA_CAOC_06425751	01/00/2004	ACTIQ National Consultant Meeting - Final Attendance Report - 4723.4911, Boca Raton Resort & club, Boca Raton, FL, January 23-25, 2004
TEVA_CAOC_06648256	2002	Individual program list
TEVA_CAOC_06648257	2003	Individual program list
TEVA_CAOC_07116467	2010	2010 Presentations raw data
TEVA_CAOC_09105006	2004	ACTIQ 2004 Dinner CME Lectures Sigh-Up Sheets
TEVA_CAOC_09429750		speaker program information
TEVA_CHI_00003805	2011	Pain Care Specialist, Second Semester 2011. Incentive Compensation Plan, Fentora Second Semester Bonus
TEVA_CHI_00006142	1/18/2007	Powerpoint: FAST Team Meeting, January 18, 2007
TEVA_CHI_00028341	9/19/2006	Letter with Submission from Cephalon to FDA re NDA 21-947 (Fentora treatment of breakthrough pain in opioid intolerant patients with cancer)
TEVA_CHI_00038587	2010	Pain Care Specialist 1st Quarter 2010 Incentive Compensation Plan
TEVA_CHI_00039257	2006	Pain Care Specialist, 4th Quarter 2006 Incentive Compensation Plan, Fentora 4th Quarter Bonus
TEVA_CHI_00041421	2006	Pain Care Specialist 4th Quarter 2006 Incentive Compensation Plan
TEVA_CHI_00042882	2003	2003 Actiq Marketing Plan
TEVA_CHI_00042951	2004	2004 Actiq Marketing Plan
TEVA_CHI_00043010	2005	2005 Marketing Plan
TEVA_CHI_00046092	9/30/2012	Teva Pharmaceuticals Report on Independent Review Organization's Engagement; Procedures, Findings and Recommendations
TEVA_CHI_00046827	9/30/2009	Teva Pharmaceuticals Report on Independent Review Organization's Engagement; Procedures, Findings and Recommendations
TEVA_CHI_00052070	6/21/2004	Email from Scott Bischoff to Shaw Steinbarth and others re: Q2 Bonus Plan and Sales Contests
TEVA_CHI_00062757	12/3/2011	Email from Michael Morreale to Corinne Gillenkirk and others re: FW Live meeting deck revised
TEVA_CHI_00062758		Fentora Prescription Savings Card
TEVA_MDL_A_00008173	2006	Actiq speaker programs 2006
TEVA_MDL_A_00008174	2006	Fentora speaker programs 2006
TEVA_MDL_A_00010836	4/00/2006	Actiq End of Lifecycle Plan
TEVA_MDL_A_00021120		Fentora objections and Company Approved Responses
TEVA_MDL_A_00025238	9/12/2006	Transmittal of Advertisements and Promotional Labeling: FENT flashcards, voucher books, note pads, lunch and learn kits, pens, Portenoy abstract, Durfee reprint, etc.
TEVA_MDL_A_00025238	10/12/2005	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use

TEVA_MDL_A_00025378	10/31/2006	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00025496	1/18/2007	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00025865	3/30/2007	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00025942	4/13/2007	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00025983	4/20/2007	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00025990	5/2/2007	Transmittal of Advertisements and Promotional Labeling: Fentora patient privacy, core sales aid, pharmacy flashcard, article "Fetanyl Buccal Tablets for the relief of breakthrough pain in opioid-treated patients with chronic low back pain: a randomized placebo-controlled study"
TEVA_MDL_A_00025990	5/2/2007	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00026098	7/2/2007	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00026107	7/6/2007	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00026618	11/16/2007	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00026707	2/8/2008	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00026715	2/22/2008	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00026762	3/7/2008	Transmittal of Advertisements and Promotional Labeling: FENT 226 Fentora voucher; Fent 219 medication guide
TEVA_MDL_A_00026762	3/7/2008	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00027170	5/2/2008	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00027239	5/12/2008	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00027251	5/23/2008	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00027556	7/31/2008	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00027637	8/28/2008	Transmittal of Advertisements and Promotional Labeling: FENT 269 FENTORA dosing and administration guide
TEVA_MDL_A_00027637	8/28/2008	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use

TEVA_MDL_A_00027646	9/12/2008	Transmittal of Advertisements and Promotional Labeling: FENT 263 FENTORA Interactive dosing guide
TEVA_MDL_A_00027646	9/12/2008	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00027669	1/15/2009	Transmittal of Advertisements and Promotional Labeling: FENT 277a Fentora voucher
TEVA_MDL_A_00027887	6/19/2009	Transmittal of Advertisements and Promotional Labeling: FEN card holder, patient FAQ
TEVA_MDL_A_00028077	6/26/2009	Transmittal of Advertisements and Promotional Labeling: FENT tear sheet, brochure, voucher
TEVA_MDL_A_00028472	3/25/2010	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00028503	4/30/2010	Transmittal of Advertisements and Promotional Labeling: FEN content converter, oncology leave behind
TEVA_MDL_A_00028716	8/26/2010	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00029394	1/10/2011	Transmittal of Advertisements and Promotional Labeling: FENT 2201 FENTORA voucher
TEVA_MDL_A_00029407	1/14/2011	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00029495	3/11/2011	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00029820	3/25/2011	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00029984	5/26/2011	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00030300	9/1/2011	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00038282	2007	FDA letter to Cephalon re: IND 65,447
TEVA_MDL_A_00266216	5/16/2005	Transmittal of Advertisements and Promotional Labeling: Dosing Guide, Patient Profiles, Coupon Book, etc.
TEVA_MDL_A_00266319	9/22/2005	Transmittal of Advertisements and Promotional Labeling: Core Sales Aids
TEVA_MDL_A_00267691	2004	FDA letter to Cephalon re: NDA #20-747 Actiq warning stickers, journal and detail ads
TEVA_MDL_A_00338667	2006	Fentora speaker budgets and summaries 2006
TEVA_MDL_A_00359434	6/22/2007	Model Sales Call Behavior
TEVA_MDL_A_00363031	2010	Fentora 2010 Brand Plan
TEVA_MDL_A_00364495	2007	Fentora Marketing Plan 2007
TEVA_MDL_A_00365382	5/18/2006	FEBT Launch Playbook, Steering Committee Presentation, May 18, 2006
TEVA_MDL_A_00368405	12/00/2005	FEBT, 2005 - 2006 Marketing Plan
TEVA_MDL_A_00375244	7/2/2008	Fentora Marketing Plan, July 2, 2008
TEVA_MDL_A_00381966	4/29/2010	Fentora Cynthia Condodina Sr. Product Manager, April 29th 2010

TEVA_MDL_A_00390736	2006	Handling Objections Workshop, Leader Guide
TEVA_MDL_A_00399532	9/26/2005	Pain Medicine Executive Advisory Board; FEBT Marketing PMEAB Meeting
TEVA_MDL_A_00454816	2002	Actiq 2002 Marketing Plan
TEVA_MDL_A_00455000		2005 Actig Marketing Plan
TEVA_MDL_A_00455086		2012-2016 Opioid Market Share Calculations
TEVA_MDL_A_00455095		CA Call Notes, 2006 - 2016
TEVA_MDL_A_00455200	2006	CA Call Notes
TEVA_MDL_A_00455201		Teva Pharmaceutical USA List of Opioid Containing Products, 2000-2016
TEVA_MDL_A_00498707	12/00/2011	draft agenda, project scope and objectives re: Hydrocodone LA Advisory Board Meeting, December, 2011
TEVA_MDL_A_00501903	5/23/2012	Message Recall Tracking Study,
TEVA_MDL_A_00505311		Etiology of Migraine
TEVA_MDL_A_00551447		optimize onset with Fentora
TEVA_MDL_A_00552850	10/00/2006	Cephalon Sales Policy Handbook
TEVA_MDL_A_00553218		payments 2009-2017
TEVA_MDL_A_00556008	7/15/2010	Fentora 2011 Brand Plan, ERL Tactical Recommendations
TEVA_MDL_A_00556885	07/00/2005	FEBT Strategic Publications Plan, 2005 - 2006
TEVA_MDL_A_00564864	2006	Pain Medicine Independent Medical Education, 2006 Year-End Report
TEVA_MDL_A_00565051		Grants information, 2012-2017
TEVA_MDL_A_00575195	4/9/2004	Email from Andy Pyfer to Michael Wetherholt and others re: Important News New Tools Available
TEVA_MDL_A_00679308		Securing the Future of Fentora: The Launch of the Secure REMS Program in Support of Fentora and Actiq, by Fallon Medica, LLC
TEVA_MDL_A_00681247		CA Call Notes, 2010 - 2011
TEVA_MDL_A_00694962		Prescription Drug Abuse & Alliance to Prevent the Abuse Medicines
TEVA_MDL_A_00695346	4/10/2006	Transmittal of Advertisements and Promotional Labeling: Actiq Prescription Pad and Reimbursement Hotline Information, etc.
TEVA_MDL_A_00695743	3/25/2012	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_00700492		Specialty Code Description spreadsheet
TEVA_MDL_A_00710057	2012	Letter from FDA to Christine Kampf, Cephalon re NDA 021947/S-015
TEVA_MDL_A_00739357	4/15/2008	Sales Bulletin re: WLF Policy Update
TEVA_MDL_A_00755335	6/28/2012	2013 Marketing Mix presentation by ZS
TEVA_MDL_A_00763714		list of Fentora voucher distributions to HCPs, 2012-2016
TEVA_MDL_A_00763716		spreadsheet re Fentora starter vouchers
TEVA_MDL_A_00763717		CA Call Notes, 2006 - 2016
TEVA_MDL_A_00763718	2006	CA Call Notes

TEVA_MDL_A_00766429	2/17/2007	Cepahlon, Inc. FQ$ 2006 Earnings Call Transcripts
TEVA_MDL_A_00772008	9/30/2012	Teva Pharmaceuticals Report on Independent Review Organization's Engagement; Procedures, Findings and Recommendations (DRAFT)
TEVA_MDL_A_00773975	9/30/2013	Cephalon, Inc d/b/a Teva Pharmaceuticals Report on Independent Review Organization's Engagement; Procedures, Findings and Recommendations (draft)
TEVA_MDL_A_00773981	9/30/2013	Cephalon, Inc d/b/a Teva Pharmaceuticals Report on Independent Review Organization's Engagement; Procedures, Findings and Recommendations (draft)
TEVA_MDL_A_00782538	9/30/2013	Cephalon, Inc d/b/a Teva Pharmaceuticals Report on Independent Review Organization's Engagement; Procedures, Findings and Recommendations
TEVA_MDL_A_00784389	9/30/2011	Cephalon, Inc d/b/a Teva Pharmaceuticals Report on Independent Review Organization's Engagement; Procedures, Findings and Recommendations
TEVA_MDL_A_00786495	9/30/2010	Report on Independent Review Organization's Engagement; Procedures, Findings and Recommendations,
TEVA_MDL_A_00830750	2006	“The Clinical Management of Breakthrough Pain Current and Emerging Perspectives” Pain Medicine News
TEVA_MDL_A_00850584	2/4/2009	TRIM Archiving Cover Memo from Kimber Titus to Legal Department Archives re: Fully-Executed Agreement(s) for Archiving in Central Files; Independent Educational Program Grant Agreement with MediCom Worldwide
TEVA_MDL_A_00851811	2008	Binder or book covers/spines re Medical Learning Solutions, references, Tool Kit
TEVA_MDL_A_00852662	12/7/2007	TRIM Archiving Cover Memo from Carol Bruton to Legal Department Archives re: Fully-Executed Agreement(s) for Archiving in Central Files; American Pain Society grant for CLE
TEVA_MDL_A_00857857	2/21/2014	Email from Deborah Bearer toJamie Rosenberger re: Vantrela ER Market Access Tactical Review 2_20_14v10.pptx
TEVA_MDL_A_00857858	2/21/2014	powerpoint: Vantrela ER Market Access Strategy and Tactical Review
TEVA_MDL_A_00865833	2009	Pain Care Specialist 1st Quarter 2009 Incentive Compensation Plan
TEVA_MDL_A_00865836	1/1/2004	Incentive Compensation Plan Payment Policies for All Cephalon Field Sales Personnel
TEVA_MDL_A_00874852	1/8/2014	E-mail from Matthew Day to Chinedu Momah Fw: Fentora slide deck
TEVA_MDL_A_00874854	07/00/2013	Perspectives in Oncology: Managing Breakthrough Pain slides

TEVA_MDL_A_00874858	07/00/2013	Managing breakthrough pain in patients with cancer slides
TEVA_MDL_A_00881567	2012	The Q4 2012 brand team meeting,
TEVA_MDL_A_00881680	7/00/2013	Strengthening Fentora's Position in the Marketplace; HCP Wave 2 Tracker, July 2013
TEVA_MDL_A_00890304	11/25/2008	Meeting invite from Amy Jordheim to Dean Robinson, Paula Castagno, Matthew Day and others re: Oncology bFOCUSED team meeting
TEVA_MDL_A_00981245	9/29/2012	Email from Nathan Ross to Chris Brown and others re: New Digital Sales Aid User Guides
TEVA_MDL_A_00981259	9/00/2012	Fentora October Digital Sales Aid (DSA) iPad User Guide
TEVA_MDL_A_01088845	8/28/2007	Unrestricted Educational Grant Agreement btwn Cephalon and Federation of State Medical Boards Research & Education Foundation
TEVA_MDL_A_01089593	9/00/2006	Review and Approval of grant request to American Chronic Pain Association for patient brochure and media tour on BTP during September Pain Awareness Month
TEVA_MDL_A_01090493	6/19/2007	Email from Stacey Beckhardt to Paula Castagno re: FW APF Distributed the Treatment Options Guidebook to Soldiers and Family Members (attaches: American Pain Foundation "Treatment Options: A Guide for People Living with Pain")
TEVA_MDL_A_01105100	10/3/2007	E-mail from Carol Stewart to Sales PCS East Managers cc: Randy Spokane Re: New Rentora slides
TEVA_MDL_A_01105101		Fentora slides
TEVA_MDL_A_01108856	4/28/2004	Email from Andy Pyfer to Stacey Beckhardt re Associated Press Article: "Increase in abuse reported of narcotic lollipops for cancer patients" (Terifay Ex. 010)
TEVA_MDL_A_01130614		CA Call Notes, 2016 - 2018
TEVA_MDL_A_01130623		printed spreadsheet of Fentora list of sales aids and leave behind materials, up to 2018; Hassler Ex. 18
TEVA_MDL_A_01132030	01/00/2014	Fentora "Now available with preferred, Tier 2 formulary status" and important safety information
TEVA_MDL_A_01135672	2017	Fentora indications and usage
TEVA_MDL_A_01136529	5/00/2015	Pain Matters: Evolving Roles, Same Goals Video Script
TEVA_MDL_A_01149871	04/00/2009	Understanding your treatment; an educational brochure for patients from the makers of FENTORA
TEVA_MDL_A_01150240	05/00/2009	"Don't make them count the moments, make their moments count," Fentora information
TEVA_MDL_A_01159082	11/16/2000	Actiq Master Plan
TEVA_MDL_A_01159143	1/00/2001	2001 Actiq Marketing Plan
TEVA_MDL_A_01159437	8/14/2003	Email from Andy Pyfer to Christine Wells re: FW Executive Summaries (Pyfer Ex. 023)

TEVA_MDL_A_01159525	2/23/2004	Letter from Dave Brennan to Kerry Woods, FDA re: Cephalon compliance issues
TEVA_MDL_A_01159577	2003	Executive Summary, Regulatory Affairs - Actiq Risk Management Program, Audit April 1 and May 16, 2003
TEVA_MDL_A_01171101	8/00/2005	Review and Approval of grant request to Howard Regional Health Systems for Grand Rounds program
TEVA_MDL_A_01171351	8/00/2004	Review and Approval of grant request to American Academy of Physical Medicine and Rehabilitation ro Industry Relations Council program
TEVA_MDL_A_01174115	1/00/2007	Review and Approval of grant request to American Pain Foundation for dissemination of patient education and related materials
TEVA_MDL_A_01174116	12/19/2006	Memo from Stacey Beckhardt to Grant Review Committee re: Unrestricted Educational Grant to Disseminate Patient Education Materials Developed by American Pain Foundation
TEVA_MDL_A_01184456	1/5/2010	FENTORA 2011 Brand Plan, January 5, 2010 DRAFT
TEVA_MDL_A_01184706		spreadsheet with data re Sales and Marketing Actuals, 2008-2010
TEVA_MDL_A_01197034		Dashboard, Fentora Summary, 2012, 2013
TEVA_MDL_A_01204102	1/24/2014	Email from Ryan Daufenbach to Momah Chinedu and others re: Strat Plan
TEVA_MDL_A_01204103	12/23/2013	2014 Vantrela ER Launch Plan DRAFT
TEVA_MDL_A_01208119	12/00/2011	Special Report, An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl citrate (ACTIQ). Brought to you by Anesthesiology News, Clinical Oncology News, Pain Medicine News.
TEVA_MDL_A_01261646	12/4/2013	Email from Will Rose to James Peterson and others re CLAD Core Team Meeting Deck_12/4
TEVA_MDL_A_01261647	12/4/2013	powerpoint: CLAD Core Leadershipin Abuse Deterrence, core Team Meeting, December 4, 2013
TEVA_MDL_A_01281971		CA Call Notes, 2013 - 2014
TEVA_MDL_A_01317332	1/23/2017	Email from Jeffrey Callahan to Joseph Smith and others re: Week 3-NeuroPsych, Pain and Migraine Shipments
TEVA_MDL_A_01317334	1/23/2017	CNS Weekly Sales File Q1 Week 3.xlsb
TEVA_MDL_A_01317336	2017	2017 TRx Tracker.xlsm
TEVA_MDL_A_01399742	12/13/2006	Email from Stacey Beckhardt to Paula Castagno re: Do You Still Have Pain (attaches: Breakthrough Pain, Do you still have pain?)
TEVA_MDL_A_01399743	3/26/2004	Breakthrough Pain, Do you still have pain?
TEVA_MDL_A_01401514	2/23/2006	Email from Andy Pyfer to Adrien Menna and others re: Pain Team 2006 MICPs (Pyfer Ex. 006)
TEVA_MDL_A_01465597	3/10/2015	Email from Colleen McGinn to Jason Gardner re: DEA Quota Letter
TEVA_MDL_A_01491886	10/00/2005	When Onset Matters... Actiq Responds - sales aid

