NO. 22-_____

In the Supreme Court of the United States

SUNTREE PHARMACY AND
SUNTREE MEDICAL EQUIPMENT, LLC,

Petitioners,

v.

DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

PETITION FOR A WRIT OF CERTIORARI

RONALD W. CHAPMAN II
COUNSEL OF RECORD
CHAPMAN LAW GROUP
1441 W. LONG LAKE RD., STE. 310
TROY, MI 48098
(248) 644-6326
RWCHAPMAN@CHAPMANLAWGROUP.COM

MATTHEW J. PELCOWITZ
CHAPMAN LAW GROUP
701 WATERFORD WAY, STE. 340
MIAMI, FL 33126
(305) 712-7177
MPELCOWITZ@CHAPMANLAWGROUP.COM

AUGUST 3, 2022 *COUNSEL FOR PETITIONERS*

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QUESTION PRESENTED

On February 14, 2022, a three-judge panel of the Eleventh Circuit upheld the DEA Administrator's decision to revoke Suntree Pharmacy's DEA registration interpreting 21 C.F.R. § 1306.04(a) to not require evidence of a prescription's illegitimacy before deciding it was dispensed in violation of the regulation.

This vague regulation is fraught with misconceptions. In *Gonzales,* the Attorney General thought he could interpret "legitimate medical purpose" under § 1306.04(a). *Gonzales v. Oregon*, 546 U.S. 243 (2006). The Court explained, however, he exceeded his limited authority under the Act. *Id*. More recently, a circuit split as to whether "knowingly" applied to "except as authorized" under the CSA brought the regulation back before the Court. *Ruan v. United States*, 597 U.S. ___ (2022) (slip op.).

This Petition raises a third misconception. In ignoring *Gonzales*, the DEA has interpreted "legitimate medical purpose" so that a pharmacy violates its corresponding responsibility whether or not there is evidence of a prescription's illegitimacy. *Holiday CVS,* Fed. Reg. 62316 (2012). This *ultra vires* authority has allowed the DEA to discipline pharmacists for failing to resolve "red flags" before filling a prescription. *See Id*. Sadly, when challenged in court, the DEA hides behind the great deference awarded to administrative agencies. This Petition seeks to fight this harmful deference and asks the Court:

Whether a pharmacy violates its corresponding responsibility under 21 C.F.R. § 1306.04(a) and knowingly fills a prescription for a controlled substance not issued for a legitimate medical purpose where the prescription's legitimacy remains undetermined?

PARTIES TO THE PROCEEDINGS

Petitioners

- Suntree Pharmacy
- Suntree Medical Equipment, LLC

Hereinafter, collectively "Suntree Pharmacy"

Respondent

- Drug Enforcement Administration

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, neither Suntree Pharmacy nor Suntree Medical Equipment, LLC is a publicly held company, has a parent corporation, or has a publicly held company which owns 10 percent or more of its stock.

LIST OF PROCEEDINGS

Administrative Law Judge

Department of Justice,
Drug Enforcement Administration

85 Fed. Reg. 73753

Suntree Pharmacy & Suntree Med. Equip., LLC,
Plaintiff, v. *Drug Enforcement Administration,*
Defendant

Date Decision Issued: Nov. 19, 2020

Date Decision Effective: December 21, 2020

Direct Appeal

United States Court of Appeals for the Eleventh Circuit

Case No.: 20-14626

Suntree Pharmacy & Suntree Med. Equip., LLC,
Plaintiff, v. *Drug Enforcement Administration,*
Defendant

Date of Judgment: February 14, 2022

Date of Rehearing Denial: May 5, 2022

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The opinion of the U.S. Court of Appeals for the Eleventh Circuit appears in the Appendix at App.1a and can be found at *Suntree Pharmacy and Suntree Medical Equip, LLC v. DEA*, No. 20-14626, 2022 U.S. App. (11th Cir. Feb. 14, 2022). (App.1a). This opinion was not designated for publication. The decision and order of the Department of Drug Administration appears in the appendix at App.17a and can be found in the Federal Register at Fed. Reg. 73753.

JURISDICTION

On February 14, 2022, a three-judge panel of the Eleventh Circuit Court of Appeals entered its opinion in *Suntree Pharmacy and Suntree Medical Equip, LLC v. DEA*, No. 20-14626, 2022 U.S. App. (11th Cir. Feb. 14, 2022). (App.1a). Plaintiff, Suntree Pharmacy filed a Petition for Panel Rehearing, or alternatively, En Banc Rehearing, which the Court denied on May 5, 2022 (App.281a). This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

REGULATIONS AND STATUTES INVOLVED

21 C.F.R. § 1306.04(a)

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. § 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 U.S.C. § 824
Denial, revocation, or suspension of registration

This statute is included in the appendix at App.283a.

INTRODUCTION

A. An Overview of the Controlled Substances Act and the Authority Granted to the Drug Enforcement Administration.

The Controlled Substances Act (CSA) is a closed regulatory system enacted by Congress, making it unlawful to manufacture, distribute, dispense, or possess any controlled substance, except in a manner authorized by the Act. 21 U.S.C. § 801 et seq.; *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 827, 830 (11th Cir. 2018) (quoting *Gonzales v. Raich*, 545 U.S. 1, 13 (2005)). The Act entrusts the Attorney General with the authority to develop regulations to monitor and control provider registration for prescribing and dispensing controlled substances. 21 U.S.C. § 823(f); 21 U.S.C. 824(a); *Gonzales*, 546 U.S. at 262 (observing "Sections 823(f) and 824(a) explicitly grant the Attorney General the authority to register and deregister physicians . . . "). The Attorney General has delegated this authority to the Drug Enforcement Administration (DEA) Administrator, under which the Administrator has developed regulations to oversee provider registration. 21 U.S.C. § 871; *Gonzales*, 546 U.S. at 262; *Final Rule: Redelegation of Functions; Delegation of Authority to Drug Enforcement Administration Official,* 75 Fed. Reg. 4982 (Feb. 1, 2010). One of these regulations includes 21 C.F.R. § 1306.04(a), which places a corresponding responsibility on pharmacies to refuse to fill prescriptions that are not issued for a legitimate medical purpose. 21 C.F.R. § 1306.04(a).

Given that the DEA Administrator draws his authority under the CSA from the Attorney General, the Administrator can have no greater authority than he does. *See Final Rule: Redelegation of Functions; Delegation of Authority to Drug Enforcement Administration Official,* 75 Fed. Reg. at 4982-83. The Administrator, however, has exceeded his limited authority of overseeing provider registration and has instead created a new category of "unauthorized prescriptions". Without notice, the DEA Administrator has interpreted § 1306.04(a) so that prescriptions filled in the face of unresolved "red flags" are not "issued for a legitimate medical purpose"; whether or not the prescriptions are actually illegitimate. *See Holiday CVS, LLC, d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62316, 62341 (2012) (declaring the "DEA has interpreted the "legitimate medical purpose" feature of the corresponding responsibility duty "as prohibiting a pharmacist from filling a prescription for a controlled substance when he either knows or has reason to know that the prescription was not written for a legitimate medical purpose . . . "").

There, the DEA Administrator found that Holiday CVS violated its corresponding responsibility under § 1306.04(a) solely on the basis that it filled controlled substance prescriptions without resolving "red flags". *Id*. at 62342-45. Holiday CVS argued that these "red flags" were based on the testimony of one "expert" witness and were not supported by case law, administrative decision, or published DEA guidance. *Id*. at 62317-18. Relying on his—and the DEA's—prior decisions, the Administrator simply responded that DEA precedent dictates the DEA interprets the "legitimate

medical purpose" feature of the corresponding responsibility duty as prohibiting a pharmacist or pharmacy from filling prescriptions with unresolved "red flags". *Id*. at 62341.[1] [2]

The Administrator's decision, however, is indefensible in light of the Court's decision in *Gonzales*, 546 U.S. at 262. There, the Court clarified the Attorney General's —and by extension the DEA Administrator's—authority under the CSA is limited to registering physicians and scheduling drugs:

> It would be anomalous for Congress to have so painstakingly described the Attorney General's limited authority to deregister a single physician or schedule a single drug, but to have given him, just by implication, authority

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[1] The DEA Administrator cited to the following decisions: *Sun & Lake Pharmacy, Inc.*, 76 Fed. Reg. 24523, 24530 (2011); *Liddy's Pharmacy, LLC,* 76 Fed. Reg. at 48895; *East Main Street Pharmacy,* 75 Fed. Reg. 66149, 66163 (2010); *Lincoln Pharmacy*, 75 Fed. Reg. 65667, 65668 (2010); *Bob's Pharmacy,* 74 Fed. Reg. at 19601; *Carlos Gonzalez*, 76 Fed. Reg. 63118, 63142 (2011) (citing *Holloway Distrib*., 72 Fed. Reg. 42118, 42124 (2007)).

[2] Other decisions include: *Paul J. Volkman,* 73 Fed. Reg. 30,630 (2008) (discussing drug cocktails issued by physician for oxycodone, benzodiazepines and carisoprodol, expert testimony of abuse potential of these drugs, and red flag of patient travelling long distance to fill prescriptions); *George Pharmacy, Inc.; Decision and Order*, 87 Fed. Reg. 211,45 (2022) (finding a pharmacy violated its corresponding responsibility because it filled prescriptions with unresolved "red flags"); *see e.g., Pronto Pharmacy, LLC; Decision and Order,* 86 Fed. Reg. 647,14 (2021); *Superior Pharmacy I and Superior Pharmacy II; Decision and Order*, 81 Fed. Reg. 313,09 (2016); *The Medicine Shoppe; Decision and Order*, 79 Fed. Reg. 595,04 (2014); *Health Fit Pharmacy; Decision and Order*, 83 Fed. Reg. 243,48 (2018).

> to declare an entire class of activity outside "the course of professional practice," and therefore a criminal violation of the CSA. (citation omitted)).

Id.

Clearly, the authority the DEA Administrator lays claim to does not arise out of the CSA or the Court's prior decisions. Instead, the DEA has systematically extended its authority through decisions like *Holiday CVS, LLC*, 77 Fed. Reg. 62316, and this case, and in doing so, has created a new category of "unauthorized prescriptions"—*i.e.*, prescriptions that bear the markers of unenumerated "red flags" that were not developed by notice-and-comment, statute, or medical expertise. In fact, in this case, not only did the DEA Administrator fail to determine the legitimacy of the prescriptions Suntree Pharmacy filled, but he also discouraged such a determination by preventing Suntree Pharmacy from calling the physicians who prescribed the controlled substances it filled to testify and by failing to gather testimony from patients who were prescribed these controlled substances. *See Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. 73753, 73754 (2020) (App.17a). Rather, to streamline revocation, only one "expert", Dr. Gordon, testified, providing a list of DEA-created unresolved "red flags". *Id.* at 73754-55. Indeed, Dr. Gordon even admitted she developed this list of "red flags" based on DEA decisions and that she was unable to cite to medical literature supporting any of the "red flags". Transcript at 21-311; ALJ Recommended Ruling, at 8-11 (App.128a).

Crucially, this overreach by the DEA has resulted in an impossible standard for pharmacists and pharmacies, where they must refuse to fill prescriptions if there are unresolved "red flags" that only the DEA and the DEA's experts can identify with confidence. *See Holiday CVS, LLC*, 77 Fed. Reg. 62317-18 (noting there is no published DEA guidance on "red flags" to refer to). This impossible standard not only affects pharmacists' ability to practice, but it also adversely affects patients because pharmacists increasingly refuse to fill prescriptions out of fear of having their DEA registrations revoked.[3] If the DEA's improper interpretation of § 1306.04(a) continues there is no telling how many more patients will suffer. Unfortunately, the great deference reviewing courts award to the DEA's interpretation has allowed this grave problem to persist.

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[3] Amy Pavuk, *Pain Patients Decry Oxycodone Shortage, But DEA Disagrees,* ORLANDO SENTINEL (Sep. 29, 2012, 6:49 PM), https://www.orlandosentinel.com/news/breaking-news/os-oxycodone-shortage-dea-florida-20120929-story.html; Matt Grant, *New Allegations Made On DEA'S Role In Pain Prescription Denials,* WESH 2 (Jul. 30, 2015, 5:59 PM), https://www.wesh.com/article/new-allegations-made-on-dea-s-role-in-pain-prescription-denials/4443955#; Press Center, *A Misguided Department of Justice Lawsuit Forces Pharmacists Between Patients And Their Doctors* (Dec. 22, 2020), https://corporate.walmart.com/newsroom/2020/12/22/a-misguided-department-of-justice-lawsuit-forces-pharmacists-between-patients-and-their-doctors; Katie Adams, *DEA Takes Hard Stance on Pharmacies Administering Buprenorphine,* BECKER'S HOSPITAL REVIEW (Nov. 8, 2021), https://www.beckershospitalreview.com/opioids/dea-takes-hard-stance-on-pharmacies-administering-buprenorphine.html.

B. The Great Deference Awarded to Administrative Agencies and Whether the Drug Enforcement Administration is Entitled to this Deference.

Administrative agencies are one of the few, perhaps only, governmental bodies that largely act free of the Separation of Powers prescribed by the Framers.[4] A freedom tied to the Court's decision in *Auer*, Justice Scalia deeply regretted the *Auer* decision as he awakened to its pernicious impact. *Id*. (emphasizing the *Auer* decision enables agencies to pass vague regulations and construe them opportunistically while enjoying great [*Auer*] deference from a reviewing court).

In what has come to be known as *Auer* deference, the Court held if an agency's regulation remains genuinely ambiguous after employing all traditional tools of construction, the agency's interpretation of its regulation is entitled to deference from a reviewing court if: 1) the interpretation is reasonable, such that it falls within the zone of ambiguity identified by the reviewing court, and 2) an independent inquiry into the character and context of the agency's interpretation entitles it to controlling weight. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415-16 (2019) (observing " . . . we give *Auer* deference because we presume, for a set of reasons relating to the comparative attributes of courts and agencies, that Congress would have wanted us to." (citation omitted)). While there is no exhaustive test to determine if an agency's interpretation is entitled to controlling weight,

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[4] Evan D. Bernick, *Enough Is Enough: Justice Scalia, Auer Deference, and Judicial Duty,* The Federalist Society (Mar. 3, 2016), available at https://fedsoc.org/commentary/fedsoc-blog/enough-is-enough-justice-scalia-auer-deference-and-judicial-duty.

the Court has identified specific markers to determine when *Auer* deference is and is not appropriate. *Id.*[5]

One important marker focuses on whether the agency's interpretation involves its substantive expertise, like issues involving highly technical and specialized knowledge. *See Id*. at 2417 (noting "[a]dministrative knowledge and experience largely account [for] the presumption that Congress delegates interpretive lawmaking power to the agency." (citation omitted)). For good reason then, when a rule is technical, agencies are believed to possess a nuanced understanding of the regulations they administer and the case for *Auer* deference is strengthened. *See Id*. Conversely, "deference ebbs when [t]he subject matter of the [dispute is] distan[t] from the agency's ordinary duties or fall[s] within the scope of another agency's authority." (citation omitted). *Id*.

At issue in this case is the CSA, which as discussed, entrusts the Attorney General with the authority to develop regulations to monitor and control provider registration for prescribing and dispensing controlled substances; power the Attorney General has delegated to the DEA. 21 U.S.C. § 871; *Gonzales*, 546 U.S. at 262. At first blush, one might think *Auer* deference should apply to this closed system given that § 1306.04(a) is recognized as genuinely ambiguous. *Gonzales*, 546 U.S. at 258 (observing "[a]ll would agree, we should think, that the statutory phrase "legitimate medical

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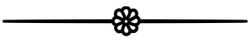
[5] *Kisor,* 139 S. Ct. at 2406 (noting the regulatory interpretation must be the agency's authoritative or official position, rather than any more adhoc statement not reflecting the agency's views, the agency's interpretation in some way must implicate its substantive expertise, and an agency's reading of a rule must reflect its fair and considered judgment (citation omitted)).

purpose" is a generality, susceptible to more precise definition and open to varying constructions, and thus ambiguous in the relevant sense."). However, such an understanding is inapposite given the Court's opinion in *Gonzales*, 546 U.S. at 256-57.