TEVA_MDL_A_01492872	2006	"Fentanyl buccal tablets," Lynn R. Webster.
TEVA_MDL_A_01512147	10/31/2006	Email from Jerri Ann Thatcher to Arvind Narayana re: ISS idea from Mike Brennan
TEVA_MDL_A_01541365	4/24/2007	Email from Suzanne Richards to Beth Huston re: Portenoy Low Back Pain Article
TEVA_MDL_A_01541366		citation: Portenoy RK, Messina J, Fang X.: Fentanyl buccal tablet (FBT) for relief of breaktthrough pain in opioid-treated patients with chronic low back pain: a randomized, placebo-controlled study. Current Medical Research and Opinion 12(1): 223-233, 2007.
TEVA_MDL_A_01541367	3/26/2007	Fentora WLF Overview & Implementation Guide
TEVA_MDL_A_01575289	7/12/2004	Cephalon letter and materials in response to FDA requests re Actiq
TEVA_MDL_A_01575973	7/26/2004	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_01575973	7/26/2004	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_01582360	2004	FDA letter to Carol Marchione, Cephalon re Actiq promotional and safety aspects
TEVA_MDL_A_01583458	2004	FDA letter to Carol Marchione, Cephalon re Actiq NDA information inadequate
TEVA_MDL_A_01584000	4/14/2004	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_01584607	6/16/2004	Letter from Tracey Parker (Cephalon) to Jialynn Wang FDA re: Actiq NDA 20-747 Educational Material
TEVA_MDL_A_01584978	2004	FDA letter to Carol Marchione, Cephalon re Actiq NDA , enclosing minutes of 8/30/04 meeting
TEVA_MDL_A_01584999	5/16/2005	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_01585102	9/22/2005	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_01853080		Grants information, 2005
TEVA_MDL_A_01868375	3/15/2010	Email from Valerie Kaisen to Michael Morreale re: vouchers
TEVA_MDL_A_02024224	4/8/2005	email from Terrence Terifay to Edward Hoey and Mina Patel re: FW Emerging Solutions in Pain Activity Report 4-7-05
TEVA_MDL_A_02030685	3/23/2007	Email from Paula Castagno to Stacey Beckhardt, Catherine Collier and Jacqueline Davis re: my ppt so far
TEVA_MDL_A_02030686	2007	Cephalon Pain Franchise Health Care Professional Adivory Board, March 30-April 1, 2007 slides
TEVA_MDL_A_02030687		ShareYourPain.org promotional material
TEVA_MDL_A_02030696		Breakthroughpain.com promotional material
TEVA_MDL_A_02047670	2006	2006 ACTIQ Marketing
TEVA_MDL_A_02238110		distribution list for item FEN-2201, by quanity and recipient, Feb. 2011

TEVA_MDL_A_02241320	6/7/2011	Email from Jenifer Antonacci to Denise Madden re: FW Corporate Invoices - Cephalon
TEVA_MDL_A_02293476	11/30/2012	E-mail from Amanda McGeary to Matthew Day, Christine Cervone Re: Fentora Promo Deck
TEVA_MDL_A_02293477		Breakthrough Pain: An Important Component of Chronic Pain in Patients with Cancer slides
TEVA_MDL_A_02315382	5/30/2018	Email from Sharyn Albrecht to Anthony Giannone and others re: IQVIA MARKET SHARE DATA
TEVA_MDL_A_02315384	2018	2018 IQVIA Weekly Tracking Report
TEVA_MDL_A_02351662	2/27/2012	Email from Kent Schurr to Jay Jacobs and others re 2012 Bonus Roll-Out presentation (James Mara CA deposition, Exh. 010)
TEVA_MDL_A_02376171	6/16/2006	Email from Andy Pyfer to Pranay Patel with attachment (Pyfer Ex. 029)
TEVA_MDL_A_02382115	2012	2012 Teva Pain Care Sales Annual Field Sales Awards
TEVA_MDL_A_02386158	11/5/2007	Fentanyl Buccal Tablet for the Relief of Breakthrough Pain in Opioid-Tolerant Adult Patients with Chronic Neuropathic Pain: A Mulitcenter, Randomized, Double-Blind, Placebo-Controlled Study.
TEVA_MDL_A_02397625	8/5/2004	Email from Bill Cunningham to Terrence Terifay re: ACTIQ Brand Plan Reimbursement/MC Section
TEVA_MDL_A_02401119		spreadsheet with invoice/grant payment information, 2003-2018
TEVA_MDL_A_02416207		CA Call Notes, 2001 - 2005
TEVA_MDL_A_02416208		2011-2017 Net Sales Spreadsheet
TEVA_MDL_A_02419959		2012-2015 Net Sales Spreadsheet
TEVA_MDL_A_02475899	9/18/2016	Email from Donald Lohman to Robert Giacalone and others re: ADIWG Meeting
TEVA_MDL_A_02475900	8/17/2016	Anti-Diversion Industry Working Group (ADIWG) [Draft #5; 8/17/16]
TEVA_MDL_A_02592029	1/00/2006	Chronic Pain Assesment Tool
TEVA_MDL_A_02867804	6/9/2004	Email from Wendy Congleton to Andy Pyfer and others re: Actiq Inventory - Current.xls
TEVA_MDL_A_02894055	5/5/2008	Email from Terrence Terifay to Dana Luscombe re : Fentora Call History for TT - 05052008.xls (cover email to TEVA_MDL_A_02894057)
TEVA_MDL_A_02894057	5/5/2008	Call Notes, 2006 - 2008
TEVA_MDL_A_02914333		list of Teva Generic and Transmucosal Immediate Release Fentanyl documents and document numbers (spreadsheet)
TEVA_MDL_A_02936923	11/14/2007	Email from Robert Roche to Valli Baldassano re: ROCHE POA SPEECH DALLAS 11 09 07.doc
TEVA_MDL_A_02953031	1/8/2010	Email from Deborah Bearer to Cynthia Condodina re: Fentora Reimbursement assistance hotline
TEVA_MDL_A_02974065	12/21/2017	Email from Matthew Day to John Hassler re: Vantrela
TEVA_MDL_A_03193699	2/13/2012	email from Jeffrey Sipia to Wendy Miller re: 2011 FY Hist Sales Data.xlsx

TEVA_MDL_A_03206965		Cephalon Speaker Bureau Policy
TEVA_MDL_A_03237316		Actiq Eulogy
TEVA_MDL_A_03242925	3/12/2007	HCS - Brand Marketing Initiatives Matt Felker, March 12, 2007
TEVA_MDL_A_03248905	2002	2002 Marketing Plan
TEVA_MDL_A_03252903	12/2/2004	powerpoint: Directors Meeting ACTIQ, December 2, 2004
TEVA_MDL_A_03272549	1/24/2005	Email from Stacey Beckhardt to Terrence Terifay and others re: JAMA (1.19) Research Letter Finds Increased Reports of Methadone Diversion and Abuse
TEVA_MDL_A_03274424	4/26/2005	E-mail from Darrin Kiessling to Susan Larijani, Steve Shoemaker cc: Bonnie Shoemaker, Kiumars Vadiei, Terrence Terifay, Dean Robinson RE: ACTIQ MCO slides
TEVA_MDL_A_03274427		ACTIQ Managed Care Slide Set
TEVA_MDL_A_03315345	12/6/2006	Independent Educational Program ("IEP") Grant Agreement between Cephalon and Medical Learning Solutions, Inc. and MedCom Worldwide, Inc.
TEVA_MDL_A_03316708	11/25/2003	Email from Stacey Beckhardt to Victor Raczkowski and others re: Actiq Investigation segment on Channel 6 News (Beckhardt Ex. 003)
TEVA_MDL_A_03317918	2004	FDA letter to Carol Marchione, Cephalon re Actiq promotion
TEVA_MDL_A_03400542	9/10/2007	Dr. Healthcare Professional letter re Key Safety Information -- Fentora
TEVA_MDL_A_03413816		payments 2007 - 2017
TEVA_MDL_A_03548147	9/2/2015	Government Affairs Summit (draft)
TEVA_MDL_A_03572982		Promotional Guidelines
TEVA_MDL_A_03913568	9/2/2005	E-mail from Susan Larijani to Kevin Verbosh cc: Darrin Kiessling, Liumars Vadiei RE: Actiq Speakers Bureau Slides - revised
TEVA_MDL_A_03913569		Opioids and Respiratory Depression
TEVA_MDL_A_03913570		Economic Impact of Pain slides
TEVA_MDL_A_03913571		Actiq Cancer Pain Overview
TEVA_MDL_A_03913572		Actiq Cancer Pain Overview
TEVA_MDL_A_03913573		Actiq Clinical Trials - Pharmacologic Management t of Cancer Pain
TEVA_MDL_A_03913574		Actiq - Indication OTS Technology Pharmacokinetics Pharmacodynamics and Relative Potency, Additional Studies slides
TEVA_MDL_A_03913575		Actiq - Clinical Trials - Dose Titration Studies slides
TEVA_MDL_A_03913576		Actiq - Clinical Trials - Placebo controlled study slides
TEVA_MDL_A_03913577		Actiq - Clinical Trials - Long Term Safety Study slides
TEVA_MDL_A_03913578		Actiq - Safety Profile
TEVA_MDL_A_03913579		Actiq Clinical Trials Dosage and Administration slides
TEVA_MDL_A_03913580		Actiq clinical Trials - Risk Management Program

TEVA_MDL_A_03913581		Actiq clinical trials - Comparison of Actiq to Morphine Sulfate Immediate Release (MSIR) slides
TEVA_MDL_A_03913582		Opioid Abuse Addiction and Diversion slides
TEVA_MDL_A_03913583		Assessing Functional Limitations in Chronic Pain Patients slides
TEVA_MDL_A_04108856	4/28/2004	Email from Andy Pyfer to Stacey Beckhardt re Associated Press Article: "Increase in abuse reported of narcotic lollipops for cancer patients" (Pyfer Ex. 032)
TEVA_MDL_A_04110562	4/11/2005	email from Matthew Geandreau to Andy Pyfer and others re: Fw copy of Transcription
TEVA_MDL_A_04154661	6/19/2006	Email from Steve Shoemaker to Terrence Terifay re: News Article - FYI - Abuse of fentanyl patch from chronic pain increasing
TEVA_MDL_A_04313917		spreadsheet with invoice/payment information to pain groups, advocacy, etc., 2006-2011
TEVA_MDL_A_04358944	2012	CA Call Notes
TEVA_MDL_A_04420139	2/22/2005	Email from Bill Cunningham to Janette Bearch and other re: FW Hotline
TEVA_MDL_A_05303906	5/2/2000	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_05313123	02/00/2001	Actiq Marketing Slides
TEVA_MDL_A_05349714	8/27/2004	Email from Michael Thiem to Roy Craig re Top Actiq Coupon Users - Feedback
TEVA_MDL_A_05445644	6/14/2004	Memo from Lauren Magnus to Cephalon Sales Organization re Prior Authorization Guide (Sales Bulleting #17)
TEVA_MDL_A_05509299	08/00/2004	Review and Approval of grant request to American Pain Foundation for Target initiative program
TEVA_MDL_A_05510585	10/00/2004	Cephalon check request (and related documentation) for payee American Pain Society re CD-Rom of 24th Annual Scientific Meeting Proceedings
TEVA_MDL_A_05666277	12/13/2005	2005 Marketing Slides, sales training
TEVA_MDL_A_05734046	3/00/2002	2002 Marketing Slides, sales training
TEVA_MDL_A_05965744	2002	2002 Marketing Plan
TEVA_MDL_A_06378820	4/14/2009	Email from Karen Lowney to Valli Baldassano re: Letter to the OIG-DDMAC Letter
TEVA_MDL_A_06378821	3/26/2009	FDA violation letter from Michael Sauers to Carole S. Marchione, Cephalon
TEVA_MDL_A_06378826	4/8/2009	Letter from Carole Marchione, Cephalon to Michael Sauers, FDA
TEVA_MDL_A_06384299	11/28/2006	Email from Cynthia Condodina to Michael Richardson re: Decision Tree
TEVA_MDL_A_06384302		chart of questions and responses - decision tree
TEVA_MDL_A_06410406	1/3/2013	E-mail from Matthew Day to Bill M Smith Fw: OPDP submission - materials date of first use 1/4/13

TEVA_MDL_A_06410408		Managing Breakthrough Pain in Patients with Cancer
TEVA_MDL_A_06474725	11/28/2006	email from Michael Richardson to Cynthia Condodina re: Decision Tree
TEVA_MDL_A_06560910	10/1/2003	Actiq Speaker Bureau Training Guidelines
TEVA_MDL_A_06561363	2005	Speaking Engagements, 2005
TEVA_MDL_A_06570130	1/2/2008	Email from Kathleen Merlwether to Valli Baldassano re: Happy New Year (Cephalon SOW 12-21-07DRAFT.doc.zip)
TEVA_MDL_A_06570138	1/10/2008	Email from Kathleen Merlwether to Valli Baldassano re: SOW
TEVA_MDL_A_06764039	5/2/2008	Independent Educational Program Grant Agreement between Cephalon and MedCom Worldwide, Inc.
TEVA_MDL_A_06766836	1/15/2009	Independent Educational Program Grant Agreement between Cephalon and Beth Israel Medical Center
TEVA_MDL_A_07093742	2/27/2012	A Brand New Day, Bonus Plan overview to Pain Specialists, First Semester 2012
TEVA_MDL_A_07201534	9/29/2008	Email from Valli Baldassano to 965 Global Compliance re: CIA
TEVA_MDL_A_07417449	12/18/2006	Email from Stacey Beckhardt to Michael Richardson and others re FW Radio Media Tour: Tuesday, December 19th with Dr. John Peppin
TEVA_MDL_A_07419580	8/15/2006	E-mail from Arvind Narayana to Rand Posmantur cc: Susan McGaurn, Steven Valliere, Jeffrey Dayno RE: Fentora Presentation slides
TEVA_MDL_A_07419582	8/12/2006	Cephalon Pain Franchise Speaker Training slides
TEVA_MDL_A_07663830	9/8/2011	E-mail from Lori Lush to Arvind Narayana, Matthew Napoletano Re: Fentora Promotional deck
TEVA_MDL_A_07663831		Managing Breakthrough Cancer Pain with Fentora
TEVA_MDL_A_07846839	2007	Fentora Strategic Marketing Plan, 2007
TEVA_MDL_A_08083636	2011	Ready for REMS Campaign Performance, March 1, 2011 - April 20, 2011
TEVA_MDL_A_08238220	12/10/2004	Email from Stacey Beckhardt to Roy Craig and others re Media Coverage of Arrest of Dr. Lisnichy (Terifay Ex. 011)
TEVA_MDL_A_08238912	1/4/2006	E-mail from Susan Larijani to Jessica Adams cc: Arpana Sehgal, Carol Marchione Re: DDMAC approved Actiq training slides
TEVA_MDL_A_08238913		Actiq (oral transmucosal fentanyl citrate) training slides
TEVA_MDL_A_08238914		Actiq (oral transmucosal fentanyl citrate) training slides
TEVA_MDL_A_08242371	6/7/2004	Email from Carol Marchione to Francine Del Ricci re: FW FDA Contact Report - FDA Raises Concerns about Actiq Off-Label Use and Diversion
TEVA_MDL_A_08399245		Discipline Review Letter from FDA to Cephalon re NDA 21-947 (2005/2006)
TEVA_MDL_A_08657807	2015	powerpoint: 2015 Medical Education Programs

TEVA_MDL_A_08741610	2/6/2017	Email from Matthew Day to Tholen Courtney re: Fentora Leave Behind
TEVA_MDL_A_08760982	2005	PainMatters.com - Analytics Report, April 15 - May 17, 2015
TEVA_MDL_A_08778247	6/13/2014	Email from Naik Santosh to Alexis DeAngelo and Matthew Day re: Vantrela Onboarding Guide
TEVA_MDL_A_08778248	3/24/2014	Vantrela ER Strategic Brand Plan, March 24, 2014
TEVA_MDL_A_08789928		speaker list
TEVA_MDL_A_08793787	10/23/2014	E-mail from Amanda Tollen to Jeff Gudin cc: Matthew Day Re: Fentora Program
TEVA_MDL_A_08793790	08/00/2013	Managing breakthrough pain in patients with cancer slides
TEVA_MDL_A_08802273	1/27/2015	Performance Management Full Report, Matthew M. Day - 2014
TEVA_MDL_A_08857270	2015	Actiq Reimbursement Hotline Flyer
TEVA_MDL_A_08860362	2011	2011 National Sales & Marketing Meeting, PCS Breakout - Managed Care Discussion
TEVA_MDL_A_08873064	5/24/2004	Email from Dana Luscombe to UG Sales re: Sales Bulletin #16 - MEP Speakers Bureau Changes - IMPORTANT
TEVA_MDL_A_09058990	2007	Cephalon, Inc. Pain Care Specialist, 1st Quarter 2007 Bonus Calculator
TEVA_MDL_A_09068255	10/3/2006	E-mail from Carol Stewart to Sales PCS East Managers cc: Randy Spokane Re: Promotional Slide Deck
TEVA_MDL_A_09068256		Fentora slides
TEVA_MDL_A_09088727		slipsheet
TEVA_MDL_A_09544530	12/21/2007	Email from Stacey Beckhardt to Arvind Narayana, Susan Larijani and Arpana Sehgal re: FW Target Card from the American Pain Poundation
TEVA_MDL_A_09544532		Target Chronic Pain
TEVA_MDL_A_09544534		Remember to Target Chronic Pain
TEVA_MDL_A_09610652	9/24/2010	E-mail from Michael Morreal to Michael Warken Re: Current approved CSP deck
TEVA_MDL_A_09610654		Fentora and Breakthrough Pain slides
TEVA_MDL_A_09655240	1/9/2017	email from Brenda Hunsberger to Carla Hedrick and others re: Follow-Up Meeting: Status Check - ANDA Holder Fee Clean-Up
TEVA_MDL_A_09655245		2017 Teva Companies and ANDA Number Spreadsheet
TEVA_MDL_A_10028329	4/29/2003	Email from Paula Williams to Sales PCS Reps; Sales Medical Liaisons and others re migraine topic added to CEP lecture website
TEVA_MDL_A_10061799	4/26/2005	E-mail from Darrin Kiessling to Steve Shoemarker, Susan Larijani cc: Bonnie Shoemaker RE: Actiq MCO slides
TEVA_MDL_A_10061802		ACTIQ Managed Care Slide Set Supplemental Slides

TEVA_MDL_A_10070142	11/10/2004	E-mail from Dean Robinson to Kevin Verbosh cc: Susan Larijani, Kiumars Vadiei RE: ACTIQ Promotional slide kit
TEVA_MDL_A_10070143		ACTIQ C-II oral transmucosal fentanyl citrate Powerpoint slides
TEVA_MDL_A_10070432	1/20/2005	Email from Stacey Beckhardt to Lisa Weiss re: ACPA 2005 Medications and Chronic Pain Supplement.doc (suggested revisions to American Chronic Pain Association)
TEVA_MDL_A_11087241	2012	Letter from FDA to Christine Kampf, Cephalon re NDA 020747/S-034
TEVA_MDL_A_11110449	7/6/2001	Transmittal of Advertisements and Promotional Labeling: Actiq Sales Aid, Coupon, Magnet, and Dosing Guide
TEVA_MDL_A_11115315	3/5/2002	Letter from Cephalon to FDA re submission of Actiq promotional material
TEVA_MDL_A_11115489	3/11/2002	Transmittal of Advertisements and Promotional Labeling: Pocket Dosing Guide
TEVA_MDL_A_11115531	4/15/2002	Transmittal of Advertisements and Promotional labeling for drugs and biologics for human use
TEVA_MDL_A_11187003	10/20/2004	Exit Interview: Andrea BeDan
TEVA_MDL_A_11191309	3/18/2008	E-mail from Carol Stewart to Sales Area Marketing & Field Effectiveness
TEVA_MDL_A_11191312		Fentora slides
TEVA_MDL_A_11320671	1/22/2008	Email from Susan Larijani to Andrea Bonhomme re: FW most recent Fentora promotional deck
TEVA_MDL_A_11320672		powerpoint: Fentora
TEVA_MDL_A_11429532	5/12/2011	Email from Karen Lowney to Capri Miller re: FW Internal Audit Sales & Marketing Compliance Programs
TEVA_MDL_A_11429534	02/00/2008	Internal Audit, US Sales & Marketing Compliance Programs at Cephalon, February 2008
TEVA_MDL_A_11436747	9/29/2008	Email from Karen Lowney to Christopher Rausch, Juie assis and Heather Powell re: FW Press release
TEVA_MDL_A_11436748	9/29/2008	Pharmaceutical Company Cephalon to Pay $425 Million for Off-Label Drug Marketing
TEVA_MDL_A_11440517	8/18/2010	Email from Lisa Peletsky to Karen Lowney re: FENTORA Materials (attached materials for 2009 and 2010 "that the reps distributed during that time")
TEVA_MDL_A_11578212	4/20/2004	Email from Roy Craig to Sales Reps, Sales Managers, Sales Market Development, Sales Directors, Sales Managed Care & Reimbursement re: Payment Policies
TEVA_MDL_A_11578216	7/22/2004	Email from Gregory Martin to Sales Reps re: 3rd Quarter Bonus Plan
TEVA_MDL_A_11892838	10/00/2004	Policy on Providing Reimbursement Information to Customers

TEVA_MDL_A_11892883	10/00/2004	VI. Policy Preceptorships
TEVA_MDL_A_12122432	3/6/2007	2007 Teva Press Release re Selling Generic Oxycodone
TEVA_MDL_A_12150091	11/18/2008	2008 Teva Market Share Report
TEVA_MDL_A_13610631		speaker expenses, 2013 - 2017
TEVA_MDL_A_13610632		speaker expenses, 2002 - 2013
TEVA_MDL_A_13744430	8/00/2006	Prevalence and Characteristics of Breakthrough Pain in Opioid-Treated Patients with Chronic Noncancer Pain
TEVA_MDL_A_13747278		Actiq Prescribing Information
TEVA_MDL_A_13755704	11/5/2010	Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study
TEVA_MDL_JD_00001606		Teva Annual Bonus Policy, effective 2018 and 2019
TEVA_RI_00000001		video clip - "Pain Lingers"
TEVA_RI_00000002		video clip - "A Few Good Sales Men"
TEVA_RI_00000003		video clip -
TEVA_RI_00000004		video clip
TEVA_RI_00000005		video clip (Austin Powers spoof)
TEVA-SC-00379964	5/18/2009	CA Call Notes
US-DEA-00001767	9/27/2006	DEA letter re diversion from Joseph T. Rannazzisi
US-DEA-00001771	12/27/2007	DEA letter re diversion from Joseph T. Rannazzisi
US-DEA-00017912	12/27/2007	DEA letter re diversion from Joseph T. Rannazzisi
US-DEA-00022463	2/7/2007	DEA letter re diversion from Joseph T. Rannazzisi
	10/18/2018	NH Merrimack Complaint (Janssen)
	8/2/2019	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s First Supplemental Response to Plaintiff's First Set of Interrgatories, Nos. 5 and 8-12 (State of NH v. Johnson & Johnson)
	6/26/2019	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Combined First Response to Plaintiff's First Set of Interrogatories, Nos. 1-15 (State of NH v. Johnson & Johnson)
	6/26/2019	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Responses and Objections to Plaintiff's First Set of Requests fro Production of Documents (State of NH v. Johnson & Johnson)

	8/9/2019	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Second Supplemental Response to Plaintiff's First Set of Interrogatories Nos.3, 14 &15 (State of NH v. Johnson & Johnson)
	11/29/2019	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Responses and Objections to First Set of Requests for Admissions (State of NH v. Johnson & Johnson)
	11/29/2019	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Responses and Objections to Second Set of Interrogatories (4) (State of NH v. Johnson & Johnson)
	4/6/2020	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Combined Amended Responses and Objections to Plaintiff's Request for Admissions Nos. 3-7, and 14 (State of NH v. Johnson & Johnson)
	8/00/1990	Exh. 1 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label (State of NH v. Johnson & Johnson)
	01/00/1991	Exh. 2 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, August 1990, January 1991 (State of NH v. Johnson & Johnson)
	6/00/1991	Exh. 3 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, January 1991, June 1991 (State of NH v. Johnson & Johnson)
	6/00/1991	Exh. 4 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, January 1991, June 1991 (State of NH v. Johnson & Johnson)
	4/00/1992	Exh. 5 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, June 1991, April 1992 (State of NH v. Johnson & Johnson)
	3/00/1993	Exh. 6 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, April 1992, March 1993 (State of NH v. Johnson & Johnson)

	9/00/1993	Exh. 7 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, March 1993, August 1993 (State of NH v. Johnson & Johnson)
	1/00/1994	Exh. 8 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, August 1993, January 1994 (State of NH v. Johnson & Johnson)
	6/00/1994	Exh. 9 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, January 1994, June 1994 (State of NH v. Johnson & Johnson)
	6/00/1994	Exh. 10 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, January 1994, June 1994 (State of NH v. Johnson & Johnson)
	6/00/1997	Exh. 11 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, June 1994, June 1997 (State of NH v. Johnson & Johnson)
	4/00/1998	Exh. 12 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, June 1997, April 1998 (State of NH v. Johnson & Johnson)
	11/00/1999	Exh. 13 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, Rev April 1998, November 1999 (State of NH v. Johnson & Johnson)
	1/00/2000	Exh. 14 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, November 1999, January 2000 (State of NH v. Johnson & Johnson)
	2/00/2001	Exh. 15 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, January 2000, February 2001 (State of NH v. Johnson & Johnson)
	5/20/2003	Exh. 16 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, May 20, 2003 Modified Indication Label (State of NH v. Johnson & Johnson)
	2/4/2004	Exh. 17 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, February 4, 2004 (State of NH v. Johnson & Johnson)
	2/7/2008	Exh. 18 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, February 7, 2008 (State of NH v. Johnson & Johnson)
	7/31/2009	Exh. 19 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, July 31, 2009 (State of NH v. Johnson & Johnson)

	7/9/2012	Exh. 20 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, July 9, 2012 (State of NH v. Johnson & Johnson)
	9/23/2013	Exh. 21 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, September 23, 2013 (State of NH v. Johnson & Johnson)
	4/16/2014	Exh. 22 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, April 16, 2014 (State of NH v. Johnson & Johnson)
	12/16/2016	Exh. 23 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, December 16, 2016 (State of NH v. Johnson & Johnson)
	1/24/2018	Exh. 24 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Duragesic Label, January 24, 2018 (State of NH v. Johnson & Johnson)
	11/20/2008	Exh. 25 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Nucynta IR Tablet Label, November 20, 2008 (State of NH v. Johnson & Johnson)
	11/9/2009	Exh. 26 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Nucynta IR Tablet Label, November 9, 2009 (State of NH v. Johnson & Johnson)
	11/1/2010	Exh. 27 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Nucynta IR Tablet Label, November 1, 2010 (State of NH v. Johnson & Johnson)
	7/11/2013	Exh. 28 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Nucynta IR Tablet Label, July 11, 2013 (State of NH v. Johnson & Johnson)
	10/31/2013	Exh. 29 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Nucynta IR Tablet Label, October 31, 2013 (State of NH v. Johnson & Johnson)
	12/16/2016	Exh. 30 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Nucynta IR Tablet Label, December 16, 2016 (State of NH v. Johnson & Johnson)
	10/15/2012	Exh. 31 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Nucynta IR Oral Solution Label, October 15, 2012 (State of NH v. Johnson & Johnson)

	11/17/2014	Exh. 32 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Nucynta IR Oral Solution Label, November 17, 2014 (State of NH v. Johnson & Johnson)
	12/16/2016	Exh. 33 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Nucynta IR Oral Solution Label, December 16, 2016 (State of NH v. Johnson & Johnson)
	8/25/2011	Exh. 34 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Nucynta ER Label, August 25, 2011 (State of NH v. Johnson & Johnson)
	7/9/2012	Exh. 35 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Nucynta ER Label, July 9, 2012 (State of NH v. Johnson & Johnson)
	8/28/2012	Exh. 36 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Nucynta ER Label, August 28, 2012 (State of NH v. Johnson & Johnson)
	4/16/2014	Exh. 37 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Nucynta ER Label, April 16, 2014 (State of NH v. Johnson & Johnson)
	12/16/2016	Exh. 38 to Janssen Supplemental Response to Plaintiff's First Interrogatories: Nucynta ER Label, December 16, 2016 (State of NH v. Johnson & Johnson)
	7/28/2020	Transcript of remote Deposition of Caroline A. Mosseau (State of NH v. Johnson & Johnson)
	6/27/2019	Joint motion for entry of a stipulated protective order (C. Mosseau Ex.1) (State of NH v. Johnson & Johnson)
	7/22/2020	Notice of Remote Deposition of Caroline Mosseau (C. Mosseau Ex. 2) (State of NH v. Johnson & Johnson)
	2/28/2020	Deposition of Tricia Yap in NH - transcript and exhibits (State of NH v. Johnson & Johnson)
		Deposition of Caroline A. Mousseau, exhibit 8 (State of NH v. Johnson & Johnson)
		Deposition of Caroline A. Mousseau, exhibit 9 (State of NH v. Johnson & Johnson)
		Deposition of Caroline A. Mosseau, exhibit 10 (State of NH v. Johnson & Johnson)
		Deposition of Caroline A. Mosseau, exhibit 12 (State of NH v. Johnson & Johnson)
		Deposition of Caroline A. Mosseau, exhibit 13 (State of NH v. Johnson & Johnson)
	7/30/2020	Transcript of remote Deposition of Matthew Mosseau (State of NH v. Johnson & Johnson)

	7/22/2020	Notice of Remote Deposition of Matthew Mosseau (M. Mosseau Ex. 1) (State of NH v. Johnson & Johnson)
	6/27/2019	Joint motion for entry of a stipulated protective order (M. Mosseau Ex.2) (State of NH v. Johnson & Johnson)
		Deposition of Matthew Mosseau, exhibit 7 (State of NH v. Johnson & Johnson)
	8/18/2020	Transcript of remote deposition of Donna Nicolosi (NH) (State of NH v. Johnson & Johnson)
	7/31/2020	Notice of Remote Deposition of Donna Nicolosi (Nicolosi Ex. 1) (State of NH v. Johnson & Johnson)
		Deposition of Donna Nicolosi, exhibit 2 (State of NH v. Johnson & Johnson)
		Deposition of Donna Nicolosi, exhibit 9 (State of NH v. Johnson & Johnson)
		Deposition of Donna Nicolosi, exhibit 10 (State of NH v. Johnson & Johnson)
		Deposition of Donna Nicolosi, exhibit 13 (State of NH v. Johnson & Johnson)
	2010	2010 Business Plan by Donna Nicolosi Territory 2060105 (Deposition of Donna Nicolosi Ex. 15) (State of NH v. Johnson & Johnson)
		Blank slip-sheet "Not Marked" (Nicolosi Ex. 13) (State of NH v. Johnson & Johnson)
	2010	2010 Business Plan by Donna Nicolosi Territory 2060105 (Nicolosi Ex. 15) (State of NH v. Johnson & Johnson)
	10/7/2020	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Supplemental Responses and Objections to Notice of Deposition Pursuant to Rule 26(m), Topic Nos. 2, 3, and 6 (State of NH v. Johnson & Johnson)
	12/17/2020	Senate report: Opioid industry has paid advocacy groups $65M. G. Mulvihill. Associated Press. 12/17/2020. https://apnews.com/article/health-chuck-grassley-medication-ron-wyden-opioids-d0a96ff0728a254f5e51447175cfe7d5
	12/16/2020	Senate Finance Committee Findings from the Investigation of Opioid Manufacturers' Financial Realtionships with Patient Advocacy Groups and Other Tax-Exempt Entities

	10/21/2020	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Supplemental Responses and Objections to Notice of Deposition Pursuant to Rule 26(m), TOPIC No. 4 (State of NH v. Johnson & Johnson)
	11/13/2020	JANSSEN Verification of Rule 26(m) Written Responses
	10/21/2020	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Supplemental Responses and Objections to Notice of Deposition Pursuant to Rule 26(m), TOPIC No. 5 (State of NH v. Johnson & Johnson)
	12/17/2020	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Supplemental Responses and Objections to Notice of Deposition Pursuant to Rule 26(m), TOPIC Nos. 1 & 9 (State of NH v. Johnson & Johnson)
	10/7/2020	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Supplemental Responses and Objections to Notice of Deposition Pursuant to Rule 26(m), TOPIC Nos. 2, 3 and 6 (State of NH v. Johnson & Johnson)
	11/6/2020	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Supplemental Responses and Objections to Notice of Deposition Pursuant to Rule 26(m), TOPIC No. 11 (State of NH v. Johnson & Johnson)
	10/20/2020	Amended Notice of Deposition Pursuant to Rule 26(m) to Defedants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McMeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica's Inc. (Deem-Eshleman Ex. 1) (State of NH v. Johnson & Johnson)
	2020	Kimberly A. Deem-Eshleman Curriculum Vitae (Deem-Eshleman Ex. 3) (State of NH v. Johnson & Johnson)
	10/29/2020	Deposition transcript -- Kimberley Deem-Eshleman -- NH (State of NH v. Johnson & Johnson)

	8/18/2020	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Supplemental Responses and Objections to Notice of Deposition Pursuant to Rule 26(m) (State of NH v. Johnson & Johnson)
	9/8/2020	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Supplemental Responses and Objections to Notice of Deposition Pursuant to Rule 26(m), TOPIC No. 6 (State of NH v. Johnson & Johnson)
	10/13/2020	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Supplemental Responses and Objections to Notice of Deposition Pursuant to Rule 26(m), TOPIC No. 13 (State of NH v. Johnson & Johnson)
	10/13/2020	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Supplemental Responses and Objections to Notice of Deposition Pursuant to Rule 26(m), TOPIC No. 15 (State of NH v. Johnson & Johnson)
	10/21/2020	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Supplemental Responses and Objections to Notice of Deposition Pursuant to Rule 26(m), TOPIC No. 7 (State of NH v. Johnson & Johnson)
	12/17/2020	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Supplemental Responses and Objections to Notice of Deposition Pursuant to Rule 26(m), TOPIC No. 10 (State of NH v. Johnson & Johnson)
	10/21/2020	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Supplemental Responses and Objections to Notice of Deposition Pursuant to Rule 26(m), TOPIC No. 7
	9/22/2020	Deposition of Carol Allocco - transcript (State of NH v. Johnson & Johnson)
	9/4/2020	Notice of Deposition of Carol Allocco (Allocco Exh. 1) (State of NH v. Johnson & Johnson)