There, the Court held § 1306.04(a) as "nearly equivalent" to the language Congress used in drafting the statutes in the CSA (*i.e.*, 21 U.S.C. § 812(b); § 829(c); § 830(b)(3)(A)(ii); § 802(21)). *Id.* (holding " . . . the near equivalence of the statute and regulation belies the Government's argument for *Auer* deference."). This "near equivalency" lead the Court to conclude that *Auer* deference was inappropriate because, even though the Attorney General claimed he was interpreting § 1306.04(a), he had actually tried to interpret the meaning of the statutes found in the CSA—power that Congress has yet to entrust to the Attorney General. *See Id.* (clarifying "[s]imply put, the existence of a parroting regulation does not change the fact that the question here is not the meaning of the regulation but the meaning of the statute."). But even if the Attorney General were interpreting the regulation, his interpretation would still prove ineffective because as the Court recognized "the structure of the CSA [] convey[s] [Congress'] unwillingness to cede medical judgments to an executive official [Attorney General] who lacks medical expertise." *Gonzales*, 546 U.S. at 266. This unwillingness applies equally to all executive officials who lack medical expertise, whether that be the Attorney General interpreting § 1306.04(a), as in *Gonzales*, or the then-Acting DEA Administrator, Timothy Shea, interpreting the regulation in this case.

Following *Gonzales*, more recent decisions from the Court have further reinforced the Acting DEA

Administrator's interpretation of § 1306.04(a) is not entitled to *Auer* deference. Instead, for the reasons set forth below, the Court should hold that the DEA's interpretation of the regulation is improper and that its revocation of Suntree Pharmacy's registration, based on this improper interpretation, should be reversed.



STATEMENT

On October 5, 2016, the DEA issued an Order to Show Cause ("OSC") to Suntree Pharmacy. R. 1. The OSC alleged that Suntree filled prescriptions in contravention of its corresponding responsibility under 21 C.F.R. § 1306.04(a). R. 1 at 2. Specifically, the OSC claimed that Suntree violated this responsibility by "repeatedly fill[ing] controlled substance prescriptions that contained multiple red flags of diversion and/or abuse without addressing or resolving those red flags and under circumstances indicating that the pharmacists were willfully blind or deliberately ignorant of the prescriptions illegitimacy." R. 1 at 2.

An administrative hearing was held from April 24, 2017, to April 26, 2017, following which, on August 15, 2017, the Administrative Law Judge ("ALJ") filed his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision. (App.128a) R. 5; *Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. at 73753-54. On September 18, 2017, the ALJ transmitted his recommended decision along with records from the hearing to the then-Acting DEA Administrator, Timothy Shea. *Id.*; *Id.* On November 9, 2020, the Acting Administrator

rendered his decision, finding Suntree Pharmacy had violated its corresponding responsibility under § 1306 .04(a), and issuing an Order revoking Suntree Pharmacy's registration, effective December 21, 2020. *Id.* (App.17a).

In his decision, the Acting Administrator determined that Suntree's actions of filling "hundreds" of prescriptions in the face of "red flags" was egregious conduct that necessitated revocation. *Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. at 73776-77. The Acting Administrator also found Suntree Medical Equipment, LLC's registration should be revoked because "Respondent LLC could pick up where the Pharmacy left off without missing a beat. Accordingly due to that commonality, it is appropriate to treat the Pharmacy and Suntree Medical as one integrated enterprise." (App.128a).[6]

At no point did the Acting Administrator determine the legitimacy of the underlying controlled substance prescriptions that Suntree Pharmacy filled, nor did any qualified healthcare professional comment on whether the prescriptions were issued for a legitimate medical purpose. *Id.* at 73774-75. The Acting Administrator also never heard testimony from any patients and prevented testimony from the physicians who prescribed the controlled substances Suntree Pharmacy filled. *Id.* at 73754. Instead, the Acting Administrator simply relied on "red flags" identified by Dr. Gordon, a clinical hospice pharmacist for ProCare RX, working from home as a

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[6] Suntree Medical LLC was a separate closed-door pharmacy that did not dispense retail prescriptions. Suntree Medical had a separate DEA registration and was not in any way engaged in the conduct in the Order to Show Cause.

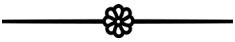
consultant (*i.e.*, not a retail pharmacist), and used these "red flags" as a proxy to conclude the prescriptions were illegitimate. *Id.* at 73754, 73774-75; R. 6 at 21; *See* Br. at 15-20 (describing in detail Dr. Gordon's testimony). To this day, the DEA has never followed-up with or penalized the medical providers who prescribed these "illegitimate" controlled substances that Suntree Pharmacy filled.

Suntree Pharmacy appealed the Acting DEA Administrator's decision to the Eleventh Circuit Court of Appeals. Br. 1. It had jurisdiction to challenge the DEA Administrator's Order in the Eleventh Circuit Court of Appeals pursuant to 21 U.S.C. § 877, which vests jurisdiction for appeal of a DEA Order in either the Court of Appeals for the District of Columbia or the circuit in which Suntree's principal place of business is located. 21 U.S.C. § 877.

On February 14, 2022, the Eleventh Circuit issued its decision upholding the Acting Administrator's revocation of Suntree Pharmacy's registration, finding the Acting Administrator's factual findings were supported by "substantial evidence" and thus conclusive. Op. Issued by Ct. 15-16. In the decision, the Court simply deferred to the Acting Administrator's interpretation of § 1306.04(a), and in doing so, held the Acting DEA Administrator could use "red flags" as a proxy for finding a controlled substance prescription was not issued for a legitimate medical purpose, without actually needing to determine the legitimacy of the underlying prescription. *Id*. at 15 (holding "[h]ere, the Acting Administrator found that circumstantial evidence—the "blatant" red flags identified by Dr. Gordon and ignored by Suntree—showed that the prescriptions were not issued for a14 legitimate medical

purpose. And the Acting Administrator found that Suntree violated its corresponding responsibility by filling the prescriptions even though it knew—or was willfully blind to—the prescriptions' illegitimacy. The Acting Administrator's finding that Suntree violated its corresponding responsibility is supported by substantial evidence, and it is therefore conclusive.").

In the same way the then-Acting Administrator used "red flags" as a proxy to determine the legitimacy of a controlled substance prescription (without actually making such a determination; either by himself or via a medical expert), the Eleventh Circuit used the length of time the DEA has interpreted § 1306.04(a) as allowing the same as a proxy for whether it should simply defer to the DEA's interpretation. *See Id.* at 14. Unfortunately, the Eleventh Circuit failed to further examine whether the DEA's long-held interpretation of § 1306.04(a) was reasonable and should be upheld. *Id.* at 1-17. Even when the Court was given a second chance, following the filing of Suntree Pharmacy's Petition for Panel Rehearing and En Banc Rehearing, it again simply deferred to the DEA's interpretation and denied the Petition on May 5th, 2022. *See* Order Issued by Ct. (App.281a). This lack of inquiry from the Eleventh Circuit is unsurprising given the great [*Auer*] deference administrative agencies, like the DEA, are awarded when interpreting their regulations.



SUMMARY OF THE ARGUMENT

The DEA has developed a range of regulations to monitor and control provider registration for prescribing

and dispensing controlled substances. One such regulation, 21 C.F.R. § 1306.04(a), places a corresponding responsibility on pharmacists and pharmacies to refuse to fill prescriptions that are not issued for a legitimate medical purpose. The DEA has interpreted § 1306.04(a) so that a pharmacy violates its corresponding responsibility if it fills controlled substance prescriptions without resolving "red flags". Under this interpretation, the DEA Administrator need not determine the underlying legitimacy of the prescriptions a pharmacy filled, but rather, may use "red flags" as a proxy to presume a prescription was illegitimate.

Although § 1306.04(a) has been held genuinely ambiguous, the DEA's interpretation of the regulation is not entitled to the [*Auer*] deference customarily awarded to an agency when it interprets its own regulation. This is because *Auer* deference is only appropriate where an agency's interpretation of its genuinely ambiguous regulation is reasonable and an independent inquiry into the character and context of the agency's interpretation entitles it to controlling weight.

In this case, the DEA's interpretation of § 1306.04(a) is unreasonable given the "near equivalence" of the regulation to the statutes in the CSA. This "near equivalency" means that it is these statutes the DEA has interpreted and not the regulation—power Congress has not entrusted to the DEA. The DEA's interpretation is also unreasonable because it is inapposite given the Court's characterization of willful blindness, which requires the existence of the fact a defendant is found willfully blind of. Here, that fact being whether the prescriptions Suntree Pharmacy filled were not issued for a legitimate medical purpose.

Further, even if the DEA's interpretation of § 1306.04(a) is held reasonable, *Auer* deference is still inappropriate because an independent inquiry into the character and context of the DEA's interpretation reveals it is not entitled to controlling weight. This is because the DEA's interpretation removes § 1306.04(a) from the highly technical and specialized sphere of science and medicine, and instead, places the regulation directly into the purview of the Court.

Auer deference is also inappropriate because the DEA's interpretation does not reflect its fair and considered judgment and "unfairly surprises" pharmacies. Rather than fair and considered judgment, the DEA simply drafted § 1306.04(a) parroting the statutes Congress drafted as part of the CSA. This creates an "unfair surprise" not only because the statutes in the CSA with identical language are enforced disparately, but also because the DEA failed to use notice-and-comment rulemaking in expanding the regulation's reach beyond the statutes of the CSA that it parrots.

Finally, the DEA's interpretation of § 1306.04(a) is not entitled to *Auer* deference because this is an "extraordinary case" and there is no "clear congressional authorization" supporting the authority the DEA has improperly acquired from its interpretation. Specifically, under its interpretation, the DEA has declared an entire class of activity—filling (*i.e.*, dispensing under § 841(a)) a prescription for a controlled substance with unresolved "red flags" whether or not the prescription was issued for a legitimate medical purpose—a criminal violation of the CSA. The Court, however, has recognized that the Attorney General's—who the DEA draws its power from—authority under

the CSA is limited to registering physicians and scheduling drugs. The CSA therefore contains no "clear congressional authorization" supporting the DEA's authority to criminalize an entire class of activity.

Accordingly, the Court should not defer to the DEA's improper interpretation of § 1306.04(a) and instead should enforce the regulation so that it reflects the Court's prior decisions, Congress' intent, and does not "unfairly surprise" pharmacies. The Court should therefore hold that a violation of a pharmacy's corresponding responsibility requires a determination of the legitimacy of the prescriptions it filled, and further, that this determination uncover prescriptions were "not issued for a legitimate medical purpose".

REASONS FOR GRANTING THE PETITION

I. THE REVOCATION OF PETITIONER'S REGISTRATION SHOULD BE REVERSED BECAUSE A VIOLATION OF ITS CORRESPONDING RESPONSIBILITY REQUIRES A DETERMINATION OF THE LEGITIMACY OF THE PRESCRIPTIONS IT FILLED.

The revocation of Suntree Pharmacy's registration should be reversed because it could not have violated its corresponding responsibility under § 1306.04(a) unless it filled controlled substance prescriptions that were not issued for a legitimate medical purpose. 21 C.F.R. § 1306.04(a); *see Ruan*, 597 U.S. ___ (slip op. at 3). (affirming "[w]e assume, as did the courts below and the parties here, that a prescription is "authorized" and therefore lawful if it satisfies this standard [issued for a legitimate medical purpose by an individual

practitioner acting in the usual course of his professional practice].”). Even the plain language of the regulation supports pharmacies do not violate their corresponding responsibility where they fill a prescription issued for a legitimate medical purpose. *Id*. The DEA though is willfully blind of this requirement and has instead interpreted § 1306.04(a) to penalize pharmacies, like Suntree Pharmacy, regardless of the underlying legitimacy of the prescriptions it filled, so long as there are unresolved “red flags”. *Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. at 73759-60, 73774-75. To make matters worse, when challenged in federal court, as Suntree has done in this case, the reviewing court simply defers to the DEA’s interpretation under the principles of *Auer* deference. Op. Issued by Ct. at 13-16. But should the DEA’s interpretation of § 1306.04(a) be provided *Auer* deference?

Given the Court’s decision in *Gonzales*, where it recognized § 1306.04(a) is genuinely ambiguous, *Auer* deference is appropriate if the DEA’s interpretation of the regulation is reasonable, and an independent inquiry of the character and context of the DEA’s interpretation entitles it to controlling weight. 546 U.S. at 258 (“[a]ll would agree, we should think, that the statutory phrase “legitimate medical purpose” is a generality, susceptible to more precise definition and open to varying constructions, and thus ambiguous in the relevant sense.”); *see Kisor*, 139 S. Ct. at 2415-16. Thoughtful review, however, reveals the DEA’s interpretation is not entitled to deference because it is unreasonable, thereby exceeding the zone of ambiguity identified by this Court’s prior cases. But even if the DEA’s interpretation were reasonable, *Auer* deference is still inappropriate because

its interpretation is not entitled to controlling weight insofar as it exceeds the authority Congress has granted under the CSA and falls short of the agency's "fair and considered judgment", creating an "unfair surprise" to regulated parties.

A. The DEA's Interpretation of § 1306.04(a) Is Unreasonable and Not Entitled to *Auer* Deference Because the Regulation Is "Nearly Equivalent" to the Statutes in the CSA.

As established in *Gonzales*, § 1306.04(a) is "nearly equivalent" to the statutes Congress drafted under the CSA. 546 U.S. at 256-57 (" . . . the near equivalence of the statute and regulation belies the Government's argument for *Auer* deference . . . "). Because these statutes impose criminal liability, every element of each statute [the crime] must be proven beyond a reasonable doubt. *See, e.g.*, *In re Winship*, 397 U.S. 358, 364 (1970) (holding due process requires proof beyond a reasonable doubt of every fact necessary to constitute the crime charged); *Christoffel v. United States*, 338 U.S. 84, 89 (1949). As an example, to convict a defendant under 21 U.S.C. § 841(a), the government must prove beyond a reasonable doubt that a controlled substance was not issued for a legitimate medical purpose. 21 U.S.C. § 841(a) ("[e]xcept as authorized by this subchapter . . . "). Though the burden of proof is not the same for § 1306.04(a) given the regulation does not impose criminal liability, the "near equivalence" of the regulation supports that, like § 841(a), each of the regulation's elements must be proven, including that a pharmacy filled a prescription for a controlled substance that was

not issued for a legitimate medical purpose.[7] 21 C.F.R. § 1306.04(a).

To be sure, in *Gonzales*, the Court observed that though the Attorney General argued he was interpreting "legitimate medical purpose" as it pertained to § 1306.04(a), given the regulation's "near equivalency" to the statutes found in the CSA, he was in fact trying to interpret the statutes—power that Congress has yet to entrust to the Attorney General. 546 U.S. at 257, 262 (acknowledging "[a]n agency does not acquire special authority to interpret its own words when, instead of using its expertise and experience to formulate a regulation, it has elected merely to paraphrase the statutory language."). The Court explained that if the Attorney General could interpret § 1306.04(a) so that he could determine what class of activity was and was not medically legitimate (*i.e.*, outside the course of professional practice), he would have the power to criminalize the actions of DEA registered physicians. *Id.* at 262 ((advising "[i]t would be anomalous for Congress to have so painstakingly described the Attorney General's limited authority to deregister a single physician or schedule a single drug, but to have given him, just by implication, authority to declare an entire class of activity outside "the course of professional practice," and therefore a criminal violation of the CSA." (citation omitted)); *see*

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[7] This means that like 21 U.S.C. § 841(a), the DEA's regulation § 1306.04(a) must also require a healthcare professional with medical expertise to determine the legitimacy of a controlled substance prescription, rather than simply identifying "red flags" from which the then-Acting DEA Administrator may presume a prescription's legitimacy. *See Gonzales,* 546 U.S. at 266 (affirming "[t]he structure of the CSA [] conveys unwillingness to cede medical judgments to an executive official [*i.e.*, the then-Acting DEA Administrator] who lacks medical expertise.").

also H.R. Rep No. R45948, at 17 (2021) (observing "[a] violation of the CSA's registration requirements [] . . . generally does not constitute a criminal offense unless the violation is committed knowingly [*i.e.*, 21 C.F.R. § 1306.04(a)]. However, in the event of a knowing violation, DOJ may bring criminal charges against both individual and corporate registrants."). As a result, the Court held the Attorney General's interpretation of § 1306.04(a) was not entitled to *Auer* deference. *Gonzales*, 546 U.S. at 257-58, 264-66.