	2019	Carol Allocco LinkedIn profile (Allocco Exh. 3) (State of NH v. Johnson & Johnson)
		DEA Drug Scheduling (Allocco Exh. 4) (State of NH v. Johnson & Johnson) www.dea.gov/drug-scheduling (9/6/2020) (State of NH v. Johnson & Johnson)
	7/21/2011	CS/Pain State Issues (Allocco Exh. 28) (State of NH v. Johnson & Johnson)
	9/10/2020	Deposition of Kevin Buckley - transcript (State of NH v. Johnson & Johnson)
	8/27/2020	Notice of Deposition of Kevin Buckley (Buckley Exh. 1) (State of NH v. Johnson & Johnson)
	2018	Kevin Buckley LinkedIn profile (Buckley Exh. 3) (State of NH v. Johnson & Johnson)
		DEA Drug Scheduling (Buckley Exh. 4) (State of NH v. Johnson & Johnson) www.dea.gov/drug-scheduling (9/6/2020) (State of NH v. Johnson & Johnson)
	2/25/2020	Deposition of Haya Taitel in NH & NY - transcript and exhibits
	11/13/2020	CA Expert Report of Anna Lembke (People of CA v. Purdue, et al)
	11/13/2020	CA Expert Report of Lacey Keller (People of CA v. Purdue, et al)
	11/13/2020	CA Expert Report of Pradeep Chintagunta (People of CA v. Purdue, et al)
	11/13/2020	CA Expert Report of Henry Grabowski (People of CA v. Purdue, et al)
	11/13/2020	CA Expert Report of Justin McCrary (People of CA v. Purdue, et al)
	11/13/2020	CA Expert Report of Sean Nicholson (People of CA v. Purdue, et al)
	11/13/2020	CA Expert Report of Frank Torti (People of CA v. Purdue, et al)
	11/13/2020	CA Expert Report of David Chan (People of CA v. Purdue, et al)
	11/13/2020	CA Expert Report of Carl Peck (People of CA v. Purdue, et al)
	11/13/2020	CA Expert Report of Carol Warfield (People of CA v. Purdue, et al)
	11/13/2020	CA Expert Report of Margaret Kyle (People of CA v. Purdue, et al)
	11/13/2020	CA Expert Report of Edward Michna (People of CA v. Purdue, et al)
	11/13/2020	CA Expert Report of Howard Dorfman (People of CA v. Purdue, et al)

	11/13/2020	CA Expert Report of Melanie Rosenblatt (People of CA v. Purdue, et al)
	11/13/2020	CA Expert Report of Steven Lieberman (People of CA v. Purdue, et al)
	1/19/2021	CA Rebuttal Report of Carol Warfield (People of CA v. Purdue, et al)
	1/19/2021	CA Rebuttal Report of Justin McCrary (People of CA v. Purdue, et al)
	1/19/2021	CA Rebuttal Report of Margaet Kyle (People of CA v. Purdue, et al)
	1/19/2021	CA Rebuttal Report of Minnie Baylor-Henry (People of CA v. Purdue, et al)
	1/19/2021	CA Rebuttal Report of Henry Grabowski (People of CA v. Purdue, et al)
	1/19/2021	CA Rebuttal Report of Sean Nicholson (People of CA v. Purdue, et al)
	1/19/2021	CA Rebuttal Report of Melanie Rosenblatt (People of CA v. Purdue, et al)
	1/19/2021	CA Rebuttal Report of Edward Michna (People of CA v. Purdue, et al)
	1/19/2021	CA Rebuttal Report of Pradeep Chintagunta (People of CA v. Purdue, et al)
	6/00/2018	Stipulated Protective Order (CA) (People of CA v. Purdue, et al.)
	6/8/2018	Sixth Amended Complaint (CA) (People of CA v. Purdue, et al.)
	4/3/2018	Allergan Finance's Responses to 1st Set of Form Interrogatories Allergan PLC's Responses to 1st Set of Form Interrogatories (CA) (People of CA v. Purdue, et al.)
	9/7/2018	Allergan Finance PLC Responses and Objections to Plaintiffs 1st Set of Special Interrogatories Allergan PLC's Responses and Objections to Plaintiffs 1st Set of Special Interrogatories (CA) (People of CA v. Purdue, et al.)
	2/25/2019	Allergan Finance's Amended Responses to 1st Set of Form Interrogatories Allergan PLC's Amended Responses to 1st Set of Form Interrogatories (CA) (People of CA v. Purdue, et al.)
	2/25/2019	Allergan Finance PLC's Amended Responses and Objections to Plaintiffs 1st Set of Special Interrogatories Allergan PLC's Amended Responses and Objections to Plaintiffs 1st Set of Special Interrogatories (CA) (People of CA v. Purdue, et al.)

	7/23/2019	Allergan's Written Responses to PMK Topics 2(H)-(I), corresponding Portions of Topic 3, and topics 4-5 (CA) (People of CA v. Purdue, et al.)
	6/13/2019	Allergan PMK witness Julie Snyder - deposition transcript and exhibits (CA) (People of CA v. Purdue, et al.)
	2/4/2020	Allergan PMK witness Julie Snyder - deposition transcript and exhibits continued deposition (CA) (People of CA v. Purdue, et al.)
	7/12/2019	Allergan PMK witness Mary Woods - deposition transcript and exhibits (CA) (People of CA v. Purdue, et al.)
	11/12/2019	Allergan Sales Rep deposition transcript and exhibits - Shelley Marie Fitch (CA) (People of CA v. Purdue, et al.)
	11/13/2019	Allergan Sales Rep deposition transcript and exhibits - Robin Hagy (CA) (People of CA v. Purdue, et al.)
	11/14/2019	Allergan Sales Rep deposition transcript and exhibits - Adriana A. Knoblauch (CA) (People of CA v. Purdue, et al.)
	12/4/2019	Allergan Sales Rep deposition transcript and exhibits - Carl Balzanti (CA) (People of CA v. Purdue, et al.)
	2/11/2020	Allergan Sales Rep deposition transcript and exhibits - Christopher Hepp (CA) (People of CA v. Purdue, et al.)
	2/12/2020	Allergan Sales Rep deposition transcript and exhibits - Mark Killion (CA) (People of CA v. Purdue, et al.)
	4/3/2018	Endo Health Solutions Responses and Objections to Plaintiff's 1st Set of Form Interrogatories (CA) (People of CA v. Purdue, et al.)
	4/3/2018	Endo Pharmaceuticals Responses and Objections to Plaintiff's 1st Set of Form Interrogatories (CA)
	9/7/2018	Endo Health Solutions and Endo Pharmaceuticals Objections and Responses to Plaintiff's 1st Set of Special Interrogatories (CA) (People of CA v. Purdue, et al.)
	7/10/2019	Endo Health Solutions and Endo Pharmaceuticals Supplemental Response to People's 1st Set of Form Interrogatories No. 4.1 and 1st Set of Special Interrogatories Nos. 1, 9, 19, 21, 26 (CA) (People of CA v. Purdue, et al.)
	9/30/2019	Endo Health Solutions and Endo Pharmaceuticals Supplemental Responses to People's 1st Set of Form Interrogatories No. 15,1 and 1st Set of Special Interrogatories Nos. 6, 7, 8, 9, 10, 12, 14, 15, 17, 19, 21, 27 (CA)

	7/3/2019	Endo PMK witness Brian Lortie - deposition transcripts and exhibits (CA) (People of CA v. Purdue, et al.)
	12/3/2019	Endo Sales Rep deposition and exhibits - Beatrice Aguilar (CA) (People of CA v. Purdue, et al.)
	12/10/2019	Endo Sales Rep deposition and exhibits - Matthew Berry (Cont. 1/14) (CA) (People of CA v. Purdue, et al.)
	1/14/2020	Endo Sales Rep deposition and exhibits - Matthew Berry (Continued deposition) (CA) (People of CA v. Purdue, et al.)
	12/10/2019	Endo Sales Rep deposition and exhibits - Craig Hernandez (CA) (People of CA v. Purdue, et al.)
	12/17/2019	Endo Sales Rep deposition and exhibits - Corey Katouli (CA) (People of CA v. Purdue, et al.)
	12/18/2019	Endo Sales Rep deposition and exhibits - Ellen Keane (CA) (People of CA v. Purdue, et al.)
	12/20/2019	Endo Sales Rep deposition and exhibits - Treca Adams (CA) (People of CA v. Purdue, et al.)
	12/20/2019	Endo Sales Rep deposition and exhibits - Kelvin Chung(CA) (People of CA v. Purdue, et al.)
	4/3/2018	Defendants Johnson & Johnson and Janssen Pharmaceuticals Combined Responses and Objections to the People's 1st Set of Form Interrogatories (CA) (People of CA v. Purdue, et al.)
	9/7/2018	Defendants Johnson & Johnson and Janssen Pharmaceuticals Combined Responses and Objections to the People's 1st Set of Special Interrogatories (CA) (People of CA v. Purdue, et al.)
	4/19/2019	Defendants Johnson & Johnson and Janssen Pharmaceuticals Supplemental Responses and Objections to the People's 1st Set of Special Interrogatories (CA) (People of CA v. Purdue, et al.)
	7/25/2019	Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.'s Written Responses to Topic Nos. 1(M), 1(V), 2(F), 2(G), 2(J), and 2(K) Identified in the People of the State of California's Notice of Videotaped Deposition (CA) (People of CA v. Purdue, et al.)
	7/31/2019	Janssen PMK witness Kimberly Deem-Eshleman - deposition transcript and exhibits (CA) (People of CA v. Purdue, et al.)
	12/5/2019	Janssen sales rep deposition transcript and exhibits - Susan DeGoosh (CA) (People of CA v. Purdue, et al.)
	11/22/2019	Janssen sales rep deposition transcript and exhibits - Javier Escobedo (CA) (People of CA v. Purdue, et al.)

	12/4/2019	Janssen sales rep deposition transcript and exhibits - Sheelah Hogg (CA) (People of CA v. Purdue, et al.)
	12/3/2019	Janssen sales rep deposition transcript and exhibits - Samuel Anthony Tiu (CA) (People of CA v. Purdue, et al.)
	11/25/2019	Janssen sales rep deposition transcript and exhibits - Adam Wood (CA) (People of CA v. Purdue, et al.)
	12/12/2019	Janssen sales rep deposition transcript and exhibits - Danielle Felter (CA) (People of CA v. Purdue, et al.)
	12/9/2019	Janssen sales rep deposition transcript and exhibits - Keith Jackson (CA) (People of CA v. Purdue, et al.)
	12/10/2019	Janssen sales rep deposition transcript and exhibits - Cristine Summers (CA) (People of CA v. Purdue, et al.)
	12/11/2019	Janssen sales rep deposition transcript and exhibits - Molly Chassey (CA) (People of CA v. Purdue, et al.)
	12/11/2019	Janssen sales rep deposition transcript and exhibits - Karen Martin (CA) (People of CA v. Purdue, et al.)
	12/12/2019	Janssen sales rep deposition transcript and exhibits - Russell Stough (CA) (People of CA v. Purdue, et al.)
	12/18/2019	Janssen sales rep deposition transcript and exhibits - Lauren Fanning (Maggard) (CA) (People of CA v. Purdue, et al.)
	1/3/2020	Janssen sales rep deposition transcript and exhibits - Melissa Laughlin (CA) (People of CA v. Purdue, et al.)
	1/6/2020	Janssen sales rep deposition transcript and exhibits - Robert Gibney (CA) (People of CA v. Purdue, et al.)
	4/4/2018	Actavis LLC's Responses to People's First Set of Form Interrogatories (CA) (People of CA v. Purdue, et al.)
	4/4/2018	Actavis Pharma's Responses to People's First Set of Form Interrogatories (CA) (People of CA v. Purdue, et al.)
	4/4/2018	Watson Laboratories' Responses to People's First Set of Form Interrogatories (CA) (People of CA v. Purdue, et al.)
	5/7/2018	Cephalon's Responses to People's First Set of Form Interrogatories (CA) (People of CA v. Purdue, et al.)
	5/7/2018	Teva Pharmaceutical USA's Responses to People's First Set of Form Interrogatories (CA) (People of CA v. Purdue, et al.)
	9/7/2018	Responses of Defendants Teva Pharmacueticals USA, Cephalon, Actavis LLC, Actavis Pharma, Waton Laboratories ("Teva Defendants") to People's First Set of Special Interrogatories (CA) (People of CA v. Purdue, et al.)

	9/18/2018	Responses of Defendants Teva Pharmacueticals USA and Cephalon to People's First Set of Special Interrogatories (CA) (People of CA v. Purdue, et al.)
	1/28/2020	People's Response to Teva USA's 2nd Set of Special Interrogatories (CA) (People of CA v. Purdue, et al.)
	1/30/2020	People's Response to Actavis' 2nd Set of Special Interrogatories (CA) (People of CA v. Purdue, et al.)
	3/21/2019	Letter from James Collie (counsel to Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Actavis LLC, Actavis Pharma, Inc., and Watson Laboratories, Inc.) to Mark Crawford, (counsel for People of CA) re PMK topics similar to MDL 2804 30(b)(6) topics (CA) (People of CA v. Purdue, et al.)
	6/21/2019	Teva PMK witness Doron Herman - deposition transcript and exhibits (CA) (People of CA v. Purdue, et al.)
	4/4/2019	Teva PMK witness John D. Hassler - deposition transcript and exhibits (CA) (People of CA v. Purdue, et al.)
	4/2/2019	Teva PMK witness Ellen E. McMahon - deposition transcript and exhibits (CA) (People of CA v. Purdue, et al.)
	9/22/2019	Teva sales rep deposition transcript and exhibits - Geoffrey Merris (CA) (People of CA v. Purdue, et al.)
	2/20/2019	Teva sales rep deposition transcript and exhibits - Lori B. Ceballos (CA) (People of CA v. Purdue, et al.)
	9/20/2019	Teva sales rep deposition transcript and exhibits - Meghan Grillone (CA) (People of CA v. Purdue, et al.)
	12/12/2019	Teva sales rep deposition transcript and exhibits - Megan Mohrman (CA) (People of CA v. Purdue, et al.)
	12/10/2019	Teva sales rep deposition transcript and exhibits - Michael Walker (CA) (People of CA v. Purdue, et al.)
	12/18/2019	Teva sales rep deposition transcript and exhibits - James Mara (CA) (People of CA v. Purdue, et al.)
	2/4/2020	Teva sales rep deposition transcript and exhibits - Denise Mears (CA) (People of CA v. Purdue, et al.)
	2/5/2020	Teva sales rep deposition transcript and exhibits - Chuck DeWildt (MDL)
	2/5/2020	Teva sales rep deposition transcript and exhibits - Chuck DeWildt (CA) (People of CA v. Purdue, et al.)
	2/6/2020	Teva sales rep deposition transcript and exhibits - Lou Ciampi (CA) (People of CA v. Purdue, et al.)
	2/10/2020	Teva sales rep deposition transcript and exhibits - Matthew Nikolaus (CA) (People of CA v. Purdue, et al.)

	4/3/2018	Purdue Defendants' Responses and Objections to Plaintiff's Form Interrogatories (Set One) (CA) (People of CA v. Purdue, et al.)
	9/7/2018	Purdue's Responses and Objections to Plaintiff's First Set of Special Interrogatories Served on June 19, 2018 (CA)
	05/00/2005	ACTIQ Speaker Training, Miami, FL, May 13-14, 2005
	2005	Cephalon Guilty Plea Agreement, US District Court Eastern District of Pennsylvania
		Cephalon, Entry of Plea and Sentencing, US District Court Eastern District of Pennsylvania
	2/19/2019	"Assessment of the FDA Risk Evaluation and Mitigation Strategy for Transmucosal Immediate-Release Fentanyl Products," Jeffrey Eric Rollman, James Heyward, Lily Olson, Peter Lurie, Joshua Sharfstein, Caleb Alexander. JAMA. 2019:321(7):676-685.
	12/30/2019	"Evaluation of the Extended-Release/Long-Acting Opioid Prescribing Risk Evaluation and Mitigation Strategy Program by the US Food and Drug Administration A Review," James Heyward, Lily Olson, Joshua Sharfstein, Elizabeth Stuart, Peter Lurie, Caleb Alexander. JAMA Internal Medicine online.
	12/31/2019	"As Tens of Thousands Died, F.D.A. Failed to Police Opioids," Abby Goodnough and Margot Sanger-Katz. NYT. Published 12/30/19, Updated 12/31/19
	2020	The "Nuts and Bolts" of Opioid Marketing: Promotional Messages to Family Doctors in Sacramento, Vancouver, Montreal, and Toulouse, by Barbara Mintzes, PhD and Joel Lexchin, MD. J Gen Intern Med.
	1/23/2019	MDL Deposition transcript - Ron R. Kuntz (vol. 1)
	1/24/2019	MDL Deposition transcript - Ron R. Kuntz (vol. 2)
	6/8/2012	Letter from Federation of State Medical Boards to United States Senators Max Baucus and Chuck Grassley in response to letter of May 8, 2012 re abuse and misuse of opioids
	2/10/2020	Deposition transcript of Sanjay Kurani (CA) (People of CA v. Purdue, et al.)
	2/14/2020	Deposition transcript of Rebecca Trotsky-Sirr (CA) (People of CA v. Purdue, et al.)
	2/10/2020	Deposition transcript of Brian Hurley (CA) (People of CA v. Purdue, et al.)
	2/28/2020	Deposition transcript of Tricia Yap (NH, Merrimack & Suffolk County, NY)

	12/10/2001	The Halo Effect - Forbes Magazine Article re: Big Pharma quoting J&J Chairman Ralph Larsen Weblink: https://www.forbes.com/forbes/2001/1210/062s01.html#5679b8df580e
	9/18/2020	Letter from Endo counsel to Plaintiff's counsel re new Endo productions
	1/15/2019	Deposition transcript of Linda Kitlinski - MDL
	1/3/2020	Statement of Decision, People v. Johnson and Johnson,superior Court of Calif, San Diego, Central Branch (Case No. 37-2016-00017229-CU-MC-CTL)
	9/00/2020	FDA's Risk Evaluation and Mitigation Strategies: Uncertain Effectiveness in Addressing the Opioid Crisis. Suzanne Murrin, Deputy Inspector General for Evaluation and Inspections, HHS. September 2020.