In the same way the Attorney General tried to interpret the statutes in the CSA, here too, the Acting DEA Administrator was interpreting these same statutes when he claimed a pharmacy violates its corresponding responsibility under § 1306.04(a) without determining the legitimacy of the controlled substance prescriptions it filled. *Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. at 73774-75; *see also Holiday CVS, LLC*, 77 Fed. Reg. at 62341. In fact, under the DEA's interpretation of § 1306.04(a), the Acting DEA Administrator declared an entire class of activity (*i.e.*, filling (*i.e.*, dispensing under § 841(a)) a prescription for a controlled substance with unresolved "red flags" whether or not the prescription was issued for a legitimate medical purpose) as outside the course of professional practice, and therefore, a criminal violation of the CSA.[8] *See e.g.*, 21 U.S.C. § 841(a); *see* H.R. Rep No. R45948, at 17; *see*

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[8] *See United States v. Binder*, 26 F. Supp. 3d 656, 662-63 (E.D. Mich. 2014) (confirming where no expert determination was made as to the suitability of treatment involved in a case, "red flags" are insufficient); *see also United States v. Tran Trong Cuong*, 18 F.3d 1132, 1141 (4th Cir. 1994); *United States v. Jones*, 570 F.2d 765, 769 (8th Cir. 1978).

Holiday CVS, LLC, 77 Fed. Reg. at 62341 (DEA Administrator declaring the "DEA has interpreted the "legitimate medical purpose" feature of the corresponding responsibility duty "as prohibiting a pharmacist from filling a prescription for a controlled substance when he either knows or has reason to know that the prescription was not written for a legitimate medical purpose . . . ".). However, as discussed, due process requires a prescription to not be issued for a legitimate medical purpose outside the course of professional practice.[9] *See In re Winship*, 397 U.S. at 364; *Christoffel*, 338 U.S. at 89. All this to say, as in *Gonzales*, it was the statutes of the CSA that the Acting DEA Administrator was interpreting rather than § 1306.04(a)—power that Congress has not entrusted to the DEA.

For the foregoing reasons, the Acting DEA Administrator's interpretation of § 1306.04(a) is unreasonable, exceeding the zone of ambiguity identified by the Court's decision in *Gonzales*, and therefore, *Auer* deference is not appropriate. *Kisor*, 139 S. Ct. at 2415-16. Instead, § 1306.04(a) should be enforced consistent with 21 U.S.C. § 801 et seq., as requiring a qualified professional with medical expertise to determine whether a prescription was issued for a legitimate medical purpose. The Acting Administrator's decision that Suntree Pharmacy violated § 1306.04(a), thereby revoking its registration, should therefore be reversed.

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[9] A determination that must be made by a qualified professional with medical expertise. *See Gonzales*, 546 U.S. at 266.

B. The DEA's Interpretation of § 1306.04(a) Is Unreasonable and Not Entitled to *Auer* Deference Given the Court's Characterization of Willful Blindness.

The Acting DEA Administrator determined that filling controlled substance prescriptions where there are unresolved "red flags" was sufficient to find that Suntree Pharmacy violated its corresponding responsibility under § 1306.04(a). *Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. at 73774-75. According to the Administrator, Suntree Pharmacy, by failing to resolve "red flags", was "willfully blind" to the existence of facts that, in the Administrator's view, suggest the prescriptions it was filling were illegitimate. *Id.* at 73772; Op. Issued by Ct. 15. But this is not sufficient for a violation of § 1306.04(a), as discussed above, and it is not sufficient for a finding of "willful blindness" because no evidence was submitted to show that the prescriptions were actually illegitimate. *Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. at 73754 (confirming that prescribing physicians and patients did not testify nor did a qualified professional with medical expertise on the legitimacy of the prescriptions Suntree Pharmacy filled); *see also Global-Tech Appliances, Inc.*, 563 U.S. 754 (2011). There, the Court held:

> While the Courts of Appeals articulate the doctrine of willful blindness in slightly different ways, all appear to agree on two basic requirements: (1) the defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning

> of that fact. We think these requirements give willful blindness an appropriately limited scope that surpasses recklessness and negligence." (citation omitted).

Id. at 769.

Under this definition, the Court found that the Federal Circuit's use of willful blindness exceeded the doctrine's limits by holding there was adequate evidence to support a finding that "Pentalpha deliberately disregarded a known risk that SEB had a protective patent" even though the record contained no direct evidence that Pentalpha knew of SEB's patent prior to the lawsuit. *Global-Tech Appliances, Inc.*, 563 U.S. at 759, 766.

As it relates to § 1306.04(a), the Court has yet to determine whether a defendant acts knowingly under the regulation if he is found willfully blind. Rather, the doctrine of willful blindness is anchored in criminal statutes, where it is used much more often than it is in civil statutes or administrative regulations. *Id.* at 766-67. However, given the doctrine's past use in non-criminal cases and its widespread acceptance across the Federal Judiciary, it is expected the Court agrees with its application under § 1306.04(a). *Id*. at 768.

Returning to this case, the Acting Administrator's failure to determine the underlying legitimacy of the prescriptions Suntree Pharmacy filled stands in opposition of the Court's characterization of willful blindness in *Global-Tech Appliances, Inc.* 563 U.S. at 769 (holding willful blindness requires "the defendant [] take deliberate actions to avoid learning of [] [a] fact."). As the Court explained, though willful blindness surpasses recklessness and negligence, it is limited in

scope, one such limitation being that the fact a defendant is willfully blind of must actually exist so that he could have learned of the fact but for his deliberate actions in avoiding so. *See Id.* (holding "[w]e think th[is] requirements give[s] willful blindness an appropriately limited scope that surpasses recklessness and negligence."). Otherwise, the defendant is not blind by choice, but rather, he is blinded by a reality in which the fact never existed. *See Id.* (confirming that a defendant must take deliberate actions to avoid learning of a fact). Indeed, the Eleventh Circuit's own case law supports this limitation.

In *Obstfeld*, the Eleventh Circuit held that "[u]nder the doctrine of willful blindness or deliberate ignorance, which is used more often in the criminal context than in civil cases, knowledge can be imputed to a party who knows of a high probability of illegal conduct and purposely contrives to avoid learning of it." *Williams v. Obstfeld*, 314 F.3d 1270, 1278 (11th Cir. 2002) (citing *United States v. Perez-Tosta*, 36 F.3d 1552, 1564 (11th Cir. 1994) (holding "[a] 'deliberate ignorance' instruction is appropriate when 'the facts . . . support the inference that the defendant was aware of a high probability of the existence of the fact in question and purposely contrived to avoid learning all of the facts in order to have a defense in the event of a subsequent prosecution." (citation omitted))). This holding confirms the Eleventh Circuit's characterization of willful blindness is consistent with the Court's, and that both require a defendant to have taken deliberate action to avoid learning of a fact. *See Id.*; *see also Global-Tech Appliances, Inc.*, 563 U.S. at 769. Quite significantly, the only way a defendant could have learned of a fact is if

the fact existed at some point in time over the course of the defendant's lifetime.

Given this important limitation, the Acting DEA Administrator's interpretation of § 1306.04(a), finding Suntree Pharmacy knowingly violated the regulation because it filled prescriptions in the face of unresolved "red flags", without actually determining the legitimacy of the prescriptions, was unreasonable. Rephrased, the Acting Administrator never determined whether the fact (*i.e.*, filling prescriptions for controlled substances not issued for a legitimate medical purpose) Suntree Pharmacy was found willfully blind of existed in the first place.

Despite the *Obstfeld* decision, the Eleventh Circuit deferred to the DEA Administrator's interpretation of § 1306.04(a), without examining whether it was entitled to *Auer* deference. See Op. Issued by Ct. at 15. This decision illustrates the significant harm—the pernicious impact Justice Scalia warned of—*Auer* deference causes, where a reviewing court all too readily defers to an Agency's interpretation of its regulation even though its interpretation is unreasonable.

The deference the Eleventh Circuit awarded the DEA's interpretation of § 1306.04(a) demonstrates the need for the Court to abolish *Auer* deference. Though the Court's decision in *Kisor* limits the zone of ambiguity in which an agency's interpretation must come within to what is considered reasonable after a court has employed its interpretative tools to the agency's regulation, this zone does not capture a court's prior interpretation of other relevant statutes and regulations, under which an agency's interpretation may be unreasonable. *See* 139 S. Ct. at 2415-16. In this case, though the Court's decision in *Global-Tech*

Appliances, Inc., 563 U.S. at 769, was in reference to 35 U.S.C. § 271(b), it nonetheless is relevant to the DEA's interpretation of knowingly under § 1306.04(a). Because the DEA's interpretation is unreasonable under this decision, it exceeds the zone of ambiguity under which *Auer* deference is appropriate.

For the foregoing reasons, the Acting DEA Administrator's interpretation of § 1306.04(a) is unreasonable, thereby exceeding the zone of ambiguity identified by the Court in *Global-Tech Appliances, Inc.,* and therefore, *Auer* deference is not appropriate. *Kisor*, 139 S. Ct. at 2415-16. Instead, § 1306.04(a) should be enforced consistent with this Court's characterization of willful blindness, requiring a determination of the legitimacy of the prescriptions filled by a pharmacist or pharmacy, and further, that such a determination be made by a qualified professional with medical expertise. The Acting Administrator's decision finding Suntree Pharmacy violated § 1306.04(a), thereby revoking its registration, should therefore be reversed.

C. Even If the DEA's Interpretation of § 1306.04(a) Were Reasonable Its Interpretation Is Still Not Entitled to *Auer* Deference Because Its Interpretation Removes the Regulation from the Highly Technical Sphere of Science and Medicine.

Even if the DEA's interpretation of § 1306.04(a) were reasonable, *Auer* deference is still inappropriate. Recall, where an agency's interpretation is held reasonable, an independent inquiry into the character and context of the agency's interpretation is necessary to determine if *Auer* deference is appropriate. *Kisor*, 139 S. Ct. at 2415-16 (observing " . . . we give *Auer*

deference because we presume, for a set of reasons relating to the comparative attributes of courts and agencies, that Congress would have wanted us to." (citation omitted)). As part of this inquiry, the Court considers whether the agency's interpretation involves its substantive expertise, like for subject matter that involves highly technical and specialized knowledge or experience. *See Id.* at 2417. When a rule is technical, agencies generally possess a nuanced understanding of the regulations they administer, and the case for *Auer* deference is strengthened. *See Id.* On the other hand, when a rule is less technical and further removed from an agency's substantive expertise, the case for *Auer* deference wanes. *Id.*

In this case, not only is *Auer* deference is inappropriate given the issue before the Court involves the interpretation of a common-law term: willful blindness, but *Auer* deference is further disfavored because the DEA's interpretation of § 1306.04(a) has removed the regulation from the highly technical sphere of science and medicine. *Kisor*, 139 S. Ct. at 2415-16 (recognizing *Auer* deference is inappropriate for interpretive issues akin to the elucidation of a simple common-law property term that more naturally falls into a judge's bailiwick).

Rather than interpreting § 1306.04(a) as requiring a medical expert to determine the legitimacy of a prescription for a controlled substance, the DEA's interpretation empowers a DEA Administrator, with no formal medical training, to determine whether a pharmacy has violated § 1306.04(a) by only using "red flags" that are unsupported by scientific or medical research. *See Holiday CVS, LLC*, 77 Fed. Reg. at 62341; *Suntree Pharmacy and Suntree Medical Equipment, LLC;*

Decision and Order, 85 Fed. Reg. at 73774-75; Op. Issued by Ct. at 14-17. This interpretation removes the highly technical and scientific layer Congress had in mind when it drafted the CSA. *See Gonzales*, 546 U.S. at 266. *Auer* deference is therefore inappropriate because the DEA's interpretation of § 1306.04(a) does not involve its substantive expertise in an area involving highly technical and specialized knowledge. *See Kisor*, 139 S. Ct. at 2415-17. Instead, the Court should preserve Congress' intent in drafting the CSA and hold a violation of § 1306.04(a) requires a determination of whether a prescription was in fact not issued for a legitimate medical purpose, and further, as Congress intended, that such a determination be made by a medical expert (and not by the then-Acting DEA Administrator). *See Gonzales*, 546 U.S. at 266 (affirming "[t]he structure of the CSA [] conveys unwillingness to cede medical judgments to an executive official who lacks medical expertise.").[10]

For the foregoing reasons, the DEA's interpretation of § 1306.04(a) is not entitled to *Auer* deference. Instead, § 1306.04(a) should be enforced in a way that is both consistent with Congress' intent in drafting the CSA and with this Court's characterization of willful blindness, requiring a qualified professional with medical expertise to determine whether a prescription was issued for a legitimate medical purpose. As

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[10] Though in *Gonzales* the executive official who the Court refused to cede medical judgements to was the Attorney General, the Court's holding should apply to the then-Acting DEA Administrator, Timothy Shea, as well as all DEA Administrators, since these DEA Administrators are executive officials who also lack the medical expertise Congress intended when making medical judgments under the CSA.

such, the Acting DEA Administrator's decision finding Suntree Pharmacy violated § 1306.04(a), thereby revoking its registration, should be reversed.

D. The DEA's Interpretation of § 1306.04(a) Is Not Entitled to *Auer* Deference Because Its Interpretation Does Not Reflect Its Fair and Considered Judgment and Creates an "Unfair Surprise" to Regulated Parties.

While the Court has clarified § 4 of the Administrative Procedure Act (APA) specifically exempts interpretative rules, like the DEA's interpretation of § 1306.04(a), from notice-and-comment requirements, *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 95-97, 101-03 (citing 5 U.S.C. § 553(b)(A)), *Auer* deference is still inappropriate where an agency's interpretation of its regulation does not reflect its fair and considered judgment and creates an "unfair surprise" to regulated parties. *Kisor*, 139 S. Ct. at 2406 (citing *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 170 (2007)). There, the Court held valid the Department of Labor's (DOL) interpretation of 29 C.F.R. § 552.109(a) from the FLSA because the interpretation reflected the agency's fair and considered judgment, and because, though it was not required to, the DOL followed full public notice-and-comment procedures, making any "unfair surprise" unlikely. *See Long Island Care at Home, Ltd.*, 551 U.S. at 161-63, 170-71 (holding " . . . as long as interpretive changes create no unfair surprise-and the Department's recourse to notice-and-comment rulemaking in an attempt to codify its new interpretation[] makes any such surprise unlikely here-the change in interpretation alone presents no separate

ground for disregarding the Department's present interpretation." (citations omitted)).

In this case, the DEA's interpretation of § 1306.04(a) falls short of the fair and considered judgment that makes *Auer* deference appropriate. *See Id*. 551 U.S. at 171 (holding " . . . here, [] [the] agency's course of action indicates that the interpretation of its own regulation reflects its considered views-the Department has clearly struggled with the third-party-employment question since at least 1993 . . . " (citation omitted)). Rather than fair and considered judgment, the DEA simply adopted a parroting regulation "nearly equivalent" to the statutes Congress drafted under the CSA. *Gonzales*, 546 U.S. at 256-57, 262. After doing so, the DEA wishes to interpret § 1306.04(a) opportunistically to streamline the revocation of provider registrations by not requiring the Administrator to determine the legitimacy of a prescription at all, much less through the use of a medical expert, so long as it is filled in the face of unresolved "red flags". *See Holiday CVS, LLC*, 77 Fed. Reg. at 62341; *Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. at 73774-75; Op. Issued by Ct. at 14-17. As the Court has acknowledged though, it is unfathomable that Congress intended for an executive official who lacks medical expertise to interpret what constitutes a "legitimate medical purpose". *Gonzales*, 546 U.S. at 266. It seems equally unfathomable that Congress would enact a loophole so that rather than trying to determine what constitutes a "legitimate medical purpose", an executive official lacking medical expertise, such as the DEA Administrator, could simply bypass

the language altogether and completely avoid determining the legitimacy of prescriptions where there are unresolved "red flags".[11]

The DEA also did not follow notice-and-comment rulemaking before adopting its unreasonable interpretation of § 1306.04(a). Instead, without notice, DEA Administrators could simply decide pharmacies filled a prescription for a controlled substance that was not issued for a legitimate medical purpose solely based on the presence of unresolved "red flags", without actually determining the legitimacy of the underlying prescription. *See Holiday CVS, LLC*, 77 Fed. Reg. at 62341; *Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. at 73774-75; Op. Issued by Ct. at 14-17. This creates an "unfair surprise" for pharmacies, not only because the CSA's statutes contain identical language but are enforced disparately (*i.e.*, requiring each element of the statute to be proven including an expert determination of medical legitimacy), but also because the plain language of the regulation includes clear and explicit language instructing pharmacies that to violate their corresponding responsibility a prescription must have not been issued for a legitimate medical purpose. *See* 21 C.F.R. § 1306.04(a); *see also Ruan*, 597 U.S. ___

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[11] Alternatively, if as the DEA claims, it is interpreting "legitimate medical purpose" to include prescriptions that are filled where there are "red flags", this is still unfathomable because, as discussed, the Administrator draws his authority under the CSA from the Attorney General and therefore cannot have any greater authority than he does. *See Holiday CVS, LLC,* 77 Fed. Reg. at 62341; *see also Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order,* 85 Fed. Reg. at 73774-75.