Schedule 5a Florida Documents - Beginning Bates
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Perri Schedule 6: Defendants' Marketing Plans

YEAR	BEG BATES NUMBER
2009	ALLERGAN_MDL_01653003
2009	ALLERGAN_MDL_01797782
2010	ALLERGAN_MDL_01211895
2011	ALLERGAN_MDL_02085906
2011	ALLERGAN_MDL_01211908
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7/25/2007	Acquired_Actavis_01389540-44
9/3/2013	Acquired_Actavis_01444248-50
12/23/2013	Acquired_Actavis_01190436
	Perfetto, 315:11-321:1
	Myers, 124:12-127:4 Allergan-Myers-009
	Myers, 221:10-223:8 Allergan-Myers-014
	Myers, 262:1-263:23 Allergan-Myers-016
	Myers, 364:21-366:5 Allergan-Myers-027
	Boyer, 316:12-317:7 Teva-Boyer 021
	Boothe, 238 ACTAVIS0506794
	Boothe, 220:4-15, 223-225, 227:13-228:12, 227:7-19, 230-231, 233, 240-241 ACTAVIS0506794
	Boothe, 152:10-156:7, 174:9-11
	Boothe, 233-235 ACTAVIS0506794
	Boothe, 197:17-198:10 ACTAVIS0965151-5154
	Dorsey, 95:11-96:8 Allergan-Dorsey-003
	Myers, 224:3-225:10 Allergan-Myers-014
	Myers, 226:6-230:10 (or change end to 246:16) Allergan-Myers-015
	Myers, 247:4-248:20 Allergan-Myers-015
	Myers, 267:1-9

	Myers, 217:22-220:7; Myers, 223:9-224:2 Allergan-Myers-014
	Myers, 264:15-265:22. Allergan-Myers-016
	Boyer, 219:11-220:16, 223:1-12 Teva-Boyer 015
	Myers, 2754:18-276:22 Allergan-Myers-016
	Myers, 332:9-333:22 Allergan-Myers-024
	Myers, 425:17-428:8 Allergan-Myers-016
2011	ACTAVIS0332107
2011	ACTAVIS0335094
2011	ACTAVIS0355241
2011	ACTAVIS0577128
2011	ACTAVIS0821941
2012	ACTAVIS0236377
2012	ALLERGAN_MDL_01006752
2012	ALLERGAN_MDL_01127900
2012	ALLERGAN_MDL_01128139
	Nataline, 39:15-39:19 Allergan-Nataline-001
	Nataline, 168:7-168:14 Allergan-Nataline-001
	Boothe, 171:14-20, 210:19-220:12, 211:17-212:1
	Altier, Deposition page 107 line 17-22. Deposition page 126 lines 1-5 FDA letter page 82; Exhibit 1 Actavis799203-799214 Exhibit 2; Exhibit 3, deposition
	Nathalie Leitch Depo. Tr. 133:19-134:5 ALLERGAN-LEITCH-Exhibit 8; ALLERGAN_MDL_01107612 ALLERGAN-Altier-Exhibit 2.
2002	ALLERGAN_MDL_01139910
2005	ACTAVIS0006930
2007	ALLERGAN_MDL_01233732
2008	ALLERGAN_MDL_01107617
2008	ALLERGAN_MDL_01107672
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2008	ALLERGAN_MDL_02521108
2009	ACTAVIS0583151
2009	ALLERGAN_MDL_01102613
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2009	ALLERGAN_MDL_01112584

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	Nataline, 168:7-168:14 Allergan-Nataline-011
	Snyder, 335:12-336:21 Allergan-Snyder 003 at 21
	Boothe, 156:20-164:17, 181:3-18, 182:22-186:11, 186:12-19, 187:20-188:14, 189:18-22, 190:1-9 Allergan_MDL_01100742, ALLERGAN_MDL_017255666-5569
	Boothe, 152:10-156:7, 174:9-11
	Altier, Deposition page 358
2009	ALLERGAN_MDL_01248192

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2012	ACTAVIS0260324
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2002	PPLPC020000023775
2003	PPLPC009000073953
2003	PDD5881560749
2005	PPLPC030000348131
2011	PPLP004040098
Undated (1989 or later)	PKY181721074
Undated (likely 1997-1998)	PDD1502301358
1991	PKY183411986
1992	PKY183412010
1996	PKY180250683
2004	PPLPC020000039953
1997	PDD8801164196
1997	PKY181312938
1998	PKY180373200
1998	PKY181256442
1998	PKY181256481
2001	PPLPC028000043141
2001	PPLPC009000051501
2005	PPLPC020000050276
2001	PPLPC028000043141
2005	PPLPC020000050461
2005	PPLPC020000050276
2009	PPLPC028000242444
2014	PPLPC019000890118
2016	PPLPC026000155117
9/28/1994	PDD1501010677
8/16/2012	PPLPC037000112609
4/10/2013	PPLPC054000105493
5/9/2013	PPLPC054000106673
3/31/2014	PPLPC029000576302
4/10/2014	PPLPC014000246854
9/25/2006	PPLPC029000176170
2004	PPLPC009000108997
9/8/2005	PPLPC046000010478
5/4/2006	PPLPC004000071381
8/8/2006	PPLPC045000012597
9/13/2006	PPLPC012000117717

10/12/2006	PDD8901791203
10/14/2006	PDD9316103002
10/18/2006	PPLPC025000096249
12/5/2006	PDD9316305283
3/1/2007	PPLPC022000134930
4/24/2007	PPLPC054000022255
5/3/2007	PPLPC028000180989
5/16/2007	PPLPC028000182751
5/31/2007	PPLPC037000069113
9/28/2007	PPLPC041000005186
4/20/2016	PPLPC046000072099
9/28/1994	PDD1501010677
3/31/2014	PPLPC029000576302
4/10/2014	PPLPC014000246854
2013	PPLPC036000209515
2013	PPLPC036000210612
2014	PPLPC036000213554
2016	PPLPC036000256480
2016	PPLPC035000263764
2006	PPLPC029000193521
2013	PPLPC036000209515
2013	PPLPC036000210612
2014	PPLPC036000213554
2016	PPLPC036000256480
2009	PDD9316307097
2010	PPLP004039967
2011	PPLP004040098
2012	PPLP004149692
2012	PPLP004149606
2013	PPLPC004000351686
2014	PPLP004040866
2014	PPLPC004000397181
2017	PPLP004039997
3/15/1994	PDD1715230721
4/10/1995	PKY182622196
9/7/1995	PDD8805163965
10/14/1996	PDD1701872218
11/22/1996	PKY181732452
11/22/1996	PKY181732469
7/3/1997	PDD1701814725
11/7/1998	PDD1701010361
4/9/1999	PDD1701411209
7/8/1999	PPLPC018000003920
10/11/1999	PPLPC018000004260
4/7/2000	E513_00137032
7/7/2000	PDD1701038208
9/15/2000	PDD9316716518

10/4/2000	PDD9316718498
12/31/2000	PKY180838271
7/23/2001	PPLPC018000019009
1/4/2002	E513_00137640
8/15/2003	PDD9316101663
10/6/2004	PDD8901768129
10/26/2004	PPLPC013000116218
1/18/2005	PDD8901213920
4/15/2005	PDD8901766376
6/27/2006	PPLPC001000002959
7/15/2006	PDD8901796334
10/12/2006	PDD9316103002
1/15/2007	PPLP004367696
4/13/2007	PPLP004367733
7/15/2007	PDD9316102866
1/3/2008	PPLP004367636
1/15/2008	PDD8901733974
1/15/2008	PDD9316101272
4/8/2008	PDD9316100309
4/16/2008	PDD9316101045
7/15/2008	PKY180013132
10/15/2008	PDD9316101002
1/16/2009	PPLP004367067
4/16/2009	PDD9316100597
4/16/2009	PPLP004367262
8/11/2009	PPLP004367526
10/22/2009	PPLP004367330
10/28/2009	PDD9316101579
2/1/2010	PPLP004367162
4/21/2010	PPLP004367046
7/27/2010	PDD8901530511
7/27/2010	PPLP004367018
7/28/2010	PPLP004316890
10/25/2010	PPLP004316353
10/25/2010	PPLP004366991
11/3/2010	PPLP004405427
1/24/2011	PPLP004366955
2/3/2011	PDD8901796609
5/3/2011	PPLP004367098
6/30/2011	PPLP004406193
8/3/2011	PPLP004366913
8/12/2011	PPLP004411723
8/12/2011	PPLP004411785
8/12/2011	PPLP004412213
9/1/2011	PPLP004406636
11/18/2011	PPLP004406987
1/17/2012	PPLP004407542

2/3/2012	PPLP004367186
2/10/2012	PPLP004407603
6/6/2012	PPLP004367290
6/19/2012	PPLP004407993
6/21/2012	PPLP004407956
7/15/2012	PPLP004149350
7/27/2012	PPLP004367360
11/1/2012	PPLP004366816
1/14/2013	PPLP004409322
2/5/2013	PPLP004366760
2/12/2013	PPLP004409377
3/21/2013	PPLP004409476
4/10/2013	PKY183212603
4/10/2013	PPLP004409601
5/3/2013	PPLP004409708
5/13/2013	PPLP004367540
6/6/2013	PPLP004409774
7/23/2013	PPLP004366699
8/14/2013	PPLP004409890
9/11/2013	PPLP004409919
9/26/2013	PPLP004409954
10/2/2013	PPLP004409965
10/31/2013	PPLP004410504
11/1/2013	PPLP004367422
11/14/2013	PPLP004410516
11/15/2013	PPLP004410528
12/13/2013	PPLP004410679
1/16/2014	PPLP004410692
2/4/2014	PPLP004367478
4/18/2014	PPLP004410817
5/13/2014	PPLP004411032
5/13/2014	PPLP004411033
5/13/2014	PPLP004411034
5/14/2014	PPLP004411049
5/30/2014	PPLP004411201
8/13/2014	PPLP004411223
9/29/2014	PPLP004411288
10/29/2014	PPLP004411617
11/3/2014	PPLP004411618
1/9/2015	PPLP004411807
3/6/2015	PPLP004411894
4/8/2015	PPLP004411368
4/14/2015	PPLP004412031
6/3/2015	PPLP004412078
8/10/2015	PPLP004412123
9/24/2015	PPLP004412226
11/18/2015	PPLP004412371

11/23/2015	PPLP004412546
12/4/2015	PPLP004412555
1/15/2016	PPLP004412586
2/29/2016	PPLP004412683
3/7/2016	PPLP004412660
4/4/2016	PPLP004412826
5/23/2016	PPLP004413092
6/15/2016	PPLP004412941
6/5/2018	PPLP004406990
6/5/2018	PPLP004407735
6/5/2018	PPLP004407765
6/5/2018	PPLP004408065
6/5/2018	PPLP004408249
6/5/2018	PPLP004408358
6/5/2018	PPLP004408478
6/5/2018	PPLP004409073
6/5/2018	PPLP004409088
6/5/2018	PPLP004409271
6/5/2018	PPLP004409302
6/6/2018	PPLP004404330
6/6/2018	PPLP004404901
6/6/2018	PPLP004405789
6/6/2018	PPLP004406095
6/6/2018	PPLP004409973
6/7/2018	PPLP004404587
6/7/2018	PPLP004404619
6/7/2018	PPLP004404784
6/7/2018	PPLP004405511
6/7/2018	PPLP004405607
6/7/2018	PPLP004405693
6/7/2018	PPLP004405858
6/7/2018	PPLP004405990
6/7/2018	PPLP004406301
6/7/2018	PPLP004406347
6/7/2018	PPLP004406509
6/7/2018	PPLP004406625
6/7/2018	PPLP004406668
6/7/2018	PPLP004406675
6/7/2018	PPLP004406761
6/7/2018	PPLP004406827
6/7/2018	PPLP004406869
6/7/2018	PPLP004406952
YEAR	**BEG BATES NUMBER**
2004	TEVA_MDL_A_00677574
2004	TEVA_MDL_A_01547072
2004	TEVA_MDL_A_00667755

2004	TEVA_MDL_A_00667543
2005	TEVA_MDL_A_00668591
2005	TEVA_MDL_A_01086424
2006	TEVA_MDL_A_02935867
2006	TEVA_MDL_A_00364515
2006	TEVA_MDL_A_00677232
2006	TEVA_MDL_A_00364515
2006	TEVA_MDL_A_02383088
2006	TEVA_MDL_A_02383087
2006	TEVA_MDL_A_00677232
2006	TEVA_MDL_A_02376544
2007	TEV_FE00000494
2007	TEVA_MDL_A_01535423
2007	TEVA_MDL_A_00677793
2007	TEVA_MDL_A_00366948
2007	TEV_FE00030796
2007	TEVA_MDL_A_00339113
2007	TEV_FE00044610
2008	TEVA_MDL_A_00372019
2009	TEV_FE00000889
2009	TEVA_MDL_A_01191736
2009	TEVA_MDL_A_00366950
2010	TEV_FE00001503
2010	TEVA_MDL_A_00556060
2010	TEVA_MDL_A_01396649
2010	TEVA_MDL_A_00555493
2010	TEVA_MDL_A_00708814
2011	TEV_FE00112547
2011	TEVA_MDL_A_00500776
2011	TEVA_MDL_A_00500950
2011	TEVA_MDL_A_00498325
2012	TEVA_MDL_A_00499083
2012	TEVA_MDL_A_00499080
2012	TEVA_MDL_A_00500130
2012	TEVA_MDL_A_00755335
2012	TEVA_MDL_A_00703781
2012	TEVA_MDL_A_00703780
2013	TEVA_MDL_A_00499079
2014	TEVA_MDL_A_02296065
2014	TEVA_MDL_A_02767666
2015	TEVA_MDL_A_03153815
2016	TEVA_MDL_A_02973952
2011	TEVA_MDL_A_00498325
2015	TEVA_MDL_A_02832357
2000	TEVA_CHI_00042757
2000	TEVA_CHI_00042757
2001	TEVA_MDL_A_01159143

2001	TEVA_MDL_A_05313123
2001	TEVA_MDL_A_00454808
2001	TEVA_CHI_00049296
2002	TEVA_MDL_A_05965700
2002	TEVA_MDL_A_00454816
2002	TEVA_MDL_A_05965744
2002	TEVA_MDL_A_00454816
2003	TEVA_CHI_00042882
2003	TEVA_CHI_00042882
2004	TEVA_CHI_00042951
2004	TEVA_CHI_00042951
2005	TEVA_CHI_00043010
2005	TEVA_CHI_00043010
2005	TEVA_MDL_A_01163388
2006	TEVA_MDL_A_05666277
2005	TEVA_CHI_00368405
2005	TEVA_MDL_A_00684805
2005	TEV_FE00017484
2005	TEV_FE00018669
2006	TEVA_MDL_A_00368259
2006	TEVA_MDL_A_00365388
2006	TEVA_MDL_A_00364493
2006	TEV_FE00001041
2006	TEVA_MDL_A_02180356
2007	TEVA_MDL_A_00376298
2007	TEVA_MDL_A_00365421
2007	TEVA_MDL_A_00364977
2007	TEV_FE00021142
2007	TEVA_MDL_A_00718838
2007	TEVA_MDL_A_01128402
2007	TEVA_MDL_A_01128402
2008	TEVA_MDL_A_00398244
2008	TEVA_MDL_A_00365682
2008	TEVA_MDL_A_00375244
2008	TEVA_MDL_A_00375244
2008	TEVA_MDL_A_00402007
2009	TEVA_MDL_A_00362732
2009	TEVA_MDL_A_00363031
2009	TEVA_MDL_A_00363031
2009	TEV_FE0037945
2010	TEVA_MDL_A_00556015
2010	TEVA_MDL_A_00556008
2010	TEVA_MDL_A_00556008
2010	TEVA_MDL_A_00553831
2010	TEVA_MDL_A_00383598
2010	TEVA_MDL_A_00381966
2010	TEVA_MDL_A_00366777

2010	TEVA_MDL_A_00500834
2010	TEVA_MDL_A_00556060
2010	TEV_FE00112586
2011	TEVA_MDL_A_01211474
2011	TEVA_MDL_A_02003403
2012	TEVA_MDL_A_00755335
2012	TEVA_MDL_A_01201520
2012	TEVA_MDL_A_01211474
2013	TEVA_MDL_A_00886031
2014	TEVA_MDL_A_00502023
2014	TEVA_MDL_A_00875349
2014	TEVA_MDL_A_00881917
2014	TEVA_MDL_A_00883097
2014	TEVA_MDL_A_01202606
2015	TEVA_MDL_A_01066645
2013	TEVA_MDL_A_02372638
2013	TEVA_MDL_A_01261644
2013	TEVA_MDL_A_01204103
2014	TEVA_MDL_A_02954559
2014	TEVA_MDL_A_00857858
2014	TEVA_MDL_A_01204074
2014	TEVA_MDL_A_00943565
2015	TEVA_MDL_A_02773661
2015	TEVA_MDL_A_027773660
2015	TEVA_MDL_A_02832357
2016	TEVA_MDL_A_02994419
2016	TEVA_MDL_A_01077291
2016	TEVA_MDL_A_01536731
2013	TEVA_MDL_A_01178703
2007	TEV_FE00014507
2007	TEV_FE00048314
2007	TEVA_MDL_A_02168184
2008	TEVA_MDL_A_02168355
2008	TEVA_MDL_A_00376237
2008	TEVA_MDL_A_01989212
2010	TEVA_MDL_A_00369013
2010	TEVA_MDL_A_00368991
2014	TEVA_MDL_A_02805070
Oct-06	TEVA_MDL_A_00552850-69
Mar-07	TEVA_MDL_A_00552870
Mar-07	TEVA_MDL_A_00553033
Jun-07	TEVA_MDL_A_00552840
Jun-07	TEVA_MDL_A_00552902
Jun-07	TEVA_MDL_A_00552942
Jun-07	TEVA_MDL_A_00553036-52
Sep-07	TEVA_MDL_A_00553057
Jan-09	TEVA_MDL_A_00552730

Schedule 7A Examples of Actavis Promotional Materials

ALLERGAN_MDL_01126762
ALLERGAN_MDL_01466309
ALLERGAN_MDL_01466324
ALLERGAN_MDL_01466348
ALLERGAN_MDL_02104539
ALLERGAN_MDL_02104585
ALLERGAN_MDL_02104760
ALLERGAN_MDL_02104775
ALLERGAN_MDL_02104857
ALLERGAN_MDL_02104934
ALLERGAN_MDL_02104948
ALLERGAN_MDL_02105236
ALLERGAN_MDL_02105256
ALLERGAN_MDL_02105271
ALLERGAN_MDL_02105286
ALLERGAN_MDL_02105564
ALLERGAN_MDL_02105628
ALLERGAN_MDL_02105658
ALLERGAN_MDL_02105779
ALLERGAN_MDL_02105796
ALLERGAN_MDL_02107016
ALLERGAN_MDL_02107030
ALLERGAN_MDL_02107034
ALLERGAN_MDL_00684866
ALLERGAN_MDL_00684867
ALLERGAN_MDL_00684896

Schedule 7B Examples of Teva Promotional Materials

TEVA_MDL_A_00025238
TEVA_MDL_A_00025378
TEVA_MDL_A_00025496
TEVA_MDL_A_00025865
TEVA_MDL_A_00025942
TEVA_MDL_A_00025983
TEVA_MDL_A_00025990
TEVA_MDL_A_00026098
TEVA_MDL_A_00026107
TEVA_MDL_A_00026618
TEVA_MDL_A_00026707
TEVA_MDL_A_00026715
TEVA_MDL_A_00026762
TEVA_MDL_A_00027170
TEVA_MDL_A_00027239
TEVA_MDL_A_00027251
TEVA_MDL_A_00027556
TEVA_MDL_A_00027637
TEVA_MDL_A_00027646
TEVA_MDL_A_00028472
TEVA_MDL_A_00028716
TEVA_MDL_A_00029394
TEVA_MDL_A_00029407
TEVA_MDL_A_00029495
TEVA_MDL_A_00029820
TEVA_MDL_A_00029984
TEVA_MDL_A_00030300
TEVA_MDL_A_00695743
TEVA_MDL_A_01584000
TEVA_MDL_A_01584999
TEVA_MDL_A_01585102
TEVA_MDL_A_05303906
TEVA_MDL_A_01575973

Schedule 7C Examples of Teva Speaker Slide Decks

TEVA_MDL_A_10070142
TEVA_MDL_A_10070143
TEVA_MDL_A_03274424
TEVA_MDL_A_03274427
TEVA_MDL_A_10061799
TEVA_MDL_A_10061802
TEVA_MDL_A_03913568
TEVA_MDL_A_03913569
TEVA_MDL_A_03913570
TEVA_MDL_A_03913571
TEVA_MDL_A_03913572
TEVA_MDL_A_03913573
TEVA_MDL_A_03913574
TEVA_MDL_A_03913575
TEVA_MDL_A_03913576
TEVA_MDL_A_03913577
TEVA_MDL_A_03913578
TEVA_MDL_A_03913579
TEVA_MDL_A_03913580
TEVA_MDL_A_03913581
TEVA_MDL_A_03913582
TEVA_MDL_A_03913583
TEVA_MDL_A_08238912
TEVA_MDL_A_08238914
TEVA_MDL_A_08238913
TEVA_MDL_A_07419580
TEVA_MDL_A_07419582
TEVA_MDL_A_09068255
TEVA_MDL_A_09068256
TEVA_MDL_A_01105100
TEVA_MDL_A_01105101
TEVA_MDL_A_11191312
TEVA_MDL_A_11191309
TEVA_MDL_A_09610652
TEVA_MDL_A_09610654
TEVA_MDL_A_07663830
TEVA_MDL_A_07663831
TEVA_MDL_A_02293476
TEVA_MDL_A_02293477
TEVA_MDL_A_06410406
TEVA_MDL_A_06410408
TEVA_MDL_A_00874852
TEVA_MDL_A_00874854
TEVA_MDL_A_00874858
TEVA_MDL_A_08793787
TEVA_MDL_A_08793790

Perri Schedule 8: Defendants' Sales Training Manuals and Scripts

YEAR	Column1	BEG BATES NUMBER
2008		ALLERGAN_MDL_01052119
2009		ALLERGAN_MDL_00441238
2009		ALLERGAN_MDL_00439499
2010		ACTAVIS0205095
2009		ALLERGAN_MDL_01898190
2010		ALLERGAN_MDL_01051295
2011		ALLERGAN_MDL_01744876
2011		ACTAVIS0355241
2011		ALLERGAN_MDL_01449866
2011		ACTAVIS0335094
2011		ACTAVIS0577128
2008		ALLERGAN_MDL_01272193
2008		ALLERGAN_MDL_01052466
2009		ALLERGAN_MDL_01102613
2009		ACTAVIS0583151
2010		ALLERGAN_MDL_01897439
2010		ALLERGAN_MDL_01897555
2010		ACTAVIS0492351
2011		ALLERGAN_MDL_00401500
2011		ALLERGAN_MDL_01201771
2011		ACTAVIS0416639
2011		ACTAVIS0355241
2011		ACTAVIS0335094 ALLERGAN_MDL_00396905
2011		ACTAVIS0577128
2011		ALLERGAN_MDL_01456552
2012		ALLERGAN_MDL_00776198
		Altier, Deposition page 95 lines 1-9,
		Myers, 120:12-124:08 Allergan-Myers-008
		Snyder Depo Tr. 256:6-257:18 Allergan-Altier 002
		Snyder Depo Tr. 268:21-270:20
		Nathalie Leitch Depo. Tr. 177:18-178:1. ALLERGAN-LEITCH-Exhibit 9

		Nathalie Leitch Depo. Tr. 245:17-247:5. ALLERGAN-LEITCH-Exhibit 15; ALLERGAN-LEITCH-Exhibit 16
2008		ALLERGAN_MDL_01272193
2009		ALLERGAN_MDL_01102613
2010		ALLERGAN_MDL_00405512
2010		ACTAVIS0492351
2011		ALLERGAN_MDL_01330509
2012		ACTAVIS0207110
2012		ALLERGAN_MDL_00072907
2012		ALLERGAN_MDL_01128302
2013		ALLERGAN_MDL_01125121
YEAR	**Column1**	**BEG BATES NUMBER**
2001		ENDO-OPIOID_MDL02748287
2003		ENDO-OPIOID_MDL-02356776
2003		ENDO-OPIOID_MDL-01653011
2003		ENDO-OPIOID_MDL-01653008
2004		ENDO-OPIOID_MDL-02940798
2006		ENDO-OPIOID_MDL-02489837
2006		ENDO-OPIOID_MDL-02489842
2006		ENDO-CHI_LIT-00053284
2006		Endo-Opioid_MDL-01053311
2007		END00000119
2008		ENDO-CHI_LIT-00555276
2009		EPI001554204
2009		EPI001554302
2010		ENDO-CHI_LIT-00012061
2010		ENDO-CHI_LIT-00545268
2010		ENDO-CHI_LIT-00237748 **- 50 (49,50 Are Attachments)**
2010		ENDO-CHI_LIT-00054102
2010		ENDO-CHI_LIT-00179318
2011		ENDO-CHI_LIT-00151713
2011		ENDO-CHI_LIT-00405471
2012		END00013911
2012		END00011457
2012		ENDO-OPIOID_MDL-02456655
2015		ENDO-CHI_LIT-00550030
		ENDO-CHI_LIT-00550036
2008		ENDO-OPIOID_MDL-01872258
2012		END00579332
		END00678859
2007		ENDO-CHI_LIT-00210472 - 7**3**
2008		ENDO-CHI_LIT-00166188

2011		ENDO-CHI_LIT-00012955
2012		ENDO-CHI_LIT-00465464
		ENDO-CHI_LIT-00012014
		END00099062
2006		ENDO-OPIOID_MDL-02489844
2011		ENDO-CHI_LIT-00086201
2012		ENDO-CHI_LIT-00550033
		ENDO-CHI_LIT-00013175
YEAR		**BEG BATES NUMBER**
2000		JAN-MS-02394253
2000		JAN-MS-02728615
2002		JAN-MS-00790267
2002		JAN-MS-02728670
2003		JAN-MS-02604409
2004		JAN-MS-00725016
2006		JAN-MS-00747121
2007		JAN-MS-02750676
2008		JAN-MS-01124778
2008		JAN-MS-00081494
2009		JAN-MS-00129452
2009		JAN-MS-00129527
2009		JAN-MS-00129538
2010		JAN-MS-00059204
2011		JAN-MS-00132212
2011		JAN00086283
2011		JAN-MS-00060341
2012		JAN00024213
2012		JAN-MS-00060704
2012		JAN-0012-0045825
2012		JAN00087357
2013		JAN-MS-00772224
2014		JAN00122814
2014		JAN00122800
2009		JAN-MS-00280657
2010		JAN-MS-00059606
2010		JAN-MS-00059922
2012		JAN-MS-01122268
2013		JAN-MS-00982914
1998		JAN-MS-02728460
1998		JAN-MS-02728413
1998		JAN-MS-02728415
1998		JAN-MS-02728554
2001		JAN-MS-00776565
2001		JAN-MS-01192118
2004		JAN-MS-00299235
2005		JAN-MS-02777941

2009		JAN-MS-00327254
2009		JAN-MS-00327255
2009		JAN-MS-00131172
undated		JAN00059484
undated		JAN00059483
undated		JAN00059486
undated		JAN-MS-00131188
2009		JAN-MS-00129467
2010 or later		JAN00012948
2010 or later		JAN00073184
2010		JAN-MS-03007292
2010		JAN-MS-00059828
2010		JAN-MS-00060004
2011		JAN-MS-00060235
2011		JAN00123620
2011		JAN-MS-01114237
2011		JAN-MS-00091939
2012		JAN00134454
2012		JAN-MS-00124828
2012		JAN-MS-00060877
2012		JAN00124092
2012		JAN00124069
2012		JAN-MS-00089718
2012		JAN-OH-00022016
2012		JAN-OH-00022017
2012		JAN00087343
2012		JAN00087344
2013		JAN-MS-01378623
2013		JAN00130530
2014		
		JAN00077892
2009		JAN-MS-00129495
2010		JAN-MS-03007298
2010		JAN00129833
2014		JAN-MS-02527254
YEAR		**BEG BATES NUMBER**
2010		MNK-T1_0001161032
2010		MNK-T1_0003022001
2011		MNK-T1_0000995466

2011		MNK-T1_0001027612
2011		MNK-T1_0001348629
2012		MNK-T1_0000941520
2012		MNK-T1_0002142446
2013		MNK-T1_0000673611
2013		MNK-T1_0000925048
2014		MNK-T1_0000718230
2014		MNK-T1_0000626241
2014		MNK-T1_0000529044
2014		MNK-T1_0000143852
2014		MNK-T1_0000706894
2014		MNK-T1_0001045829
2014		MNK-T1_0001517743
2014		MNK-T1_0004151314
2012		MNK-T1_0000771204
2011		MNK-T1_0000984417
2011		MNK-T1_0001190327
2011		MNK-T1_0000253454
2014		MNK-T1_0001517650
2010		MNK-T1_0000918167
2010		MNK-T1_0001028027
2010		MNK-T1_0000949065
2010		MNK-T1_0000995467
2010		MNK-T1_0001028040
2012		MNK-T1_0000730788
2012		MNK-T1_0000751417
2014		MNK-T1_0000146531
2014		MNK-T1_0001013321
YEAR		**BEG BATES NUMBER**
1993		PKY180270823
1995		PDD1701876593
1996		PKY181822861
1998		PKY181559345
~1998		PDD1701865940
~1998		PDD1701876159
~1998		PDD1701876211
~1999		PKY180283923
2000		PKY180222667
2001		ABT-MDL-KY-0012834
2001		PDD8013006433
2002		PDD1503480550
2003		PDD1503511116
2003		PDD1503511112
2003		PDD1761003989
2013		PPLP003531520
2013		PPLP003531324

2013		PPLP003531389
2013		
2015		PPLPC020000982709
2015		PPLPC010000077762
2015		PPLPC014000319666
2016		PPLP003578668
2016		PPLP003493454
		PPLP003531453
		PKY180227291
		PKY181881613
		PKY181144901
		PPLP004031735
2001		PKY182702441
2002		PDD1503492499
2005		PPLP003288877
2005		PPLPC053000015942
2010		PPLP003555997
2011		PPLPC051000331209
2012		PURCHI-000005255
2013		PPLP003449768
2013		PPLPC001000131046
2013		PPLP003449934
2014		PPLP003345305
2014		PPLPC051000273192
2015		PPLPC051000290381
2015		PPLPC051000331196
2016		PURCHI-000004682
early 2000s		PKY181246683
2000		SHC-000006985
2001		ABT-MDL-KY-0012834
2001		PPLPC009000075486
2005		PURCHI-003289278
2011		PPLP004002927
2011		PURCHI-000004945
2011		PURCHI-000004950
2011		PURCHI-000005007
2012		PPLP003443404
2012		PPLP003443965
2013		PPLP003449934
2013		PPLP003451831
2013		PPLPC001000132199
2014		PPLP003345126
2014		PPLP003345305
2014		PPLP003454134
2014		PPLP003455760
2014		PPLP004016567

~1998		PDD1701876159
~1998		PDD1701876211
1996		PKY181655688
early 2000s		PKY181246683
2000		E16_00005273
2000		PKY181168868
2000		TRANSCRIPTS0001995
2002		PDD1503492122
2012		PPLP003443965
2014		PPLP003455760
		SHC-000026461
1995		PKY181424155
1998		PKY181548418
1999		PKY181098922
1999-2000		PPLP003996510
2001		PPLPC045000003850
2004		PURCHI-003287817
2005		PURCHI-003289282
2005		PURCHI-003289280
2006		PPLP003548496
2007		PPLP003342053
2007		PPLP003342309
2008		PURCHI-000007927
2010		PPLP003343372
2010		PPLP003343579
2010		PPLP003343707
2010		PPLP003555604
2010		PPLP003555997
2010		PURCHI-000005496
2010		PPLP003555604
2010		PPLP003555997
2011		PPLP003294008
2011		PPLP003344011
2011		PPLP003435011
2011		PPLP003437134
2011		PPLP004002860
2011		PPLP004007495
2011		PURCHI-000004867
2011		PURCHI-000004869
2011		PURCHI-000004897
2011		PURCHI-000005310
2011		PURCHI-000004954
2011		PURCHI-000005009
2011		PURCHI-000005011
2011		PURCHI-000004996

2011		PURCHI-000004914
2012		PPLP003445046
2012		PURCHI-000005225
2013		PPLP003449712
2013		PPLP003449768
2013		PPLP003449843
2013		PPLP003451234
2013		PPLP003517710
2013		PPLP003535675
2014		PPLP004016567
2016		PPLP003287473
2016		PPLP003346059
2016		PPLP003577822
YEAR		**BEG BATES NUMBER**
2006		TEVA_MDL_A_00404021
2007		TEVA_MDL_A_01129009
2007		TEVA_CHI_00011992
2009		TEVA_CHI_00013869
2009		TEVA_CHI_00008482
2010		TEVA_MDL_A_03412936
2010		TEVA_CHI_00008007
2010		TEVA_MDL_A_00393716
2010		TEVA_MDL_A_00383401
2010		TEVA_MDL_A_00396569
2010		TEVA_MDL_A_00395998
2011		TEVA_MDL_A_00342635
2011		TEV_FE00076616
2011		TEVA_MDL_A_00396414
2011		TEVA_MDL_A_00343200
2011		TEVA_MDL_A_00352212
2011		TEV_FE00059322
2011		TEVA_MDL_A_00546434
2011		TEVA_MDL_A_00545543
2011		TEVA_MDL_A_00545063
2011		TEVA_MDL_A_01522260
2011		TEVA_MDL_A_02003158
2011		TEVA_MDL_A_00344096
2011		TEVA_MDL_A_01145889
2011		TEVA_MDL_A_01145859
2012		TEVA_MDL_A_02396899
2012		TEVA_MDL_A_02396920
2012		TEVA_MDL_A_02396921
2012		TEVA_MDL_A_01147203
2012		TEVA_MDL_A_01147563
2014		TEVA_MDL_A_00404998
2009		TEVA_MDL_A_00387906

2009		TEVA_CHI_00010035
2006		TEVA_CHI_00007220
2010		TEVA_CHI_00009433
2010		TEVA_CHI_00009434
2010		TEVA_MDL_A_00345559
2010		TEVA_MDL_A_00395400
2010		TEVA_MDL_A_00345500
2010		TEVA_CHI_00009440
2010		TEVA_MDL_A_00392467
2010		TEV_FE00077504
2010		TEVA_MDL_A_00681897
2011		TEVA_MDL_A_00348157
2011		TEVA_MDL_A_00346406
2011		TEVA_CHI_00001206
2011		TEVA_CHI_00001268
2011		TEVA_MDL_A_00546391
2011		TEVA_MDL_A_01146412
2011		TEVA_CHI_00016447
		TEVA_MDL_A_02700290
2011		TEVA_MDL_A_000346383
2011		TEVA_MDL_A_00349644
2011		TEVA_MDL_A_00394119
2012		TEVA_MDL_A_00548026