(slip op. at 3) (affirming " . . . a prescription is "authorized" and therefore lawful if it satisfies this standard [issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice].").

For the foregoing reasons, *Auer* deference is inappropriate and § 1306.04(a) should be interpreted in a way that is consistent with Congress' intent in enacting the CSA, while also allowing adequate notice to pharmacists and pharmacies of when a violation of the regulation occurs. As such, the regulation should be interpreted as requiring a qualified professional with medical expertise to determine whether a prescription was issued for a legitimate medical purpose. The Acting DEA Administrator's decision finding Suntree Pharmacy violated § 1306.04(a), thereby revoking its registration, should therefore be reversed.

E. The DEA's Interpretation of § 1306.04(a) Is Not Entitled to *Auer* Deference Because It Is Not Supported by "Clear Congressional Authorization" in the CSA.

The Court's recent decision in *West Virginia v. EPA* reminds us that oftentimes an agency must point to "clear congressional authorization" for the authority it claims. No. 20-1530 (2022) (slip op. at 17-19). In "extraordinary cases", those in which "history and the breadth of the authority that [the agency] has asserted, and the economic and political significance of that assertion, provide a reason to hesitate before concluding that Congress meant to confer such authority", precedent advises that an agency must point to "clear congressional authorization" for the authority it claims. *Id.* at 17 (quotations and citation omitted). The DEA's

interpretation of § 1306.04(a) is clearly an "extraordinary case" given the Court's findings in *Gonzales*, 546 U.S. at 265-66.

There, the Court held the Attorney General exceeded the authority granted to him under the CSA when he tried to make medical judgments regarding assisted suicide. *Id*. at 262 (observing "the Attorney General claims extraordinary authority."). The Court found that Congress limited the Attorney General's authority to registering physicians to prescribe controlled substances and scheduling drugs, but that by making medical judgments, the Attorney General declared an entire class of activity (*i.e.*, assisted suicide) as outside the course of professional practice (*i.e.*, not medically legitimate), and therefore, a criminal violation of the CSA. *Id*. Moving forward, the *Gonzales* decision reinforced that the Attorney General did not have the "extraordinary authority" he claimed, and that he could not determine what classes of activity were criminal violations of the CSA.

In this case, the DEA tries to claim this "extraordinary authority" the Attorney General declared in *Gonzales*, 546 U.S. at 262, 265-66. That is, as discussed, the DEA's interpretation of § 1306.04(a) has allowed the DEA Administrator to declare an entire class of activity (*i.e.*, filling (*i.e.*, dispensing under § 841(a)) a prescription for a controlled substance with unresolved "red flags" whether or not the prescription was issued for a legitimate medical purpose) as outside the course of professional practice, and therefore, a criminal violation of the CSA.[12] *See Holiday CVS, LLC*, 77 Fed.

[12] As discussed, due process under the U.S. Constitution requires a qualified professional with medical expertise to determine whether a prescription was not issued for a legitimate medical

Reg. at 62341; *Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. at 73774-75; 21 U.S.C. § 841(a); *see also* H.R. Rep No. R45948, at 17. However, the DEA Administrator draws his authority under the CSA from the Attorney General. 21 U.S.C. § 871; *See Final Rule: Redelegation of Functions; Delegation of Authority to Drug Enforcement Administration Official*, 75 Fed. Reg. at 4982-83. The Administrator therefore cannot have any greater authority than the Attorney General does under the Act. The fact that the Administrator has nonetheless claimed such "extraordinary authority" represents an "extraordinary case" where the breadth of the authority the DEA has claimed should provide the Court reason to hesitate before concluding that Congress meant to confer the DEA with such authority. *West Virginia*, No. 20-1530 (slip op. at 17-19).

Given this is an "extraordinary case", the DEA must point to "clear congressional authorization" for the authority it claims under its interpretation of § 1306.04(a). *Id.* Nowhere in the CSA does it authorize the Attorney General or the DEA Administrator to determine what classes of activity qualify as criminal violations of the Act. *See* 21 U.S.C. § 801 et seq.; *Gonzales*, 546 U.S. at 262; *Federal Maritime Comm'n v. Seatrain Lines, Inc.*, 411 U.S. 726, 744 (1973). This lack of "clear congressional authorization" further

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purpose outside the course of professional practice to sustain a conviction under the CSA. *See Ruan*, 597 U.S. ___ (slip op. at 1-3) (citing 21 U.S.C. § 841(a)); *see In re Winship*, 397 U.S. at 364; *Christoffel,* 338 U.S. at 89.; *see also Gonzales*, 546 U.S. at 266 ("the structure of the CSA [] convey[s] [Congress'] unwillingness to cede medical judgments to an executive official [Attorney General] who lacks medical expertise.").

supports that the Acting DEA Administrator's interpretation of § 1306.04(a) is not entitled to *Auer* deference given an independent inquiry into the character and context of the DEA's interpretation does not entitle it to controlling weight. *Kisor*, 139 S. Ct. at 2415-16 (observing " . . . we give *Auer* deference because we presume, for a set of reasons relating to the comparative attributes of courts and agencies, that Congress would have wanted us to." (citation omitted)).

For the foregoing reasons, *Auer* deference is inappropriate and § 1306.04(a) should be interpreted in a way that is consistent with the authority Congress granted to the Attorney General—and by extension the DEA—under the CSA. Because this authority is limited to deregistering physicians and scheduling drugs—and not declaring an entire class of activity unlawful—a qualified professional with medical expertise must determine the underlying legitimacy of prescriptions a pharmacist or pharmacy filled under § 1306.04(a). Therefore, the then-Acting DEA Administrator's decision finding Suntree Pharmacy violated § 1306.04(a), thereby revoking its registration, should be reversed.

CONCLUSION

For the foregoing reasons, the revocation of Suntree Pharmacy's registration should be reversed, and the Court should grant Petitioner's writ of certiorari to settle the important issues discussed throughout.

Respectfully submitted,

RONALD W. CHAPMAN II
COUNSEL OF RECORD
CHAPMAN LAW GROUP
1441 W. LONG LAKE RD., STE. 310
TROY, MI 48098
(248) 644-6326
RWCHAPMAN@CHAPMANLAWGROUP.COM

MATTHEW J. PELCOWITZ
CHAPMAN LAW GROUP
701 WATERFORD WAY, STE. 340
MIAMI, FL 33126
(305) 712-7177
MPELCOWITZ@CHAPMANLAWGROUP.COM

COUNSEL FOR PETITIONERS

AUGUST 3, 2022

APPENDIX TABLE OF CONTENTS

OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT (FEBRUARY 14, 2022)

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

[DO NOT PUBLISH]

SUNTREE PHARMACY AND
SUNTREE MEDICAL EQUIPMENT, LLC,

Petitioners,

v.

DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

No. 20-14626

Petition for Review of a Decision of the
Drug Enforcement Administration
Administration No. 17-09 / 17-10

Before: NEWSOM, LUCK, and ANDERSON,
Circuit Judges.

PER CURIAM:

Suntree Pharmacy and Suntree Medical Equipment, LLC petition for review of the Acting Administrator of the Drug Enforcement Administration's

decision to revoke their registrations to dispense controlled substances and to deny their pending renewal applications. *See Suntree Pharmacy & Suntree Med. Equip., LLC*, 85 Fed. Reg. 73753 (Nov. 19, 2020). The Acting Administrator revoked and denied Suntree Pharmacy's and Suntree Medical's registrations and pending renewal applications after an administrative hearing revealed that Suntree Pharmacy had filled prescriptions for controlled substances outside of the usual course of practice and in violation of federal and state law.[1] Suntree argues that the Acting Administrator's revocation of its registrations was arbitrary and capricious and that the length of the administrative proceedings violated its procedural due process rights. We deny the petition for review.

FACTUAL BACKGROUND AND PROCEDURAL HISTORY

The Controlled Substances Act

We briefly summarize the relevant statutory framework before turning to the facts of this case. The Controlled Substances Act "creates 'a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except

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[1] Suntree Pharmacy and Suntree Medical consented to a consolidated hearing. The administrative law judge concluded that it was appropriate to treat Suntree Pharmacy and Suntree Medical "as one integrated enterprise" because of "the obvious commonality of ownership, management, and operations." The Acting Administrator agreed and concluded that Suntree Pharmacy and Suntree Medical "are essentially one and the same." Suntree Pharmacy and Suntree Medical do not challenge this part of the Acting Administrator's order on appeal. So we refer to them together as "Suntree."

in a manner authorized by the [Act].'" *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 827 (11th Cir. 2018) (quoting *Gonzales v. Raich*, 545 U.S. 1, 13 (2005)). The Act requires pharmacies that dispense prescriptions for controlled substances to obtain proper registration from the Attorney General. *Id.*

The Act places "the responsibility for the proper prescribing and dispensing of controlled substances, which must be for 'a legitimate medical purpose,' . . . on the prescribing practitioner, 'but a corresponding responsibility rests with the pharmacist who fills the prescription.'" *Id.* (quoting 21 C.F.R. § 1306.04(a)). Pharmacists therefore "have a 'corresponding responsibility' to refuse to fill prescriptions that are not issued for a legitimate medical purpose." *Id.*; *see United States v. Hayes*, 595 F.2d 258, 261 (5th Cir. 1979) ("The pharmacist is not required to have a 'corresponding responsibility' to practice medicine. What is required of him is the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute because he knows that the issuing practitioner issued it outside the scope of medical practice.").

The Attorney General has delegated his authority to deny, revoke, or suspend pharmacy registrations to the Drug Enforcement Administration. *Jones*, 881 F.3d at 827. The Administration may revoke an existing registration or deny an application for registration if the registration is or would be "inconsistent with the public interest." *Id.* at 829 (quoting 21 U.S.C. §§ 824 (a)(4), 823(f)). When the Administration proposes to revoke an existing registration, it must serve an "order to show cause" on the registrant and provide

the registrant an opportunity for a hearing before an administrative law judge in order to contest the proposed action. *Id.* at 827 (citing 21 U.S.C. § 824(c)). After the administrative law judge certifies the record to the Administrator, he or she must publish a final order with findings of fact and conclusions of law. *See* 21 C.F.R. §§ 1316.65, .67. The final order must be published "[a]s soon as practicable after the [administrative law judge] has certified the record to the Administrator." *Id.* § 1316.67.

Suntree and the Order to Show Cause

Suntree Pharmacy and Suntree Medical were registered retail pharmacies in Florida. On October 5, 2016, the Administration issued an order to show cause why Suntree's registrations shouldn't be rescinded and its pending renewal applications shouldn't be denied because Suntree's "continued registrations are inconsistent with the public interest." The Administration alleged that, from October 2013 to March 2015, Suntree filled more than two hundred controlled substances prescriptions "outside the usual course of pharmacy practice" and "in contravention of [its] 'corresponding responsibility.'" Specifically, the order to show cause alleged that Suntree violated its corresponding responsibility by: (1) filling prescriptions for patients without resolving red flags that the prescriptions were not for a legitimate medical purpose; (2) filling prescriptions for a doctor that he wrote for himself in violation of state law; and (3) filling prescriptions for "office use" in violation of federal law.

As to the prescriptions for patients, the order to show cause alleged that Suntree "repeatedly filled controlled substances prescriptions that contained

multiple red flags of diversion and/or abuse without addressing or resolving those red flags, and under circumstances indicating that [Suntree was] willfully blind or deliberately ignorant of the prescriptions' legitimacy." As to the prescriptions written by the doctor for himself, the order to show cause alleged that the prescriptions "were written in violation of Florida law . . . which prohibits a physician from 'prescribing, dispensing, or administering any' drug in Schedule II-VI 'by the physician to himself.'" And as to the prescriptions for "office use," the order to show cause alleged that Suntree "dispensed testosterone on at least fourteen different occasions pursuant to invalid prescriptions which indicated the ultimate user was an 'office,' in violation of 21 C.F.R. [section] 1306.04(b)."

The Administrative Law Judge's Decision

An administrative law judge held a hearing on the order to show cause in April 2017. At the hearing, the Administration presented the testimony of its expert witness, Dr. Tracey Gordon, Pharm.D., its diversion investigator, James Graumlich, an employee of Suntree Medical, Michael Peterson, and the owner of Suntree, Dr. Diahn Clark, Pharm.D. Suntree presented the testimony of its expert witness, Dr. Wayne Grant, Pharm.D., Suntree Pharmacy's regulatory attorney, Darren Meacham, and Dr. Clark.

On August 15, 2017, the administrative law judge issued his findings of fact and conclusions of law, recommending that the Acting Administrator revoke Suntree's registrations and deny its pending renewal applications. The administrative law judge credited Dr. Gordon's testimony that Suntree filled multiple prescriptions for controlled substances to twenty-two

patients that had one or more "red flags"—indicia that the prescriptions were not issued for a legitimate medical purpose—and should not have been filled without first investigating and resolving the red flags.

Dr. Gordon testified that the usual course of professional practice in Florida required a pharmacist to investigate and resolve red flags before dispensing a controlled substance. Dr. Gordon identified more than a dozen red flags that Suntree ignored in filling prescriptions, including: (1) patients traveling long distances some as far as 170 miles—to obtain prescriptions; (2) "groups" of patients traveling to the same physicians on the same days to obtain similar prescriptions which Suntree frequently filled at the same time; (3) patients making cash payments; (4) patients obtaining prescriptions for well-known, highly diverted and abused controlled substances; (5) patients obtaining prescriptions for the highest dosages; (6) patients obtaining repeated prescriptions for highly abused drug "cocktails"; (7) patients obtaining early refills of prescriptions; (8) patients obtaining prescriptions for two immediate release opioids that do the same thing; and (9) physicians prescribing outside the scope of their usual practice.

The administrative law judge credited Dr. Gordon's testimony and found that "[w]hen a red flag is resolved, it must be documented before the prescription is dispensed" and that "[i]f a red flag cannot be resolved, under the standard practice [of] a pharmacy in Florida, the medication should not be dispensed." The administrative law judge also credited Dr. Gordon's testimony and found that "nothing in the record resolves the red flags raised by prescriptions dispensed" by Suntree. The administrative law judge found that the "blatant"

unresolved red flags were "sufficient circumstantial evidence" to establish that the prescriptions were not written for a legitimate medical purpose. And the administrative law judge reasoned that, "while nothing in the [Administration's] regulations specifically requires a pharmacist to document the resolution of a red flag, Florida laws specifically require that a pharmacist maintain records that include discussions with licensed health care practitioners and information about a patient's drug therapy and information peculiar to a specific patient," and that, "[i]n light of these requirements, the absence of such documentation is circumstantial evidence that those requirements were not met." Based on these factual findings, the administrative law judge sustained the Administration's allegations that Suntree violated its corresponding responsibility in dispensing prescriptions written for patients because it "dispensed highly abused controlled substances to many of its customers without resolving numerous red flags raised by the prescriptions."

The administrative law judge also sustained the Administration's allegations that Suntree violated its corresponding responsibility by filling prescriptions that a prescribing physician wrote for himself because: (1) the prescribing physician violated Florida law by prescribing a controlled substance to himself; and (2) "filling such a prescription would not be in the usual course of the professional practice of a pharmacy." But the administrative law judge didn't sustain the Administration's allegation that Suntree violated its corresponding responsibility by filling prescriptions for "office use" because "these 'prescriptions' were issued to physicians" and the Administration didn't prove that

the physicians "were going to be dispensing the controlled substances to patients."