Perri Schedule 9: Defendants' Use of Advocacy

YEAR	Column1	BEG BATES NUMBER
		ALLERGAN_MDL_00814551
2007		ACTAVIS1150596
2008		ACTAVIS0583049
2010		ACTAVIS0249135
2012		ACTAVIS0998867
2012		ACTAVIS0928815
2012		ACTAVIS0928790
2012		ACTAVIS0928379
2013		ACTAVIS0656749
Unk		ALLERGAN_MDL_00814551
2007		ACTAVIS1150596
2007		ALLERGAN_MDL_00813385
2007		ALLERGAN_MDL_00813853
2008		ACTAVIS0583049
2010		ACTAVIS0249135
2012		ALLERGAN_MDL_00455441
2012		ALLERGAN_MDL_00536782
2012		ALLERGAN_MDL_00537139
2012		ALLERGAN_MDL_00546350
2004		ALLERGAN_MDL_01878052
2007		ALLERGAN_MDL_00813385
2007		ALLERGAN_MDL_00813853
2008		ALLERGAN_MDL_01134127
2009		ALLERGAN_MDL_00449946
2009		ALLERGAN_MDL_01741588
2009		ALLERGAN_MDL_01743051
2010		ALLERGAN_MDL_01145475
2010		ALLERGAN_MDL_01145537
2010		ALLERGAN_MDL_01172354
2010		ALLERGAN_MDL_01750153
2010		ALLERGAN_MDL_01890445
2011		ACTAVIS0827900
2011		ACTAVIS0828299
2011		ACTAVIS0981713
2012		ACTAVIS0002353
2012		ALLERGAN_MDL_00773907
2012		ACTAVIS0680824
2012		ALLERGAN_MDL_00091151
2012		ALLERGAN_MDL_00092074
2012		ALLERGAN_MDL_00536723
		ALLERGAN_MDL_01898508

		ALLERGAN_MDL_02489078
		ALLERGAN_MDL_03272884
		ALLERGAN_MDL_03491548
11/30/04		ALLERGAN_MDL_01878052
7/27/07		ALLERGAN_MDL_00813385
7/27/07		ALLERGAN_MDL_00813853
5/7/09		ALLERGAN_MDL_00449946
5/8/09		ALLERGAN_MDL_01750153
10/27/09		ALLERGAN_MDL_01741588
12/7/09		ALLERGAN_MDL_01161077
1/14/10		ALLERGAN_MDL_01890445
1/28/10		ALLERGAN_MDL_01743051
2/1/10		ALLERGAN_MDL_01145475
2/1/10		ALLERGAN_MDL_01145537
		ALLERGAN_MDL_01898508
		ALLERGAN_MDL_02489078
		ALLERGAN_MDL_02513178
2004		ALLERGAN_MDL_02159836
2008		ALLERGAN_MDL_01134122
2012		ACTAVIS0002353
2012		ALLERGAN_MDL_00773907
2012		ALLERGAN_MDL_00705936
5/27/04		ALLERGAN_MDL_01096579
11/30/04		ALLERGAN_MDL_01878052
12/21/06		ALLERGAN_MDL_02158581
7/27/07		ALLERGAN_MDL_00813385
7/27/07		ALLERGAN_MDL_00813853
1/21/09		ALLERGAN_MDL_01806378
5/7/09		ALLERGAN_MDL_00449946
5/8/09		ALLERGAN_MDL_01750153
10/26/09		ALLERGAN_MDL_01288051
10/27/09		ALLERGAN_MDL_01741588
1/14/10		ALLERGAN_MDL_01890445
1/28/10		ALLERGAN_MDL_01743051
2/1/10		ALLERGAN_MDL_01145475
2/1/10		ALLERGAN_MDL_01145537
4/15/10		ALLERGAN_MDL_01412050
5/10/10		ALLERGAN_MDL_01242807
6/24/10		ALLERGAN_MDL_01771927
5/31/11		ALLERGAN_MDL_02071681
7/1/11		ALLERGAN_MDL_01292581
2/22/12		ALLERGAN_MDL_01780944
2/27/12		ALLERGAN_MDL_00979328
3/5/12		ALLERGAN_MDL_01980163
3/19/12		ALLERGAN_MDL_00979143
3/30/12		ALLERGAN_MDL_00548624
5/16/12		ALLERGAN_MDL_00092121

5/23/12		ALLERGAN_MDL_01208810
6/15/12		ALLERGAN_MDL_01209033
7/24/12		ALLERGAN_MDL_00759857
10/2/12		ALLERGAN_MDL_01629858
		ALLERGAN_MDL_01770280
		ALLERGAN_MDL_02155906
		ALLERGAN_MDL_02489078
		ALLERGAN_MDL_02513841
		ALLERGAN_MDL_02518511
2003		ALLERGAN_MDL_02160013
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4/6/12		ALLERGAN_MDL_01769460
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5/16/12		ALLERGAN_MDL_00092074
5/17/12		ALLERGAN_MDL_00115244
5/22/12		ALLERGAN_MDL_00091151
6/18/12		ALLERGAN_MDL_01209160
6/20/12		ALLERGAN_MDL_00455441
7/24/12		ALLERGAN_MDL_01437181
7/25/12		ALLERGAN_MDL_00537139
7/25/12		ALLERGAN_MDL_01231664
7/25/12		ALLERGAN_MDL_00537079
7/26/12		ALLERGAN_MDL_00536782
7/26/12		ALLERGAN_MDL_00536723
1/15/13		ALLERGAN_MDL_01738190
		ALLERGAN_MDL_02487542
		ALLERGAN_MDL_03270846
		ALLERGAN_MDL_03271696
		ALLERGAN_MDL_03272779
		ALLERGAN_MDL_03272884
		ALLERGAN_MDL_03289325
		ALLERGAN_MDL_03487893
		ALLERGAN_MDL_03491548
2009		ALLERGAN_MDL_00509583
2010		ALLERGAN_MDL_02085712
2012		ALLERGAN_MDL_00493137
2012		ALLERGAN_MDL_00507922
2012		ACTAVIS0745678
2009		ALLERGAN_MDL_00509583
2010		ALLERGAN_MDL_01868693
2010		ALLERGAN_MDL_01399387
YEAR		**BEG BATES NUMBER**
2001		ENDO-OPIOID_MDL-02344133
2001		ENDO-OPIOID_MDL-02356577
2002		ENDO-OPIOID_MDL-02344125

2002		ENDO-OPIOID_MDL-02344200
2003		ENDO-OPIOID_MDL-02356776
2003		ENDO-OPIOID_MDL-02356920
2005		ENDO-OPIOID_MDL-02980566
2005		ENDO-OPIOID_MDL-03389831
2006		ENDO-OPIOID_MDL-02076786
2008		ENDO-OPIOID_MDL-01764993
2012		END00321529
2003		ENDO-OPIOID_MDL-01571249
2003		ENDO-OPIOID_MDL-02356776
2003		ENDO-OPIOID_MDL-02356920
2003		ENDO-OPIOID_MDL-06203798
2004		ENDO-OPIOID_MDL-02254985
2004		ENDO-OPIOID_MDL-02255153
2004		ENDO-OPIOID_MDL-02344299
2005		ENDO-OPIOID_MDL-03257880
2006		ENDO-CHI_LIT-00539113
2007		ENDO-CHI_LIT-00538705
2008		END00049272
2009		CHI-000433679
2009		ENDO-CHI_LIT-00103330
2010		ENDO-CHI_LIT-00325840
2010		ENDO-OR-CID-01286320
2010		ENDO-CHI_LIT-00097638
2010		EPI000078324
2010		EPI000133769
2010		EPI000135460
2010		END00342552
2010		ENDO-OPIOID_MDL-01602670
2010		ENDO-OPIOID_MDL-01907912
2011		ENDO-OPIOID_MDL-01485888
2014		ENDO-CHI_LIT-00053284
2014		ENDO-CHI_LIT-00053816
2014		ENDO-CHI_LIT-00164758
2014		ENDO-CHI_LIT-00193122
2014		ENDO-CHI_LIT-00242029
4/8/99		ENDO-OPIOID_MDL-06233889
4/22/03		ENDO-OPIOID_MDL-02356776
9/24/03		ENDO-OPIOID_MDL-02356920
2/5/04		ENDO-OPIOID_MDL-02254985
2/17/04		ENDO-OPIOID_MDL-02255153
2/23/04		ENDO-OPIOID_MDL-02344299
8/29/06		ENDO-OPIOID_MDL-04797507
1/2/08		EPI000296548
2008		ENDO-CHI_LIT-00032928
2009		ENDO-CHI_LIT-00537999

2011		ENDO-CHI_LIT-00099937
2011		ENDO-CHI_LIT-00120586
8/29/06		ENDO-OPIOID_MDL-04797507
11/1/07		ENDO-CHI_LIT-00538705
2007		ENDO-CHI_LIT-00538705
12/5/07		ENDO-OPIOID_MDL-02473700
12/20/07		ENDO-OPIOID_MDL-01505105
12/20/07		ENDO-OPIOID_MDL-03420132
12/20/07		ENDO-OPIOID_MDL-03420133
1/2/08		EPI000296546
1/2/08		EPI000296547
1/3/08		ENDO-CHI_LIT-00027552
1/3/08		ENDO-CHI_LIT-00027553
1/29/08		EPI000479821
1/30/08		EPI000479828
2009		CHI_000433679
2009		CHI_000433744
7/14/09		ENDO-OPIOID_MDL-02213755
4/6/10		END00069439
4/13/10		EPI000069070
4/14/10		EPI000068412
4/23/10		EPI000131989
4/23/10		EPI000132156
4/23/10		END00143554
4/23/10		END00143579
5/6/10		EPI000069245
5/7/10		EPI000069339
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5/12/10		EPI000070083
5/14/10		EPI000070387
6/1/10		ENDO-OPIOID_MDL-02476290
6/1/10		ENDO-OPIOID_MDL-04265016
6/21/10		ENDO-OPIOID_MDL-02476454
6/23/10		ENDO-OPIOID_MDL-01765978
6/24/10		END00079002
6/24/10		END00079126
6/25/10		EPI000323564
6/25/10		EPI000578554
6/25/10		EPI000578557
6/30/10		END00081975
7/1/10		EPI000071602
7/1/10		ENDO-OPIOID_MDL-00371037
7/1/10		ENDO-OPIOID_MDL-00371142
7/8/10		END00079970
8/4/10		ENDO-OPIOID_MDL-00540017
10/8/10		EPI000323453
10/8/10		ENDO-OPIOID_MDL-00370859

10/14/10		ENDO-OPIOID_MDL-00371176
10/14/10		ENDO-OPIOID_MDL-00371380
11/4/10		ENDO-OPIOID_MDL-00371418
11/8/10		EPI000323491
11/8/10		EPI000323527
11/8/10		ENDO-OPIOID_MDL-00370965
11/8/10		ENDO-OPIOID_MDL-00371001
11/10/10		EPI000281681
11/10/10		EPI000323383
11/10/10		EPI000323490
11/10/10		END00246752
11/10/10		ENDO-OPIOID_MDL-00370789
11/10/10		ENDO-OPIOID_MDL-00370893
11/10/10		ENDO-OPIOID_MDL-00370929
2011		CHI_001213633
2011		CHI_000472157
1/19/11		END00169885
3/28/11		END00457201
4/4/11		END00695942
4/5/11		END00696119
5/17/11		END00594883
5/25/11		END00550315
6/29/11		EPI000078594
6/29/11		END00309497
6/30/11		EPI000078792
7/1/11		EPI000078886
7/1/11		EPI000079057
7/6/11		END00309662
2012		ENDO-CHI_LIT-00209385
1/27/12		EPI000206724
1/27/12		END00594245
1/27/12		END00594274
3/6/12		END00386397
1/28/13		ENDO-OPIOID_MDL-00371725
1/24/14		ENDO-CHI_LIT-00004087
3/10/14		ENDO-OPIOID_MDL-01243057
		ENDO-CHI_LIT-00540303
		END00014029
		END00016511
2001		ENDO-CHI_LIT-00541959
11/30/01		ENDO-OPIOID_MDL-02344133
12/3/01		ENDO-CHI_LIT-00541959
12/17/01		ENDO-OPIOID_MDL-01998274
12/19/01		ENDO-OPIOID_MDL-02356577
12/19/01		ENDO-OPIOID_MDL-02356612
1/7/02		ENDO-OPIOID_MDL-02344125
1/7/02		ENDO-OPIOID_MDL-02344127

1/14/02		ENDO-OPIOID_MDL-02344200
4/22/03		ENDO-OPIOID_MDL-02356776
2006		ENDO-CHI_LIT00545916
8/29/06		ENDO-OPIOID_MDL-04797507
2007		ENDO-CHI_LIT-00538705
11/22/08		ENDO-CHI_LIT-00024654
11/24/08		ENDO-CHI_LIT-00024652
11/25/08		ENDO-CHI_LIT-00024653
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2/13/03		TEVA_MDL_A_02697801
10/8/03		TEVA_MDL_A_04778649
10/9/03		TEVA_MDL_A_02698200
10/9/03		TEVA_MDL_A_02698287
10/9/03		TEVA_MDL_A_02698950
10/10/03		TEVA_MDL_A_02698340
10/31/03		TEVA_MDL_A_02698473
11/4/03		TEVA_MDL_A_02698238
11/4/03		TEVA_MDL_A_02698493
11/4/03		TEVA_MDL_A_04778738
2004		TEVA_MDL_A_01167447
2004		TEVA_MDL_A_02685653
2004		TEVA_MDL_A_02686568

3/24/04		TEVA_MDL_A_02866689
4/15/04		TEVA_MDL_A_04779176
4/21/04		TEVA_MDL_A_03432638
2/6/07		TEVA_MDL_A_02385655
2008		TEVA_MDL_A_0218717
2008		TEVA_MDL_A_00027290
3/26/08		TEVA_MDL_A_02488945
3/31/08		TEVA_MDL_A_02489062
4/1/08		TEVA_MDL_A_02488268
7/7/08		TEVA_MDL_A_00910441
8/17/09		TEVA_CHI_00007323
8/17/09		TEVA_CHI_00012666
8/20/09		TEVA_CHI_00014434
8/24/09		TEVA_MDL_A_00739055
11/24/09		TEVA_CHI_00010498
1/14/10		TEVA_MDL_A_05015635
8/24/10		TEVA_MDL_A_00348445
10/14/10		TEVA_MDL_A_00348577
10/14/10		TEVA_MDL_A_00350326
12/1/11		TEVA_MDL_A_01094966
2/15/12		Acquired_Actavis_01189169
2/20/12		Acquired_Actavis_02239393
2/21/12		Acquired_Actavis_02239408
5/17/12		Acquired_Actavis_00443874
5/22/12		Acquired_Actavis_00450018
6/18/12		Acquired_Actavis_00001518
6/18/12		Acquired_Actavis_01145732
6/18/12		Acquired_Actavis_01145892
7/24/12		Acquired_Actavis_01501163
7/24/12		Acquired_Actavis_02116973
8/27/12		TEVA_MDL_A_01092418
12/12/12		TEVA_MDL_A_00756665
9/19/17		TEVA_MDL_A_00545463
7/20/18		TEVA_MDL_A_02416207
		TEVA_MDL_A_00348511
		TEVA_MDL_A_00851578
		TEVA_MDL_A_02694858
		TEVA_MDL_A_02699423
		TEVA_MDL_A_02701162
		TEVA_MDL_A_02701171
		TEVA_MDL_A_02702367
		TEVA_MDL_A_02702683
		TEVA_MDL_A_02703207
		TEVA_MDL_A_02703208
		TEVA_MDL_A_04558134
		TEVA_MDL_A_04558408
		TEVA_MDL_A_04558884

		TEVA_MDL_A_04559736
		TEVA_MDL_A_04559816
		TEVA_MDL_A_04559898
		TEVA_MDL_A_04559990
		TEVA_MDL_A_04779255
		TEVA_MDL_A_05314196
		TEVA_MDL_A_05317004
		TEVA_MDL_A_05361114
		TEVA_MDL_A_05367766
		TEVA_MDL_A_05368488
		TEVA_MDL_A_05368651
		TEVA_MDL_A_05368923
		TEVA_MDL_A_05369349
		TEVA_MDL_A_05369763
		TEVA_MDL_A_05369841
		TEVA_MDL_A_05383171
		TEVA_MDL_A_05392996
		TEVA_MDL_A_05395228
		TEVA_MDL_A_05395308
		TEVA_MDL_A_05395534
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		TEVA_MDL_A_05395694
		TEVA_MDL_A_05395774
		TEVA_MDL_A_05396357
		TEVA_MDL_A_05396765
		TEVA_MDL_A_05396805
		TEVA_MDL_A_05405186
		TEVA_MDL_A_05748349
		TEVA_MDL_A_05750814
		TEVA_MDL_A_05750916
		TEVA_MDL_A_05751060
		TEVA_MDL_A_05751660
		TEVA_MDL_A_05751738
		TEVA_MDL_A_05752387
		TEVA_MDL_A_05753592
		TEVA_MDL_A_05754689
		TEVA_MDL_A_05758465
		TEVA_MDL_A_05862996
		TEVA_MDL_A_05938527
		TEVA_MDL_A_05938607
		TEVA_MDL_A_05938837
		TEVA_MDL_A_05938917
		TEVA_MDL_A_05939923
		TEVA_MDL_A_05942876
		TEVA_MDL_A_06070873
		TEVA_MDL_A_00826865
2007		TEVA_MDL_A_01088845

2007		TEVA_MDL_A_00376199
2009		TEVA_MDL_A_00013949
2009		TEVA_MDL_A_02257422
2010		TEVA_MDL_A_01063368
2008		TEVA_MDL_A_02893799
2010		TEVA_MDL_A_01515931
2011		TEVA_MDL_A_02011942
2011		TEVA_MDL_A_01207131
2011		TEVA_MDL_A_01207133
2013		TEVA_MDL_A_03044453
2013		TEVA_MDL_A_01136278
2014		TEVA_MDL_A_02965173
2014		TEVA_MDL_A_01088339
2014		TEVA_MDL_A_01088080
2014		TEVA_MDL_A_00886651
2015		TEVA_MDL_A_03437093

Perri Schedule 10: Evaluation of Marketing Impact by Defendants

YEAR	Column1	BEG BATES NUMBER
2008		ALLERGAN_MDL_01107617
2008		ALLERGAN_MDL_02970693
2008		ALLERGAN_MDL_01203204
2008		ALLERGAN_MDL_00448145
2008		ALLERGAN_MDL_01107617
4/3/2008		ALLERGAN_MDL_02970693
6/26/2008		ALLERGAN_MDL_01203204
10/31/2008		ALLERGAN_MDL_00448145
2009		ALLERGAN_MDL_02092534
2009		ALLERGAN_MDL_00450170
5/27/2009		ALLERGAN_MDL_00450170
4/00/2009		ALLERGAN_MDL_02092534
4/20/2010		ALLERGAN_MDL_00221533
2010		ALLERGAN_MDL_00221533
		Allergan-Myers-028
		Allergan-Snyder 003 at 19
		Allergan-Snyder 003 at 19
		Allergan-Myers-016
		Allergan-Myers-020
		Allergan-Myers-022
		Allergan-Myers-026
		Allergan-Myers-027
		Allergan-Myers-028
		Allergan-Myers-028
		Allergan-Myers-028
		Allergan-Myers-029
		Teva-Boyer 016
		Teva-Boyer 007
		Allergan-Myers-021
		Allergan-Myers-028
		Allergan-Snyder 003 at 19
		Allergan-Snyder 003 at 19
		Allergan-Myers-016
		Allergan-Myers-020
		Allergan-Myers-022
		Allergan-Myers-026

		Allergan-Myers-027
		Allergan-Myers-028
		Allergan-Myers-028
		Allergan-Myers-028
		Allergan-Myers-029
		Teva-Boyer 016
		Teva-Boyer 007
2004		ALLERGAN_MDL_03806394
2006		Acquired_Actavis_01496818
2008		ALLERGAN_MDL_01107617
2009		Acquired_Actavis_01922691
2007		ALLERGAN_MDL_00440836
2007		ALLERGAN_MDL_00440906
2008		ALLERGAN_MDL_01731972
2009		ACTAVIS0583151
2009		ACTAVIS0582687
2009		ACTAVIS0583151
3/13/2009		ALLERGAN_MDL_00448421
2010		ALLERGAN_MDL_01692522
2010		ALLERGAN_MDL_01692525
2010		ALLERGAN_MDL_01211895
2010		ALLERGAN_MDL_01692522
2010		ALLERGAN_MDL_01692525
12/00/2010		ALLERGAN_MDL_01744602
2010 or after		ALLERGAN_MDL_01199084
2011		ALLERGAN_MDL_01200047
2011		ALLERGAN_MDL_01211908
2011		ALLERGAN_MDL_01058610
2011		ALLERGAN_MDL_01201771
2011		ALLERGAN_MDL_01753248
2011		ACTAVIS0358228
2011		ACTAVIS0356896
2011		ACTAVIS0356872
2011		ACTAVIS0578697
2011		ACTAVIS0578145
2011		ACTAVIS0356896
2012		ALLERGAN_MDL_01128139
2012		ALLERGAN_MDL_01475142
2012		ACTAVIS0716745
2005		ACTAVIS0007747
2005		ACTAVIS0006930
2005		ACTAVIS0007747
2011		ACTAVIS0494576
2011		Acquired_Actavis_01935388
2011		ACTAVIS0804498
2011		ACTAVIS0520729

2011		ACTAVIS0488181
2012		ACTAVIS1027605
2012		ACTAVIS1027320
2012		ACTAVIS0472612
2012		ACTAVIS0316639
4/25/2006		ALLERGAN_MDL_02513100
1/13/2010		ALLERGAN_MDL_01692525
10/29/2010		ALLERGAN_MDL_01197701
9/13/2012		ALLERGAN_MDL_01009462
		ACTAVIS0506794
		ALLERGAN-LEITCH-Exhibit 23.
		ALLERGAN-LEITCH-Exhibit 20; see also ALLERGAN_MDL_00401644 and attachment ALLERGAN_MDL_00401647 ("High Value Kadian Targets, including Joseph Valenza.)
2007		ALLERGAN_MDL_00442308
2009		ALLERGAN_MDL_00448421
2010		ALLERGAN_MDL_01744602
2011		ALLERGAN_MDL_01199084
2011		Acquired_Actavis_00620620
2011		ALLERGAN_MDL_01199084
12/4/2007		ALLERGAN_MDL_00442308
3/13/2009		ALLERGAN_MDL_00448421
12/00/2010		ALLERGAN_MDL_01744602
2005		ACTAVIS0007747
2012		ALLERGAN_MDL_01009462
2012		ALLERGAN_MDL_01009556
2012		ACTAVIS0771302
2012		Acquired_Actavis_00450500
2012		ACTAVIS0440814
2006		ALLERGAN_MDL_02513100
2007		ALLERGAN_MDL_00814489
2010		ALLERGAN_MDL_01197701
2012		ALLERGAN_MDL_01009462
2012		ACTAVIS1027320
2012		ACTAVIS0316639
2016		ALLERGAN_MDL_02021592
YEAR		**BEG BATES NUMBER**
8/15/2007		EPI000300652
2008		EPI001514810
2012		END00563922

2012		ENDO-CHI_LIT-00387331
2010		ENDO-CHI_LIT-00012061
2006		ENDO-CHI_LIT-00550852
2007		EPI000300652
2007		ENDO-CHI_LIT-00173035
2007		ENDO-OPIOID_MDL-01723746
2008		EPI001514810
2008		ENDO-CHI_LIT-00025540
7/9/2008		ENDO-CHI_LIT-00017366
2010		ENDO-CHI_LIT-00023332
2010		ENDO-CHI_LIT-00012061
2011		ENDO-CHI_LIT-00022103
2012		ENDO-OPIOID_MDL-01006974
2012		ENDO-CHI_LIT-00308899
2006		ENDO-CHI_LIT-00550852
2007		EPI000300652
2007		ENDO-OPIOID_MDL-01928212
3/22/2007		ENDO-CHI_LIT-00544148
2010		ENDO-CHI_LIT-00023332
2012		ENDO-CHI_LIT-00387331
2012		ENDO-CHI_LIT-00011308
2013		ENDO-CHI_LIT-00122901
2006		ENDO-CHI_LIT-00550852
2007		ENDO-CHI_LIT-00550897
2007		ENDO-OPIOID_MDL-02086096
2007		ENDO-OPIOID_MDL-00681874
2007		ENDO-OPIOID_MDL-01724603
2008		ENDO-CHI_LIT-00025540
2008		ENDO-CHI_LIT-00547543
2009		ENDO-CHI_LIT-00046379
2010		ENDO-CHI_LIT-00012061
2012		ENDO-CHI_LIT-00308899
2012		ENDO-CHI_LIT-00135664
2013		END00591813
2006		ENDO-OPIOID_MDL-00677466
2007		ENDO-CHI_LIT-00544148
2005		ENDO-OPIOID_MDL-04755180
2010		ENDO-CHI_LIT-00012326

2011		ENDO-OPIOID_MDL-02838111
2011		ENDO-OPIOID_MDL-02354652
2012		ENDO-OPIOID_MDL-02978866
YEAR		**BEG BATES NUMBER**
2001		JAN-MS-00315375
2002		JAN-MS-00311391
2002		JAN-MS-00306762
2002		JAN-MS-00313615
2003		JAN-MS-00306778
2003		JAN-MS-00309600
2004		JAN-MS-00310213
2005		JAN-MS-00314171
2010		JAN-MS-00259847
2010		JAN-MS-00798634
2012		JAN-MS-02368515
2012		JAN00012389
2012		JAN-MS-00664894
2012		JAN-MS-00768695
2012		JAN-MS-00774148
2013		JAN00119068
2013		JAN00021218
2013		JAN-MS-02386116
2014		JAN00119271
2002		JAN-MS-00305691
2011		JAN00119192
2011		JAN00126528
2011		JAN00126539
2004		JAN-MS-00788350
2008		JAN-MS-02565763
2009		JAN-MS-01126863
2009		JAN00139400
2011		JAN00126528
2011		JAN00126539
2011		JAN00126250
2011		JAN-0015-0027265
2011		JAN-MS-01968621
2012		JAN-MS-00866595
2012		JAN00125893
2012		JAN00126020
2013		JAN00126649
2013		JAN00126932
2013		JAN00126454
2014		JAN00125850

2014		JAN00126691
2014		JAN-MS-00771950
Undated		JAN00024213
		JAN-MS-02114226
2002		JAN-MS-02325533
2003		JAN-MS-00307257
2008		JAN-MS-01011585
2009		JAN00138569
2011		JAN-MS-02564853
2012		JAN-MS-01053015
2012		JAN-MS-00010801
2012		JAN00012389
2012		JAN-MS-00768695
2012		JAN-MS-00774148
2013		JAN-MS-00749778
2013		JAN00025243
2013		JAN-MS-01511434
2014		JAN-MS-02527254
2003		JAN-MS-00306327
2003		JAN-MS-00778987
2004		JAN-MS-00779151
2004		JAN-MS-00479441
2009		JAN-MS-01126863
2009		JAN00139400
2010		JAN-MS-00798634
2011		JAN00126528
2011		JAN00126539
2012		JAN00119814
2001		JAN-MS-00786447
2004		JAN-MS-00460875
2007		JAN-MS-00504344
2009		JAN-MS-00838435
2011		JAN00038605
2011		JAN-MS-00403634
2011		JAN-MS-00403788
2011		JAN00038742
2012		JAN-MS-00010801
2012		JAN00038747
2012		JAN-MS-00018068
2012		JAN-MS-00403463
2012		JAN00012389
2013		JAN-MS-00455043
2013		JAN-MS-00456885
2014		JAN-MS-00418845
YEAR		**BEG BATES NUMBER**
2012		MNK-T1_0001350338

2012		MNK-T1_0000754771
2012		MNK-T1_0001193006
2012		MNK-T1_0000762380
2012		MNK-T1_0000746807
2013		MNK-T1_0000855021
2013		MNK-T1_0000947739
2013		MNK-T1_0002674394
2013		MNK-T1_0000124210
2013		MNK-T1_0004799346
2014		MNK-T1_0000132034
2014		MNK-T1_0000133095
2008		MNK-T1_0007818843
2012		MNK-T1_0005534287
2013		MNK-T1_0000738707
2010		MNK-T1_0001048580
2010		MNK-T1_0001048582
2010		MNK-T1_0001190984
2011		MNK-T1_0000923144
2012		MNK-T1_0002294608
2013		MNK-T1_0000673890
2013		MNK-T1_0002715284
2013		MNK-T1_0000673892
2013		MNK-T1_0000541918
2014		MNK-T1_0002214720
2014		MNK-T1_0001474379
2014		MNK-T1_0000640098
2014		MNK-T1_0000946339
2013		MNK-T1_0000218573/75
2013		MNK-T1_0002084660
2013		MNK-T1_0002181307
2014		MNK-T1_0008440086
2012		MNK-T1_0000751435
2012		MNK-T1_0000817224
2012		MNK-T1_0000751341
2012		MNK-T1_0001473290
2013		MNK-T1_0000182777
2013		MNK-T1_0000113702
2010		MNK-T1_0000949128
2012		MNK-T1_0001524367/68
2013		MNK-T1_0000860429
2013		MNK-T1_0000666227
2014		MNK-T1_0000610456
YEAR		**BEG BATES NUMBER**
2000		PKY181083625
2005		PPLPC001000212908
9/3/2008		PPLP003420006

2010		PPLP003433809
2011		PPLP003410392
2012		PPLP003421337
2012		PPLP003408129
2012		PPLP003408203
2012		PPLP003409867
2012		PPLP003409899
2012		PPLPC004000316506
2012		PPLPC012000369075
20120000		PPLPC012000349870
6/18/2012		PPLP003421337
2013		PPLP003449398
2013		PPLPC021000522968
2013		PPLPC021000522969
2013		PPLPC021000522970
2013		PPLPC021000539678
2013		PPLPC022000609275
2013		PPLPC023000622488
2013		PPLPC023000622489
2013		PPLPC012000418325
2013		PPLP003408377
2013		PPLP003408447
2013		PPLP003409951
2013		PPLP003409995
2013		PPLP003410040
2013		PPLP003449398
2014		PPLP004001517
2014		PPLP003408346
2014		PPLP003408531
2014		PPLP003409826
2014		PPLP003410014
2014		PPLP003410062
2014		PPLP003410121
2014		PPLP004126350
4/24/2014		PPLP004001517
2016		PPLP003408643
2016		PPLP003409874
2016		PPLP003410145
2016		PPLP003410278
		PPLP003407630
2001		PKY180709101
2001		PKY180767598
2001		PKY180767598
4/00/2001		PKY180709101
2012		PPLPC023000709845
2012		PPLPC023000709846
2012		PPLPC023000709848

2012		PPLPC023000709849
2013		PPLPC023000709829
2013		PPLPC023000709830
2014		PPLPC021000678280
2014		PPLPC021000678281
2014		PPLPC021000678282
2014		PPLPC021000678287
2014		PPLPC021000678290
2014		PPLPC023000709827
2014		PPLPC023000709834
2014		PPLPC023000709837
2000		PKY180797102
2001		PKY182024455
2001		PKY180229581
2001		PKY180137287
2001		PKY182024455
2002		PKY183284930
2002		PKY182838397
2003		E513_00140738
03/00/2003		PKY182773121
2008		PKY180003923
2009		PKY180003923
2009		PPLP004401579
2012		PPLP003409457
2012		PPLPC012000349870
2013		PPLP003450924
2013		PPLP003409516
2013		PPLP004001621
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2013		PPLP004408478
2013		PPLP003450924
2013		PPLP003420643
2014		PPLP003420643
2014		PPLPC001000148269
2014		PPLP003407959
2014		PPLPC001000148269
1996		PKY180929297
1996		PKY180673220
1999		PDD1502308570
2000		SHC-000007110
2000		PKY181096193
12/7/2000		PDD1502325091
1/17/2001		PPLPC018000012472
3/1/2001		PKY181960109
3/21/2001		SHC-000001976

2001		SHC-000001976
2001		PKY181855532
2002		JAN-MS-02325533
8/16/2002		PPLPC019000028283
2010		PPLPC012000268268
2011		PPLP003409243
2011		PPLP003410417
2011		PPLP003427247
2011		PPLP003427248
2011		PPLPC012000356788
2012		PPLP003408699
8/30/2012		PPLPC018000712431
		PPLP004096817
		PPLP004096840
		PPLPC012000356786
1994		PDD1706039146
9/28/1994		PKY180581359
1996		SHC-000004005
1996		SHC-000005054
1996		SHC-000005054
11/00/1996		PDD1502103326
1/21/1997		PKY180544129
1/21/1997		PKY181085037
2000		PKY181094276
9/00/2002		PKY181257182
10/13/2008		PPLP003418363
2010		PPLPC022000360340
2010		PPLPC022000360341
2010		PPLPC029000366545
2010		PPLPC029000366546
2012		PPLP004148463
2012		PPLP004148463
2016		PPLP003409772
2016		PPLP003409800
2013		PPLP003410175
		PPLP003408733
		PPLPC009000087636
12/7/2000		SHC-000007110
2001		PDD9316728862
2002		PDD9316729260
2006		PPLPC022000095131
2011		PPLP003408756
2011		PPLP003408872
2012		PPLP003407507
2012		PPLP003407581
2012		PPLP003407929
2012		PPLP003409733

2012		PPLP003410236
2013		PPLP003410190
undated		PDD1502324678
		PPLP003408797
		PPLP003410223
		PPLP003410248
YEAR		**BEG BATES NUMBER**
2003		TEVA_MDL_A_13619691
2008		TEVA_MDL_A_01543547
2008		TEVA_MDL_A_02936598
2008		TEVA_MDL_A_08978097
2008		TEVA_CAOC-00463853
2009		TEV-FE00109189
2010		TEV_FE00114124
2010		TEVA_MDL_A_00556014
2010		TEV_FE00111970
2010		TEVA_MDL_A_02216958
2010		TEV_FE00114124
2010		TEVA_MDL_A_00556014
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2010		TEV_FE00031248
2011		TEVA_MDL_A_02473101
2012		TEVA_MDL_A_01205575
2012		TEVA_MDL_A_00499028
2012		TEVA_MDL_A_00498935
2012		TEVA_MDL_A_02349490
2014		TEVA_MDL_A_00886031
2014		TEVA_MDL_A_02553534
ALL		
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2008		TEVA_MDL_A_00368380
2009		TEVA_CAOC-00471536
2011		TEVA_MDL_A_02241478
2006		TEVA_MDL_A_02217508
2008		TEVA_MDL_A_00375035
2009		TEV-FE00109189
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2011		TEVA_MDL_A_00555228
2012		TEVA_CAOC_00707632_Highly Confidential
ALL		
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2010		TEV_FE00111970

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2011		TEVA_MDL_A_02473101
2011		TEVA_MDL_A_01397431_Highly Confidential
2016		TEVA_MDL_A_02483004
2017		TEVA_MDL_A_00553218
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2010		TEVA_MDL_A_00500834
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2010		TEV_FE00111970
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Perri Schedule 11: Amounts Paid to Pain Advocacy Organizations & Professional Societies

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