Having sustained the Administration's allegations that Suntree violated its corresponding responsibility by filling red-flagged prescriptions for patients and by filling prescriptions that the prescribing physician wrote for himself, the administrative law judge found that that the government had met its burden to establish a prima facie case that revocation of Suntree's registrations was in the public interest. The administrative law judge then addressed whether Suntree had put forward sufficient evidence to show that it could be trusted not to engage in future misconduct. The administrative law judge concluded that Suntree hadn't done so because it hadn't accepted responsibility for its violations. The administrative law judge therefore recommended the revocation of Suntree's registrations and the denial of its pending renewal applications.

The Acting Administrator's Final Order

In September 2017, Suntree filed exceptions to the administrative law judge's recommendation and the administrative law judge certified the record to the Acting Administrator. Three years later, the Acting Administrator issued an eighty-five-page final order concluding that there was substantial evidence that Suntree's continued registrations would be inconsistent with the public interest.

Relying on Dr. Gordon's testimony, the Acting Administrator determined that Suntree had a corresponding responsibility to resolve red flags before filling prescriptions for controlled substances. The Acting Administrator agreed with the administrative law judge and found that Suntree failed to exercise its

corresponding responsibility by filling hundreds of prescriptions for patients without resolving red flags.

The Acting Administrator did "not find it necessary to find" whether Suntree violated Florida law by failing to document the resolution of red flags because Dr. Gordon's "testimony [was] independently credible that documentation of the resolution of red flags [was] a requirement of the practice of pharmacy in the State of Florida." The Acting Administrator also agreed with the administrative law judge that Suntree violated its corresponding responsibility by filling prescriptions that a prescribing physician had written for himself because, even if the prescribing physician hadn't violated Florida law in writing the prescriptions, "the fact that there was even a question about whether the prescriptions violated Florida law presented . . . a red flag" that Suntree didn't resolve. And the Acting Administrator did "not consider the allegation related to the prescriptions issued for 'office use'" because the Administration had "not adequately established a legal basis for . . . finding . . . a violation."

Based on his findings, the Acting Administrator determined that "it would be inconsistent with the public interest to permit [Suntree] to maintain its registration[s]." And Suntree couldn't be entrusted with a registration, the Acting Administrator concluded, because it had neither accepted responsibility for its violations nor offered any remedial measures. The Acting Administrator therefore revoked Suntree's registrations and denied its pending renewal applications.

STANDARD OF REVIEW

We may set aside an agency's final decision if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." *Jones*, 881 F.3d at 829 (quoting 5 U.S.C. § 706(2)(A)). "The arbitrary and capricious standard is exceedingly deferential." *Id.* (citation omitted). We "may not substitute our judgment for that of the agency so long as its conclusions are rational and based on the evidence before it." *Id.* We may, however, "set aside a decision as 'arbitrary and capricious when, among other flaws, the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency.'" *Id.* (citation omitted).

The Acting Administrator's factual findings "are conclusive if supported by substantial evidence." *Id.* (citing 21 U.S.C. § 877). "Substantial evidence is less than a preponderance of the evidence, but rather such relevant evidence as a reasonable person would accept as adequate to support a conclusion." *Id.* The Acting Administrator's factual findings are supported by substantial evidence even if "two inconsistent conclusions [could be drawn] from the evidence." *Id.* (citation omitted).

DISCUSSION

Suntree contends that the Acting Administrator's final order must be set aside for two reasons. First, it argues that the Acting Administrator's decision was arbitrary and capricious because the government failed to prove that the red-flagged prescriptions were not issued for a legitimate medical purpose. Second, it

contends that the four years between the order to show cause and the final order, and the three years between the administrative law judge's certification of the record and the Acting Administrator's entry of the final order, violated its procedural due process rights. Neither argument has merit.

Revocation and Denial

Suntree does not challenge the Acting Administrator's factual finding that Suntree failed to resolve red flags raised by prescriptions for controlled substances before it dispensed them. It argues instead that the Acting Administrator erroneously determined that this failure amounted to a violation of Suntree's corresponding responsibility because there was "no evidence that the prescriptions in question lacked a legitimate medical purpose" and the illegitimacy of a prescription must be established before finding that Suntree was willfully blind to the prescription's validity. According to Suntree, "[t]he mere showing of dispensing prescriptions in the face of 'red flags'" is insufficient to demonstrate a violation of a pharmacist's corresponding responsibility because the corresponding responsibility is not "triggered" unless a prescription lacked a legitimate medical purpose.

Suntree's argument is based almost entirely on a footnote in the Acting Administrator's decision in *Hills Pharmacy, LLC*, 81 Fed. Reg. 49816 (July 28, 2016). That footnote reads,

> Respondent argues that the Government cannot establish that a pharmacist has violated his corresponding responsibility unless it first establishes that the prescription lacked a legitimate medical purpose and that the

issuing physician acted outside of the usual course of professional practice. It argues that "neither the fact of this corresponding responsibility nor the pharmacist's performance of his corresponding responsibility affects whether the prescription was, in the first place, issued to the patient for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." And it further argues that "the test for the proper dispensing of a controlled substances remains at its foundation a medical question" and that "the Government provided not one scintilla of evidence to prove that the prescriptions at issue were issued for other than a legitimate medical purpose."

Respondent is mistaken. While it is true that a pharmacist cannot violate his corresponding responsibility if a prescription was nonetheless issued for a legitimate medical purpose, Respondent ignores that the invalidity of a prescription can be proved by circumstantial evidence. I find that to be the case here. For similar reason, I reject Respondent's contention that the Government failed to meet its burden because Mr. Parrado is a pharmacist with "no medical training or experience that would have allowed him to evaluate the legitimacy of a physician's prescribing."

* * *

Here . . . the Government relied on the circumstantial evidence that the prescriptions lacked a legitimate medical purpose. Accordingly, I reject Respondent's contention that "the

> Government provided not one scintilla of evidence to prove that the prescriptions . . . were issued for other than a legitimate medical purpose."

Id. at 49836 n.33 (citations omitted and emphasis added).

Suntree repeatedly quotes the portion of the sentence in italics that "it is true that a pharmacist cannot violate his corresponding responsibility if a prescription was nonetheless issued for a legitimate medical purpose." But, like the respondent in *Hills Pharmacy*, Suntree ignores "that the validity of a prescription can be proved by circumstantial evidence."[2]

Contrary to Suntree's assertion, the Administration "has long interpreted [21 C.F.R. section 1306.04(a)] as prohibiting a pharmacist from filling a prescription for a controlled substance when he either 'knows *or has reason to know* that the prescription was not written for a legitimate medical purpose.'" *JM Pharmacy Grp., Inc., d/b/a Farmacia Nueva & Best Pharma Corp.*, 80 Fed. Reg. 28667, 28670 (May 19, 2015) (citation omitted and emphasis added); *see also Hayes*, 595 F.2d at 261 n.6 ("[A] pharmacist can know that prescriptions

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[2] This sentence from *Hills Pharmacy* was quoted in *Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy*, 83 Fed. Reg. 10876 (Mar. 13, 2018). As in *Hills Pharmacy*, the Acting Administrator in *Pharmacy Doctors Enterprises* rejected the respondent's argument "that the Government's case must fail because the [diversion investigator] did not meet with any prescriber or speak with any customer" to establish that the prescriptions were not issued for a legitimate medical purpose because "Agency precedent has made clear that [the respondent's] argument is mistaken." 83 Fed. Reg. at 10899 & n.36 (citing *Hills Pharmacy*, 81 Fed. Reg. at 49836 n.33).

are issued for no legitimate medical purpose without his needing to know anything about medical science."). When confronted with red flags, "a pharmacist may not intentionally close his eyes and thereby avoid positive knowledge of the real purpose of the prescription, and thereafter fill the prescription 'with impunity.'" *JM Pharmacy Grp.*, 80 Fed. Reg. at 28670 (citation omitted).

Here, the Acting Administrator found that circumstantial evidence—the "blatant" red flags identified by Dr. Gordon and ignored by Suntree—showed that the prescriptions were not issued for a legitimate medical purpose. And the Acting Administrator found that Suntree violated its corresponding responsibility by filling the prescriptions even though it knew—or was willfully blind to—the prescriptions' illegitimacy. The Acting Administrator's finding that Suntree violated its corresponding responsibility is supported by substantial evidence, and it is therefore conclusive. *See* 21 U.S.C. § 877; *Jones*, 881 F.3d at 830 (finding that "[t]he record supports the [Administration's] determination that [the pharmacy] unlawfully filled numerous controlled substance prescriptions that were not issued for a legitimate medical purpose" where "the evidence showed that [the pharmacy] . . . filled over one-hundred prescriptions that had at least one red flag that [the pharmacy] did not attempt to resolve and that could not have been resolved" and "[t]he government also put forward other substantial evidence indicating that the controlled substances dispensed by [the pharmacy] were being diverted for improper use").

Based on his finding that Suntree violated its corresponding responsibility by filling prescriptions for controlled substances without resolving obvious red

flags that the prescriptions lacked a legitimate medical purpose, the Acting Administrator's decision to revoke Suntree's registrations and to deny its pending renewal applications was not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[3] *See* 5 U.S.C. § 706(2)(A).

Administrative Delay

Suntree also argues that the four years between the order to show cause and the final order, and the three years between the administrative law judge's certification of the record and the Acting Administrator's entry of the final order, violated its procedural due process rights. But Suntree had the opportunity to object to the Administration's delay, *see, e.g.*, 5 U.S.C. § 706(1); 21 C.F.R. § 1316.67, and it didn't take it.

Despite having the opportunity, Suntree never raised the delay issue before petitioning for review of the Acting Administrator's decision. Because Suntree raises the delay issue for the first time here, the issue is waived. *See United States v. L.A. Trucker Truck Lines, Inc.*, 344 U.S. 33, 36–37 (1952) ("We have recognized in more than a few decisions, and Congress has recognized in more than a few statutes, that orderly procedure and good administration require that objections to the proceedings of an administrative agency be

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[3] Because we conclude that substantial evidence supported the Acting Administrator's finding that Suntree violated its corresponding responsibility by filling prescriptions for patients without first resolving red flags, we do not need to reach the issue of whether Suntree violated Florida law by dispensing prescriptions from a prescribing physician to himself or by failing to document the resolution of red flags.

made while it has opportunity for correction in order to raise issues reviewable by the courts." (footnotes omitted)); *Polypore Int'l, Inc. v. Fed. Trade Comm'n*, 686 F.3d 1208, 1219 n.13 (11th Cir. 2012) ("Polypore [didn't] raise[] this issue before the Commission . . . so the issue is waived."); *Nuclear Energy Inst., Inc. v. Env't Prot. Agency*, 373 F.3d 1251, 1297 (D.C. Cir. 2004) ("It is a hard and fast rule of administrative law, rooted in simple fairness, that issues not raised before an agency are waived and will not be considered by a court on review.").

PETITION DENIED.

DECISION AND ORDER OF THE UNITED STATES DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION (FILED NOVEMBER 9, 2020, EFFECTIVE DECEMBER 21, 2020)

FR DOC. 2020–25531

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Billing Code: 4410-09-P

Docket Nos. 17-09 and 17-10

Before: Timothy J. SHEA, Acting Administrator.

SUNTREE PHARMACY and SUNTREE MEDICAL EQUIPMENT, LLC DECISION AND ORDER

I. Procedural History

On October 5, 2016, a former Assistant Administrator for Diversion Control of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Suntree Pharmacy (hereinafter, Respondent Pharmacy) and Suntree Medical Equipment LLC (hereinafter, Respondent LLC) (hereinafter collectively, Respondents), of Melbourne, Florida. Administrative Law Judge (hereinafter, ALJ) Exhibit (hereinafter, ALJX) 1, (OSC) at 1. The OSC proposed the revocation of and denial of any pending application to modify or renew Respondents' Certificates of Registration Nos. BS7384174 and FS2194289 "pursuant to 21 U.S.C. §§ 823(f) and

824(a)(4) for the reason that [Respondents'] continued registrations are inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f)." *Id.*

Specifically, the OSC alleged that "over the course of the seventeen month period from October 2013 through March 2015, [Respondents'] pharmacists filled over 200 controlled substances prescriptions outside the usual course of pharmacy practice in violation of 21 C.F.R. § 1306.06, and in contravention of their 'corresponding responsibility' under 21 C.F.R. § 1306.04(a)." OSC, at 2. The OSC further alleged that Respondent Pharmacy's failure to exercise its corresponding responsibility was evidenced by its "repeatedly fill-[ing] controlled substance prescriptions that contained multiple red flags of diversion and/or abuse without addressing or resolving those red flags, and under circumstances indicating that the pharmacists were willfully blind or deliberately ignorant of the prescriptions' illegitimacy." *Id.* (citing *JM Pharmacy Group, Inc., d/b/a Farmacia Nueva and Best Pharma Corp.*, 80 Fed. Reg. 28,667, 28,670 (2015)). The OSC listed seven red flags of diversion that Respondent Pharmacy allegedly did not resolve prior to filling prescriptions and listed twenty-two[1] patients whose prescriptions indicated red flags. *Id.* at 4, 5-9. Furthermore, the OSC alleged that Respondent Pharmacy was dispensing controlled substances to a physician who wrote prescriptions to himself in violation of Florida law and violated federal law in dispensing controlled substances to an

[1] The OSC listed allegations related to three patients, R.A., A.B., and E.A., which the Government withdrew during the hearing "to save time." Tr. 689.

office. *Id.* at 4 (citing Fla. Stat. § 458.331(1)(r) and 21 C.F.R. § 1306.04(b)).

The OSC alleged additional violations of Florida state law including: Title XLVI, Fla. Stat., Ch. 893.04 (2)(a) (requiring a pharmacist filling a prescription to determine "in the exercise of her or his professional judgment, that the order is valid"); Fla. Bd. of Pharm. Rule 64B16-21.810(1) (requiring a pharmacist to review the patient record before filling a new or refilling a prescription for therapeutic appropriateness); Fla. Administrative Rule 64B16-27.800 (requiring the maintenance of retrievable records including "'[p]harmacist comments relevant to the individual's drug therapy'" and "'any related information indicated by a licensed health care practitioner.'"); *Id.* at 3.

The OSC notified Respondents of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 10-11 (citing 21 C.F.R. § 1301.43). The OSC also notified Respondents of the opportunity to submit a corrective action plan. *Id.* at 11 (citing 21 U.S.C. § 824(c)(2)(C)).

On November 8, 2016, Respondents filed an appearance and a Motion for Extension of Time to File a Request for a Hearing, which the Administrative Law Judge (hereinafter, ALJ) granted in part on November 29, 2016. ALJX 2 (Extension Request), ALJX 5 (Order Granting in Part Extension). Respondents filed a Request for Hearing on November 29, 2016. ALJX 6 (Request for Hearing). The matter was placed on the docket of the Office of Administrative Law Judges and assigned to ALJ Charles W. Dorman (hereinafter, the ALJ). On November 29, 2016, the ALJ established

a schedule for the filing of prehearing statements. ALJX 7 (Order for Prehearing Statements). The Government filed its Prehearing Statement on December 20, 2016, and Respondent filed its Prehearing Statement on January 26, 2017.[2] ALJX 8 (hereinafter, Govt Prehearing) and ALJX 12 (hereinafter, Resp Prehearing). On January 31, 2017, the ALJ issued his Prehearing Ruling that, among other things, ordered that the two matters of Respondent LLC and Respondent Pharmacy would be heard in a consolidated hearing, to which both parties consented, and set out six stipulations already agreed upon and established schedules for the filing of additional joint stipulations and supplemental prehearing statements, which were filed by both the Respondent and the Government on March 8 and 20, 2017, respectively. ALJX 14 (Prehearing Ruling), at 1-5; ALJX 17 (hereinafter, Resp Supp Prehearing); ALJX 16 (hereinafter, Govt Supp Prehearing). During the prehearing proceedings, the Government filed a Motion *In Limine*, requesting that certain portions of the Respondents' testimony and evidence be excluded at the hearing. *See* ALJX 21 (hereinafter, Govt Mot *In Limine*). In response to the Government's Motion and Respondents' response, the ALJ ruled that the proposed testimony of customer J.S.3 was irrelevant, because the issue is "legal, rather than factual, in nature."[3] ALJX 27, at 3 (Order Granting in part Govt Mot *In Limine*). The ALJ denied the

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[2] Respondent filed for an extension, which the ALJ granted in part over the Government's objections. ALJX 9-11.

[3] The ALJ also excluded the testimony of a pharmacy employee who was proposed by Respondent to testify about an audit report that had not been offered as evidence and another individual who

Government's request to exclude the testimony of several practitioners, the legitimacy of whose prescriptions was at issue in the case, but Respondents ultimately did not present testimony from these individuals. I have reviewed and agree with the procedural rulings of the ALJ with the exception of some of the bases for the findings in the Order Granting in part Govt Mot *In Limine* as explained *infra* Section III(A)(1)(c) and (d). The parties agreed to stipulations about the distances between patients and doctors and Respondent Pharmacy, the schedules and brand names of controlled substances, all of which are incorporated herein. RD, at 16-21.

The hearing in this matter spanned three days.[4] The Government filed its Proposed Findings of Fact, Conclusions of Law and Argument on June 19, 2017. ALJX 35 (hereinafter, Govt Posthearing). Respondent filed its Closing Argument, Proposed Findings of Fact, and Conclusions of Law on June 19, 2017. ALJX 36 (hereinafter, Resp Posthearing). The Recommended Rulings, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge (hereinafter, RD) is dated August 15, 2017. Both the Government and the Respondents filed exceptions to the RD on September 5, 2017 (hereinafter, Govt Exceptions) and September 1, 2017 (hereinafter, Resp Exceptions) (respectively). ALJ Transmittal Letter, at 1. On September 18, 2017, the ALJ transmitted his RD, along with the certified record, to me. *Id.*

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had provided a report that was not relevant to the proceedings. ALJX 27, at 4.

[4] Hearings were held in Daytona Beach, FL from April 24-26, 2017.

Having considered this matter in the entirety, I find that the record as a whole established by substantial evidence that Respondent Pharmacy committed acts that render its continued registration inconsistent with the public interest. Respondent Pharmacy filled hundreds of prescriptions without fulfilling its corresponding responsibility and acting outside of the usual course of professional practice in Florida, in violation of federal and state law. I conclude that revocation of Respondents' registrations and denial of any pending application to renew or modify Respondents' registrations are appropriate sanctions.

I issue this Decision and Order based on the entire record before me. 21 C.F.R. § 1301.43(e). I make the following findings of fact.

II. Findings of Fact

A. Respondents' DEA Registrations

Respondents are registered with the DEA as retail pharmacies in schedules II through V under DEA Certificate of Registration Nos. FS2194289 and BS7384174 at the registered addresses of 7640 North Wickham Road, Suites 116 and 117, Melbourne, FL 32940. Government Exhibit (hereinafter, GX) 1.

B. The Government's Case

The Government's documentary evidence consists primarily of prescriptions and profile information for twenty-five patients. The Government called four witnesses: an expert, Dr. Tracey Gordon (hereinafter, Dr. Gordon), a DEA Diversion Investigator (hereinafter, the DI), an employee at Respondent LLC (hereinafter, M.P.), and Dr. Diahn Clark, Respondents' Owner and

Pharmacist in Charge (PIC) (hereinafter, Respondents' Owner and PIC), whose testimony is summarized under the Respondents' Case section.

1. Dr. Gordon

Dr. Gordon has a bachelor's degree and a doctorate in pharmacy and is currently employed as a clinical hospice pharmacist. RD, at 7; Transcript (hereinafter, Tr.) at 22; GX 26 (Dr. Gordon's resume). She holds a Florida pharmacy license and Florida consultant license and she also has twelve years of experience as a retail pharmacist, but she has not practiced as a retail pharmacist in a few years. Tr. 24. As a consultant pharmacist, Dr. Gordon inspects facilities like nursing homes and hospices to make sure that they are following Florida laws. *Id*. at 30. She is familiar with federal and Florida laws regarding dispensing controlled substances and was accepted as "an expert who is familiar with the practice of pharmacy in the State of Florida." RD, at 7; Tr. 26, 31-32. The matters to which Dr. Gordon testified included a pharmacist's corresponding responsibility in the State of Florida including the resolution of prescriptions presenting red flags, what constitutes a red flag, and her review and analysis of the prescriptions presented by the Government. Tr. 21-311. She reviewed a series of prescriptions, the Florida Prescription Drug Monitoring Program (hereinafter, E-FORCSE), documents, letters of medical necessity, medical records, computer printouts given to her by DEA from both the Agency and the Respondent "to determine if [Respondents were] exercising their corresponding responsibility by practicing within the normal scope of pharmacy practice." Tr. at 46-47. The ALJ found, and I agree, that Dr. Gordon's testimony was "sufficiently objective, detailed,

plausible, and internally consistent to be considered credible in this recommended decision."[5] RD, at 7.

2. The DI

The Government also presented the testimony of a DI who participated in the administrative investigation of the Respondents. Tr. 312-92. He testified to his training as a DEA DI and his experience in investigating over 100 pharmacies. He testified that Respondent Pharmacy was identified as "an extremely high purchaser of oxycodone, hydromorphone and methadone." *Id.* at 316-17. He further testified as to the events that transpired pursuant to the two administrative inspections of Respondent Pharmacy. *Id.* at 318-19. The DI testified that DEA investigators traveled to Respondent Pharmacy to conduct an administrative inspection on September 13, 2013, during which time M.P. signed a DEA Form 82, Notice of Inspection, in which M.P. consented to the inspection of the premises. Tr. 317; GX 32 (DEA Form 82). The DI testified that, based on the report issued by the DEA inspectors at the time, Respondents' Owner and PIC arrived at the pharmacy approximately ninety minutes afterwards. Tr. 318. During that inspection, the DI testified that the DEA inspectors expressed their intent to remove prescriptions from the pharmacy to make photocopies, but Respondents' Owner and PIC told them that she would provide them with copies later, which M.P. delivered to DEA on September 23, 2013. Tr. 318, 323; GX 33 (DEA Form 12 signed by M.P. confirming

[5] Respondents argue that Dr. Gordon's testimony was inconsistent and should not be afforded weight. As explained herein, I reject Respondents arguments regarding Dr. Gordon and I agree with the ALJ's credibility assessment. Resp Posthearing, at 53-58.

delivery). The DI also testified that he served Respondents' attorney D.M. with a subpoena in February of 2015 to obtain approximately a year and a half of prescriptions, but D.M. "questioned the validity of our ability to even issue a subpoena for records to him and stated, as far as he knew, there was no penalty for non-compliance, so he had privacy concerns, and he ended up not giving us the records." Tr. 324-27. Thereafter, in April of 2015, DEA obtained and executed an Administrative Inspection Warrant, during which DEA investigators copied portions of Respondent Pharmacy's database that it used when filling prescriptions and provided Respondent Pharmacy with an exact copy. *Id.* at 323, 326-32; RD, at 8. The DEA investigators also removed, copied and returned paper medical records for patients. Tr. at 332-33. The DI additionally testified to his research into the ownership of Respondents and his observations of the Respondents' location and business interactions. *Id.* at 323-60. The ALJ found, and I agree, that the DI's testimony was "sufficiently objective, detailed, plausible, and internally consistent. Therefore, I merit it as credible. . . . " RD, at 8.

C. Respondents' Case

1. Respondents' Owner and PIC

Respondents' Owner and PIC testified on behalf of Respondents. Tr. 529-767; 854-58. She testified that she held a degree in pharmacy and practiced until she went to law school, after which she practiced mostly in intellectual property law until she assumed sole ownership of the Respondents in or around 2009 or 2010. Tr. 530. She testified to her duties at the pharmacy, including supervising several part-time pharmacists who fill in while she is "doing other

duties as the owner." *Id.* at 533. She testified generally as to the policies and procedures of Respondent Pharmacy when she took over.

> At that time, the only statute we identified initially was legitimate medical necessity. So my interpretation of that was to derive that from the physicians. So we created a policy where the patient would have to have a Brevard County license, a general policy. Of course, exceptions allowed, but the general policy was a Brevard County patient. If they saw a physician in an adjacent county, they would be required to obtain for me, directed to me individually at the pharmacy, not a group of medical records but a letter to me describing the legitimate medical necessity or the diagnosis that I could then glean the medical necessity from.

Id. at 536.

Respondents' Owner and PIC additionally testified that Respondent Pharmacy had "broad policies that [Respondent Pharmacy's pharmacists] better have a good reason for not following or be subject to counseling. But outside of those broad policies that are stated there or that were developed over time, they had their independent judgment. . . . " *Id.* at 676-77. Respondents' Owner and PIC testified that Respondent Pharmacy has a "policy and procedure handbook that employees do receive"; however, Respondents did not produce the handbook in their defense.[6] *Id.* at 710-11.

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[6] This Agency has applied, and I apply here, the "adverse inference rule." As the D.C. Circuit explained, "Simply stated, the rule provides that when a party has relevant evidence within his control

She also stated that the policy is "updated regularly, but it's generally just a day-to-day hands-on training. I'm there all the time." Tr. 709. Respondents particularly focused on the employment of one of their employee B.S., whom Respondents' Owner and PIC had hired as a part-time pharmacist in spite of knowing that "he had been suspended by the Board of Pharmacy for a period of time" and he had a prior criminal conviction, and whom she later fired. *Id*. at 553; RX G (employment file for B.S.).

Respondents' Owner and PIC also testified as to her involvement with the resolution of red flags for her patients. As to the red flag regarding the distance her customers traveled, she testified that her wholesaler would allocate a certain amount of controlled substances to pharmacies and that "is why people drive farther than they normally would." Tr. 766. She testified that she would look at the letters of medical necessity to help resolve the red flags regarding the distance traveled to obtain prescriptions, Tr. 701, "that would be one thing we would look at, in addition to a conversation with the patient." Tr. 706.

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which he fails to produce, that failure gives rise to an inference that the evidence is unfavorable to him." *Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am. (UAW) v. Nat'l Labor Relations Bd.*, 459 F.2d 1329, 1336 (D.C. Cir. 1972). The Court reiterated this rule in *Huthnance v. District of Columbia*, 722 F.3d 371, 378 (D.C. Cir. 2013). According to this legal principle, Respondents' decision not to provide evidence within their control gives rise to an inference that any such evidence is unfavorable to Respondents. Therefore, I give little weight to instances where Respondents' Owner and PIC testified that she relied solely on her policies to ensure that red flags were resolved, such as that cash is not a red flag, "because he would have been asked if he had insurance." Tr. 719

The ALJ found, and I agree, Respondents' Owner and PIC's "testimony to be generally objective, detailed, and with some exceptions it was plausible, and internally consistent. Certain aspects of [Respondents' Owner and PIC's] testimony, however, detracted from her overall credibility. Those aspects included unnecessary contentiousness, exaggeration, and a lack of familiarity with the Pharmacy's records." RD, at 13. Specifically, the ALJ noted that she exaggerated her relationships with her customers, stating that she always had conversations with D.B. even though she had only filled prescriptions for him three times and similar exaggerations related to M.B., K.B.2, K.B.3 and A.G. He further noted that her testimony contained inconsistencies, such as that she stated the pharmacy had not filled any prescriptions after April 30, 2014, but the records showed that it had, and she stated that D.B.'s dosage had decreased when it had not. RD, at 14. The ALJ concluded, and I agree, that "to the extent, her testimony conflicts with other testimony, or exhibits, [] I find that the exhibits and the other testimony merit greater weight." RD, at 15.

2. Dr. Grant

Respondents presented testimony of an expert, Dr. Wayne Grant, who has been a pharmacist since 1990 and has a bachelor's degree and Doctorate in pharmacy. Tr. 425-527. Dr. Grant works in a "hospice and palliative care organization," where he has been employed for twelve years. *Id.* at 427. He also testified that he teaches a course online as an adjunct faculty at the University of Florida.[7] Tr. 428. Dr. Grant also

[7] The ALJ found, and I agree that Dr. Grant's faculty status at the University of Florida is not clear from his testimony. RD, at 10.

worked in an "in-house, closed pharmacy" for about fifteen years and a retail pharmacy for about five years. Tr. 431-32. Dr. Grant is licensed as a pharmacist in Ohio, and he has never worked in or been licensed as a pharmacist in Florida, although he has reviewed "mostly for comparative reasons," but not taken, some of the continuing education courses in Florida. Tr. 433, 437; RD, at 11. The Government objected to accepting Dr. Grant as an expert witness, because he lacked experience in the standard of practice in the state of Florida, but the ALJ accepted Dr. Grant as "an expert in the field of pharmacy." Tr. 237; 442.

The ALJ found, and I agree, that although generally Dr. Grant "appeared to be an honest and candid witness," his testimony merited "little weight" based on six reasons. RD, at 11. First, the ALJ reasoned that Dr. Grant was "deceptive even when answering questions about his qualifications." *Id.* Dr. Grant touted the benefits of working for the University of Florida as including continuing education, stating, "I get a lot of continuing education," but when asked whether he had taken Florida continuing education, he stated that he "had reviewed a number of those," but "mostly for comparative reasons." Tr. 433; RD, at 11. The ALJ further noted that "while professing to be an adjunct faculty member at the University of Florida, it turns out [Dr. Grant] does not teach, but only occasionally lectures." RD, at 11 (citing Tr. 428, 516-17). Second, the ALJ noted that Dr. Grant's testimony that he did not know if he had been qualified in Florida was not credible, because when the ALJ asked

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Although he testified that he was an adjunct professor, he later testified that he only lectures in Florida once a year, for an "hour, hour and a half." Tr. 517-18.

him if he had ever testified in Florida, he stated that he had not. *Id.* (citing Tr. 438). Third, in describing "corresponding duty," Dr. Grant stated, "It looks at a standard in which pharmacy practice is when we're reviewing prescriptions that come into our care." Tr. 445. I agree with the ALJ's finding that Dr. Grant's "'expert' explanation of the phrase 'corresponding duty' is almost incomprehensible." RD, at 11. Fourth, Dr. Grant initially testified that he had reviewed the prescriptions at issue in the case and there did not seem to be any prescriptions on their face that appeared to be a violation of corresponding responsibility such that there needed to be "a conversation with the patient and the prescriber," but then, on cross examination, admitted in several instances that there should have been follow up. Tr. 445, 478-79, 508-11; RD, at 12. Fifth, the ALJ took issue with Dr. Grant's testimony that the term "cocktail" was not "a common term used in pharmacology." When asked if he knew what a cocktail was, Dr. Grant said "I'm familiar with what I think that terminology is" and then later answered the same question, "Other than a drink, I'm not really sure." Tr. 455-56. Then, Dr. Grant contradicted himself by explaining what a cocktail was, stating "[i]n more nefarious [sic] perhaps, they're looking at trying to lump benzos and opioids and a whole host of skeletal muscle relaxers in there too. But we don't teach about cocktails. We don't make cocktails." *Id.* at 456. I agree with the ALJ that not only was his testimony contradictory, but also, DEA "has long discussed drug cocktails." RD, at 12. Contrary to his own statements, that he had not heard of "drug cocktails" or that the term was not used in pharmacology, he later described them accurately and the federal agency that regulates controlled substance registrations uses

the term regularly. Finally, the ALJ noted that Dr. Grant "even seemed unwilling to use the term red flag." RD, at 12. Dr. Grant testified that he was "familiar with the concept," but that he does not "teach anything about red flags" and that he had not heard the term in relation to opioids until about two or three years ago. Tr. 449, 518. The ALJ noted that Respondents' Owner and PIC had "no trouble using the term and understanding its meaning," and that DEA has used the term for many years. RD, at 12 (citing Tr. 587, 597-98, 610-11, 617-18, 642, 650, 671-72, 676, 681, 688, 701, 727, 730).

Based on the issues with the merits and credibility of Dr. Grant's testimony, the ALJ found, and I agree, that "where there is conflict between the testimony of Dr. Grant and the testimony of Dr. Gordon, I find that Dr. Gordon's testimony is more credible and is entitled to greater weight." RD, at 13. As such, I rely on Dr. Gordon's testimony to accurately describe a pharmacist's corresponding responsibility and the usual course of professional practice in the State of Florida.

3. D.M.

D.M. is an attorney who initially was representing Respondents, but who withdrew and became a fact witness prior to the start of the hearing. ALJX 28 (Motion to Withdraw); Tr. 799. He testified that he was retained by Respondent Pharmacy around 2008 to give advice on "compliance and keeping up with what the rules are, regulations, and policies and procedures." *Id.* at 801. As part of his advice, he stated that he researched and communicated red flags. *Id.* at

804-06. D.M. testified that he gave advice[8] to Respondent Pharmacy in 2008 that it was generally legal for a doctor to self-prescribe,[9] but that following the Florida Board of Pharmacy's statement to Respondent Pharmacy that it "wasn't allowed," he still thought it was legal, but recommended that Respondent Pharmacy "should not do that anymore." *Id*. at 809-10. He further testified regarding policies that he helped Respondent Pharmacy write in 2008 to not "fill for an out of county, out of the area customer" or "out of the county doctor" unless it was an established patient in which case they would "look at other factors." *Id*. at 807. D.M. also testified that in 2012 or 2013, he helped to write policies for schedule II controlled substances on letters of medical necessity. *Id*. at 821. However, D.M. also testified that he does not ensure or check compliance with the policies that he wrote. *Id*. at 825.

The ALJ found, and I agree that "D.M.'s testimony is consistent with other testimony of record. He testified in a candid and forthright manner and he was a credible witness." RD, at 15.

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[8] Although D.M. and Respondents' Owner and PIC claim this advice was given via email, neither could produce the emails. Tr. 829-30.

[9] D.M. later clarified that the question in 2008 was not specific to controlled substances, but all prescription drugs. Tr. 823. He addressed controlled substances in his advice in 2015 after the Board of Pharmacy had told Respondent Pharmacy that the prescriptions could not be filled. *Id.* at 827.

D. Corresponding Responsibility and Course of Professional Practice in Florida

Dr. Gordon credibly testified that before filling a prescription "a pharmacist should assure that the medication is safe and exercise their corresponding responsibility to make sure the medication is for a legitimate medical purpose, to look at things like drug interactions, appropriateness of dose, what doctor is writing the prescription, how far the patients traveled,[10] is it appropriate, is it safe for themselves and the community." Tr. 33. She further testified that in exercising a pharmacist's corresponding responsibility, "there's not just one or two red flags you specifically look for." *Id.* at 34. She testified that such red flags include, "the type of medication," whether the dose is appropriate, combinations of controlled substances, whether the patient is in the local community, what type of doctor is prescribing, the distance from the doctor and the pharmacy.[11] *Id.* at 34-37. Dr. Gordon

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[10] Dr. Gordon testified that she had searched for local pain management doctors and Respondents' Owner and PIC testified that there were not enough local practitioners in the area. Tr. 568. I agree with the ALJ, who determined that neither party submitted adequate support for their testimony and therefore gave the testimony of each little weight. RD, at 24 n.10.

[11] Respondents argued that Dr. Gordon was inconsistent regarding whether the red flag of distance was resolvable. Resp Posthearing, at 53 (citing Tr. 36, 110—however, the quoted material is on page 111). I disagree that this testimony was inconsistent. Dr. Gordon testified that in "this particular scenario" of the group of Dr. R.'s patients coming in together with prescriptions written on the same day and travelling a far distance, one after another in this case, the red flags were not resolvable. Tr. 111. She stated that there is room to clear red flags and gave an extreme example of all of the patients getting into the same car wreck and needing a short supply of something being a

further testified about short-acting and immediate release medication, and specifically stated that "it does not make pharmacological sense to prescribe two short-acting opioids," for example hydromorphone and oxycodone, "because they are doing the same thing," and therefore such prescriptions are red flags. *Id.* at 36-39.[12] Additionally, Dr. Gordon testified that pattern prescribing by a doctor who prescribes the same dosage and medication to all of his patients is a red flag, and there is also a red flag when those prescriptions are filled sequentially, one after the other. *Id.* at 39. Further, she testified that another red flag is a prescription cocktail, which she described as "the issuance of two or more prescriptions that do the same thing or enhance the effects of the other." *Id*. She gave examples of prescription cocktails, such as "Soma, a benzodiazepine, like Ativan or Xanax, and an oxycodone or hydromorphone," but that more recently she sees "just a Benzo with a opioid," such as "Alprazolam or Xanax or Lorazepam or Ativan, plus hydromorphone or oxycodone, or both." *Id.* at 40. Dr. Gordon testified that other red flags were when patients appeared to

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possible reason that a pharmacist could still fill the prescription, but she clearly testified that the scenario presented by Dr. R.'s patients coming in together did not present any facts that could have resolved the red flags. *Id.* Furthermore, these prescriptions contained multiple red flags, not solely the red flag regarding distance.

[12] Respondents argued that Dr. Gordon testified that it was a red flag to prescribe two short acting opioids and also to prescribe a long and a short acting opioid. Resp Posthearing, at 54 (citing Tr. 38, 83). I disagree with their characterization of Dr. Gordon's testimony. Regarding the long and the short acting opioids, she testified that "it's a red flag to see the dosage has changed or there is a different drug." Tr. 84.

come from the same household and received similar medications, when patients are going to multiple doctors or pharmacies, and that prescriptions purchased with cash[13] were a "big red flag." *Id.* at 41-42. She stated that pharmacists can detect doctor shopping through "E-FORCSE," which is a "computer program set up by the State of Florida that a pharmacy is supposed to report all of their controlled substances: the quantity, the medication, the doctor, and the pharmacy where it was filled, for every patron" and which started around 2010. *Id.* at 43.

Dr. Gordon testified that a pharmacist can resolve these red flags "by either talking to the patient and/or speaking to the physician" and in some cases "you may need to do both." She further clearly testified that the resolution of the red flag "must be documented[14] before you dispense the medication so that

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[13] Respondents stated that Dr. Gordon was inconsistent on whether cash was a red flag, but I find that she credibly testified that "[i]t's the combination of the red flags, the cash and the opioid, not just the point that they're paying cash." Tr. 295; Resp Posthearing, at 55. I agree with this statement and the ALJ's finding that cash is a red flag in combination with the other red flags. RD, at 31 n.13.

[14] Respondents suggested that Dr. Gordon "did not testify that the resolution of every red flag must be documented," but that "she testified that a pharmacist is required to 'document if you need more information to clear a red flag.'" Resp Posthearing, at 4 (citing Tr. 206). Respondents took Dr. Gordon's quote out of context. During the hearing, Respondents' counsel clarified the statement that he quoted in his brief, stating, "Okay. So document the resolution of red flags?" to which Dr. Gordon responded, "Yes. To show that—for each red flag, if there was a specific situation where you felt that the medication was for a legitimate medical purpose, that should be documented." Tr. 206. I find that Dr. Gordon was very clear that the standard of practice and usual

you can let other pharmacists know what happened the time before" and that documentation must be "either on the prescription itself or in the computer system."[15] *Id.* at 44-45. When pressed by Respondents' counsel regarding whether a pharmacy was required by statute to document the resolution of the red flag, Dr. Gordon stated that "it's not an opinion. It's the standard of practice" and further clarified "[t]he standard of practice, if there's something questionable about a prescription, you document it after you speak with the patient or the doctor." *Id.* at 215. Finally, Dr. Gordon testified that if it is impossible to resolve a red flag, such as a prescription written by a physician to himself or to a business or office, the standard of practice of pharmacy in Florida would require a pharmacist to "not dispense the medication." *Id.* at 46.

Regarding red flags, Dr. Grant stated, "the only place that I've really seen this again is with the continuing education, which I have not completed, in

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course of professional practice in Florida required a pharmacist to document the resolution of every red flag before dispensing.

[15] Respondents argued that Dr. Gordon would require a pharmacist with multiple red flags "to write paragraphs of data regarding why the patient travelled to the next county, had back pain, was seeking a 'highly abused medication,' and had insurance but was not using it to fill the medication." Resp Posthearing, at 58. There is no evidence or testimony in this case that what Dr. Gordon was proposing to be documented would be "paragraphs of data." I reject this characterization of Dr. Gordon's testimony. Respondents are trying to absolve themselves of responsibility to take any notes on their resolution of red flags by exaggerating the burden. The fact is that there was rarely any documentation as to the red flags in this case other than letters of medical necessity, so there is nothing on which to testify to or assess Respondent Pharmacy's level of detail in resolving them.

regards to Florida, where they list in—this group lists and they put red flags, and they list a whole bunch of things down there as being red flags. And they suggest pharmacists should be looking at that. But it's their process. It's nothing I'm familiar with teaching." Tr. 450. As explained above, I credit Dr. Gordon's testimony over Dr. Grant's.

Respondents' Owner and PIC testified that she was aware that when a pharmacist spots a red flag for a prescription, that she must "resolve it, and if [she] cannot resolve it, not to fill it." Tr. 566; RD, at 24. She testified that she trained her pharmacists to identify and resolve red flags. RD, at 24; Tr. 556-57. She also testified that she understands the concept of red flags and that she recognized that there are red flags in Respondent Pharmacy's prescriptions. Tr. 796. Respondents' Owner and PIC stated that, "I don't believe we did as well with documentation. I do believe we did resolve red flags. Even then, I think we could have done better at it." *Id.* at 796. Finally, she stated that she received the letters of medical necessity, because she "knew that was an absolute requirement. That's a statutory requirement. The others seemed to gradually evolve. And in my opinion, it was continued professional practice. So documentation of them was innate in my job even prior to the pain epidemic or the requirement of red flags." *Id.* at 797.

I agree with the ALJ that Dr. Gordon's testimony should be given the most weight on a pharmacy's corresponding responsibility and the ordinary course of professional practice in Florida to resolve red flags and document the resolution on the prescription or in the patient record. RD, at 13.

E. Allegation that Respondent Pharmacy Filled Prescriptions written by a Practitioner to Himself in Violation of Florida Law

The OSC alleged that Respondent Pharmacy dispensed controlled substances to a physician that were prescribed to himself in violation of Florida Statute Section 458.331(1)(r). The relevant Florida law states that it is grounds for disciplinary action or denial of a license to "dispens[e] . . . any medicinal drug appearing on any schedule set forth in chapter 893 by the physician to himself or herself, except one prescribed, dispensed or administered to the physician by another practitioner. . . . " Fla. Stat. § 458.331(1)(r).

1. Patient J.S.3

The Government alleged that between March 2014 and December 2014, Respondent Pharmacy violated its corresponding responsibility and Florida law when it dispensed six prescriptions for controlled substances to a doctor, J.S.3, who was prescribing controlled substances to himself in violation of Florida law. OSC, at 4; RD, at 27. It further alleged violations of Respondent Pharmacy's corresponding responsibility for filling twelve additional prescriptions written by J.S.3 to himself from June 2012 to June 2013. Govt Prehearing, at 8. The Government's evidence demonstrates that Respondent Pharmacy filled prescriptions written by J.S.3 to himself for various controlled substances to include: Percocet, Ambien and testosterone. GX 2, at 1-34.

Dr. Gordon testified that the prescription to J.S.3 for Ambien filled on June 12, 2012, contained a red

flag[16] because "the name of the patient is the same as the name of the physician" and that "it's against the law for a physician to write a controlled substance for himself." Tr. 49-50; GX 2, at 1, 2. She additionally testified that a prescription for oxycodone/Tylenol with the brand name Percocet filled on July 13, 2012, and all of the other prescriptions filled by Respondent Pharmacy for J.S.3 presented red flags and were in

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[16] Respondents' counsel objected to Dr. Gordon's testimony that the J.S.3 prescriptions were unresolved red flags, stating that "the Government represented that the issue with J.S.3's prescriptions was only an issue as a matter of law, that a pharmacist cannot fill a physician's prescription as a matter of law." Tr. 60. The OSC clearly stated that the J.S.3 prescriptions raised red flags, but Respondents' counsel alleged that there was discussion of this issue in pretrial conferences related to Respondents' request to provide testimony of J.S.3. *Id.* at 61. This issue became confused when Respondent proposed the testimony of J.S.3, which the ALJ excluded on the basis that "the ultimate issue with regard[] to this allegation is legal, rather than factual, in nature." ALJX 27 (Order Granting In Part the Government's Motion *In Limine*), at 3. The Government's attorney at the hearing stated that "the red flag seems to be a matter of law, and I'm simply asking the expert whether there's any indication whether the pharmacist was able to justify in its mind the dispensing of these prescriptions." Tr. 61. The ALJ sustained the Respondents' objection; however, he overruled the objection related to Dr. Gordon's opinion regarding whether filling the prescriptions was within the standard of practice. *Id.* Despite this argument at the hearing, I find that Dr. Gordon appropriately testified that the physician's prescription to himself was a red flag. I do not find that the ALJ erred in excluding the testimony of J.S.3 as irrelevant. The testimony of J.S.3 as described by the Respondent could not have added any additional facts that would alter the finding herein. However, I disagree that the issue here was solely about whether these prescriptions violated Florida law, as explained further herein. I further discuss this issue in Section III(A)(1)(c).

violation of Florida law for the same reason.[17] Tr. 51-61; GX 2, at 1-34. Dr. Gordon testified that the fact that "the patient is the physician" is a red flag and that the red flags were unresolved. Tr. 59-60. In response to the Government's question regarding whether a pharmacist applying "the minimal acceptable standard of practice of pharmacy" in Florida should have filled these prescriptions, Dr. Gordon stated that "[a] pharmacist should not have filled any prescription written by a physician that wrote it for himself, a controlled substance." *Id.* at 62.

Respondents' Owner and PIC testified that she had sought advice from her attorney, D.M. about whether it was lawful for a doctor to self-prescribe and D.M. had told her it was lawful in an email.[18] Tr. 571, 777, 809; RD, at 28. She further testified that she had received this advice "early on in my ownership of the business," which "might even have been prior to my ownership of the business. 2008, 2009." *Id.* at 777. She stated that she did not revisit his advice after that time and that she "probably should have, but [she] did not." *Id.* D.M. testified that he researched and gave advice to Respondents' Owner and PIC "in 2008, generally" regarding "could a doctor self-prescribe." Tr. 809. D.M. concluded that it was permissible and

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[17] Dr. Gordon also identified other red flags with these prescriptions, such as that the prescriptions lacked a DEA number, the prescriptions were paid for by cash, the physician called in the prescription with no hard copy in violation of Florida law; however, these red flags were not identified in the OSC or the Government's Prehearing statements, so I am not basing my decision on these red flags. Tr. 52-59.

[18] The Respondent did not submit the email as evidence.

when asked what advice he communicated to Respondent Pharmacy, he stated, "At that point in time, we were not using the words red flag. The word was scrutiny. And that it should pass the sniff test, but it wasn't prohibited and it was permissible but required scrutiny." *Id.* at 810. Respondents' Owner and PIC testified that the Board of Pharmacy visited in 2015[19] and told Respondents' Owner and PIC that "it was not lawful" to fill a prescription that a doctor had written for himself, after which D.M. confirmed his original legal advice, but recommended that Respondent Pharmacy stop filling these prescriptions, and Res-

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[19] It is noted that Respondents' version of the Patient profile for J.S.3 included in the E.O.M. or "end of month" statement a typed note that stated "cannot write personal scripts. DC" and the date the record was printed is covered by a photocopied sticky note. RX H, at 1; Tr. 698. The Government noted that the copy in the Government's evidence that was seized on April 7, 2015, and contains a print date of "April 7, 2015" does not include the same language in the E.O.M. statement. Tr. 699; GX 2, at 35. Nevertheless, Respondents' PIC and Owner stated that she made that sticky note in January of 2015 and offered no explanation for why the Government's evidence did not include the typed note in the database. Tr. 699-700. Respondents argued in their Posthearing Brief that there were no prescriptions filled for J.S.3 after January 14, 2015. Resp Posthearing, at 9 n.1. This argument does not explain why the documents in the Government's possession that were printed three months after the last prescription to J.S.3 did not contain the same typed E.O.M. note. The ALJ found, and I agree, that Respondents' PIC and Owner did not testify credibly that the document in RX H was the same record that was available to the Government on the date of seizure in April 7, 2015, because the sticky note obscures the date that the document was printed. RD, at 28 n.11. This appears to me to be a falsification of records and further undermines my ability to trust Respondents' Owner and PIC.

pondent Pharmacy did not fill any further prescriptions. Tr. 573, 763, 777, 809. The last prescription filled for J.S.3 was on January 14, 2015. GX 2, at 33-34; Tr. 762; RX H, at 2-3; RD, at 28.

Based on the evidence in the record, I find that from 2012-2015, Respondent filled numerous prescriptions from prescriber J.S.3 to himself without resolving the red flag that he was self-prescribing in violation of state law. *See infra* Section III(A)(1)(c).

F. Allegation that Respondent Pharmacy Filled Prescriptions Written for "Office Use" in violation of 21 C.F.R. § 1306.04(b)

The OSC alleged that Respondent "dispensed testosterone on at least fourteen different occasions pursuant to invalid prescriptions which indicated that the ultimate user was an 'office' in violation of 21 C.F.R. § 1306.04(b)." OSC, at 4. The Government submitted evidence of prescriptions and fill stickers, which demonstrated that between September 23, 2014, and January 28, 2015, Respondent Pharmacy filled prescriptions for office use to Dr. I's office on 8 occasions and to Dr. A's office once. GX 3; RD, at 29.[20] The Government's expert witness Dr. Gordon testified that "written for office use" means that "the pharmacy filled prescriptions for controlled substances not for an individual but for a facility." Tr. 64. She testified that the prescriptions "for office use" were not purchases

[20] Respondents' Owner and PIC and the RD mentioned thirteen prescriptions to Dr. I's office, but the Government's evidence appeared to contain only eight and one to Dr. A's office and sixteen fill stickers. GX 3; Tr. 577; RD, at 29. The prescription for Dr. A. was filled by the Respondent Pharmacy to [A's] Office on the fill sticker. GX 3, at 4.

by a medical office, but the evidence demonstrated that they were prescriptions because they were "assigned a prescription number," and had the office name in the place of a "patient's name," and further the pharmacy generated "fill stickers." *Id.* at 65. She stated that "according to the standards set by Florida, a controlled substance should be issued to an individual patient, not an office to be distributed through unknown patients," and therefore, she testified that the prescriptions dispensed for office use were dispensed outside the usual course of professional practice. *Id.* at 64, 66. Upon prompting by Respondents' counsel, Dr. Gordon further testified that "if there were an invoice and the prescription was issued to a practitioner," it would have resolved the issue, but clarified that it was not within the acceptable standard of practice to order controlled substances from a pharmacy to be distributed to a dispensing practitioner and then report it to E-FORCSE. *Id.* at 278-79; 288-89.

Respondents' Owner and PIC testified that when she "had an interest to wholesale some compounding," she asked her counsel (D.M.) about whether she could fill prescriptions for an office and that "he said it was lawful between 3 and 5 percent" of her total inventory.[21] *Id.* at 583. She also admitted that she did not ask D.M. specifically about dispensing in the context of the prescriptions to Dr. I.'s office and that she had not specifically shown him or asked him about using blank prescriptions and fill stickers. *Id.* at 696-97, 777. She testified that she had accessed the

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[21] Respondents' Owner and PIC stated that she received this legal advice in writing, but Respondent offered no evidence of the advice. Tr. 695-696; RD, at 29.

accreditations for Dr. I. and found that Dr. I. was a dispensing practitioner.[22] *Id.* at 578. However, she testified that after the Board of Pharmacy visited in 2015 and told her that wholesaling was not allowed, Respondent Pharmacy stopped dispensing to practitioners and her counsel changed his advice. *Id.* at 584.

I find that Respondent Pharmacy filled prescriptions for Dr. A.'s office and for Dr. I.'s office for office use. *See infra* Section III(A)(1)(b) for further discussion.

G. Allegation That Respondent Pharmacy Failed to Exercise Its Corresponding Responsibility When It Dispensed Controlled Substances Pursuant to Prescriptions Not Issued in the Usual Course of Professional Practice or for a Legitimate Medical Purpose

The OSC alleged that Respondent Pharmacy failed to exercise its corresponding responsibility under 21 C.F.R. § 1306.04 as evidenced by its having dispensed controlled substances without resolving "red flags of diversion" that were present, including prescriptions: for highly abused narcotics; written to individuals travelling long distances; from groups of individuals who travelled long distances, from the same doctor, presented at the same time; for multiple drugs designed to treat the same condition in the same manner; constituting obvious early refills; and, for "costly narcotic medications, which the customer repeatedly purchased with cash." OSC, at 4.

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[22] It is noted that Respondents' Owner and PIC did not offer a similar justification for the prescription to Dr. A's Office.

1. Red Flags Associated with Patients of Dr. R.

The OSC alleged that between February 12, 2014, and May 3, 2014, Respondent Pharmacy "dispensed narcotic medications to groups of customers who resided in close proximity to [Respondent Pharmacy], but who obtained their prescriptions from a physician located in Miami, Florida, more than 170 miles from their homes." OSC, at 4. The Government alleged that the distance between the prescribing practitioner and his patients , constituted red flags and Respondent Pharmacy did not adequately resolve the red flags prior to dispensing prescriptions. *Id.* Furthermore, the Government alleged that Dr. R.'s prescriptions presented additional red flags that were unresolved by the pharmacy.

The Government's evidence includes a letter from Dr. R., dated May 22, 2014, which explains that Dr. R. moved his practice from Broward County to Miami, but his Broward County patients had decided to continue under his care. GX 29, at 1. The letter provided high level details about his office protocols to ensure against diversion. *Id.* The ALJ noted that the letter did not provide any names of Dr. R.'s patients. RD, at 30. Respondents' Owner and PIC stated that the letter "was issued after [Respondents' Owner and PIC] decided to no longer accept [Dr. R's] prescriptions." Resp Posthearing, at 11 (citing RX H, at 61). Dr. Gordon opined that the letter did not resolve any of the red flags for patients "because it still doesn't explain why they're going to be driving further, putting the patients at risk." Tr. 193. She testified that although the fact that Dr. R. discusses his practice's

controls[23] could help a pharmacist evaluate the red flags, "[i]t still doesn't justify them traveling three hours." *Id.* at 272. Further, Dr. Gordon testified that nothing in the pharmacy records confirmed Dr. R.'s practice controls were actually implemented and there were no written statements from the patients as to why they chose to travel to see Dr. R., and there was no documentation of any pharmacists' discussion with Dr. R. necessitating the letter in Respondent Pharmacy's records. Tr. 270, 286-87; RD, at 72.

Respondents' Owner and PIC testified that she had spoken on the phone to Dr. R. and "found him legitimate." Tr. 555. However, she stated that she had made a policy not to fill Dr. R.'s prescriptions, around the time that she received a letter from him on May 22, 2014, and she counseled B.S.[24] for filling those prescriptions "because we don't want the scrutiny of it." *Id.* at 560, 770; 557; RX H, at 62. However, she stated that despite that policy, there were two instances where Respondents' Owner and PIC had decided to fill Dr. R.'s prescriptions as an exception to that policy. Tr. 771; 560. One was on April 7, 2014 to J.S.2. *Id.* at 773; GX 6, at 7.

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[23] Dr. Gordon also testified that there was no information in Respondent Pharmacy's files that demonstrated that any of the controls mentioned in the letter had been implemented, except for a urine screen, but "[i]t was not monthly" as Dr. R.'s letter had claimed. Tr. 286.

[24] Respondents' Owner and PIC testified that B.S. was later terminated for other reasons in 2016. Tr. 564.

a. Pattern of Filled Prescriptions for Dr. R.'s[25] Patients

The Government presented evidence that not only did Dr. R.'s patients travel long distances to receive their medication, but also they often filled the prescriptions on the same date and "at the same time, one after another." RD, at 71. On February 12, 2014, Patients J.S.1, A.J., and S.P. presented prescriptions for oxycodone and hydromorphone from Dr. R. GX 6, at 1-2; GX 5, at 3-4; GX 4, at 3-4; RD, at 70. Dr. Gordon testified that the pattern of filling in groups is a red flag, because "that's a group of patients going to see the same doctor, getting the same type of medication, same class of medication, and going to the pharmacy on the same day to get their prescriptions filled." Tr. 106. Similarly, on March 11, 2014, Patients D.G. and J.S.1 presented prescriptions from Dr. R. for oxycodone and their prescription numbers indicate that "[r]ight after one another they were filled." Tr. 107; GX 9, at 5-6; GX 6, at 3-4. On March 15, 2014, Respondent Pharmacy filled prescriptions for hydromorphone from Dr. R., for Patients E.H., S.P., and A.J, with sequential fill numbers. GX 8, at 1-2; GX 4, at 5-6; GX 5, at 5-6. On April 11, 2014, Respondent Pharmacy filled prescriptions for S.P., A.J. and E.H. for hydromorphone. GX 4, at 1-2; GX 5, at 7-8; GX 8, at 3-4. Finally, on May 3, 2014, Respondent Pharmacy filled prescriptions for J.S.1 and D.G. for oxycodone and hydromorphone with sequential fill numbers. GX, 6, at 11-12; GX 9, at 9-10.

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[25] All of the patients in this section are patients of Dr. R., but some of the patients also received prescriptions from other doctors, which also presented red flags as described herein.

Dr. Gordon further explained that under normal pharmacy procedures, these Schedule II controlled substances must be locked up and "the lock and key belongs to the pharmacist," and therefore, the pharmacist would have been aware of the pattern of group filling. Tr. 109-10. She opined that the red flags for these prescriptions were not resolvable and that she would not have filled them, because "it's an effort to take—to get that drug and take it out. And then one right after it is for the same thing." *Id.* at 110-11.

b. S.P.

On February 2, 2014, March 11, 2014, and April 11, 2014, Respondent Pharmacy filled prescriptions for hydromorphone for S.P. GX 4, at 4, 2, 6. Dr. Gordon testified that the first red flag in the initial prescription was that the prescription for hydromorphone was "written for the highest strength the drug is available." Tr. 67. Further, the prescription was "from a doctor who is about three hours away from where the patient resides."[26] *Id.* Finally, the fill stickers indicate that the patient paid with cash. *Id.* at 68; GX 4, at 2, 4, 6. The prescription dated February 2, 2014, includes a note on the prescription stating that it was "verified by Nicole." GX 4, at 3. Dr. Gordon explained that "when a technician calls the doctor's office to verify the validity of the prescription itself, that the prescription was written and issued by the physician." Tr. 68. S.P.'s file also contains a form letter with

[26] The Parties stipulated that the distance from S.P.'s home in Malabar, Florida to Dr. R. in Miami is 170 miles. RD, at 31 (citing Stipulation (hereinafter, Stip.) 7).

handwritten blanks filled in from Dr. R. faxed on February 12, 2014, that states that Dr. R. "examined and prescribed narcotic medications" to S.P. GX 4, at 8. Dr. Gordon opined that the letter provides the "reasoning for issuing this prescription," but does not resolve any of the red flags discussed and stated, "[i]t makes it worse because it's providing a diagnosis that we see a lot with prescriptions that are associated with diversion of chronic pain syndrome or some kind of back reason, and would also make me wonder how a patient could sit in a car for three hours one way to go to a doctor. . . . " Tr. 70. She concluded that the prescriptions dispensed to S.P. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. Tr. at 70.

c. A.J.

From January 21, 2014, to April 11, 2014, Respondent Pharmacy filled prescriptions from Dr. R. for customer A.J. GX 5, at 1-8. A.J.'s address on the prescriptions is Palm Bay, Florida and the distance from Dr. R's office in Miami is 176 miles. GX 5, at 3, 5, 7; RD, at 31 (citing Stipulation 8). From December 5, 2014, to March 27, 2015, Respondent Pharmacy filled eight prescriptions for A.J. from another doctor, Dr. D. GX 5, at 9-28. Dr. D.'s office in Orlando, Florida was 74 miles from A.J.'s address. RD, at 32 (citing Stipulation 9). Dr. Gordon testified that the prescriptions from Dr. R. raised numerous flags, including: the type of medication; the fact that it was the highest strength dosage available (hydromorphone eight milligrams); "the distance traveled by the patient to go see the doctor and that the patient was paying cash." Tr. 77. Dr. Gordon also testified that it was a red flag

that the prescriptions from Dr. D. included a prescription for morphine in addition to the hydromorphone at the highest dosage, both of which treat the same condition. *Id.* at 80, 84; *e.g.*, GX 5, at 9, 11. She further testified that the prescriptions from Dr. D. raised red flags because of the type of medications, the fact that A.J. was paying cash and the fact that the "codes that are on here are all back pain or chronic pain syndrome," which are "commonly seen on diverted medications."[27] *Id.*

A.J.'s profile contains an entry that states, "Dr. D. called personally about patient & will send letter over next week." GX 5, at 29. There is no letter from Dr. D. in the file and the Respondents' Owner and PIC testified that it was "generally" the policy to note the receipt of a letter in the system.[28] Tr. 735-36. The file also contains a form letter faxed on January 23, 2014,[29] from Dr. R. with the patient's name, diagnosis

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[27] Respondents argue that Dr. Gordon "seems to have an overall bias against patients with back pain." Resp Posthearing, at 54. I disagree. She testified that it had been her "experience" that people who commonly abuse medications present with prescriptions related to back pain. Tr. 220. It is noted that there are numerous red flags on the prescriptions where Dr. Gordon flagged back pain as an additional red flag.

[28] However, there was a letter from Dr. R. for patient A.J. and no corresponding notation regarding its receipt in A.J.'s profile. GX 5, at 29, 30; RD, at 32.

[29] It is noted that this letter was faxed on January 23, 2014, but the first prescription for A.J. was filled on January 21, 2014; therefore, even had this letter resolved some of the red flags for future prescriptions, which I find it did not, it was not received in time to resolve the red flags for the first prescription. *See* GX 5, at 2.

and last MRI filled in by hand. GX 5, at 30; RX H, at 59. Dr. Gordon testified that neither the notation regarding Dr. D., nor the letter from Dr. R. resolved the red flags associated with A.J.'s prescriptions, because there was no documentation explaining the long distances that A.J. traveled to see these doctors. Tr. 85-86; *see* GX 5, at 29, 30; RX H, at 59. She concluded that the prescriptions dispensed to A.J. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. Tr. at 86.

d. D.G.

From January 14, 2014, to May 3, 2014, Respondent Pharmacy filled prescriptions for customer D.G. written by Dr. R. GX 9, 1-10. D.G.'s address on the prescriptions is in Palm Bay, Florida and the distance from Dr. R.'s office in Miami is 175 miles. GX 9, at 2, 4, 6, 8; RD, at 33 (citing Stipulation 13). D.G.'s customer file also includes a prescription, dispensed on October 15, 2014, written by another doctor, Dr. B., in Winter Garden, Florida, which is 76 miles from D.G.'s address. GX 9, at 11; RD, at 33 (citing Stipulation 17). Dr. Gordon testified that these prescriptions raised multiple red flags including: "the type of medication, which is an opioid, the strength[30] of the medication, the distance traveled from the patient's home to the doctor, and cash." Tr. 94-95. Further, she testified that the prescriptions from Dr. B. had the same red flags and that the patient was traveling an hour away, which would

[30] Dr. Gordon further explained that the strength is a concern "because it's the highest dose the drug is available in in an immediate-release form." Tr. 94.

still trigger a red flag. Tr. 97. The Government's evidence includes a form letter from Dr. R. stating that the date of visit was February 11, 2014,[31] and a diagnosis of lower back pain. GX 9, at 14. Dr. Gordon testified that nothing in the file,[32] including the letter, resolves the red flags, because it does not explain why he is traveling such a distance, particularly considering that he allegedly had lower back pain. Tr. 98. She concluded that the prescriptions dispensed to D.G. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.* at 98.

e. E.H.

From March 15, 2014, to May 9, 2014, Respondent Pharmacy filled prescriptions for customer E.H. written by Dr. R. GX 8, 1-6. E.H.'s address on the prescriptions is in Palm Bay, Florida and the distance from Dr. R's office in Miami is 175 miles. *Id.* at 2, 4, 6; RD, at 34 (citing Stipulation 20). E.H.'s customer file also includes prescriptions filled July 23, 2014, to April 1, 2015, written by various doctors at a pain management clinic in Orlando, Florida, which is 74 miles from E.H.'s address. GX 8, at 7-24; RD, at 34 (citing Stipulation 21). Dr. Gordon testified that these prescriptions

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[31] It is noted that although the letter was undated, it had to have been sent after the last visit identified in the letter as February 11, 2014, which was after Respondent Pharmacy's first fill on January 17, 2014, for this patient. GX 9, at 2.

[32] The patient profile for D.G. includes a note in the memo section that states "3/17/2015 must have new letter of med necessity for any further fills." GX 9, at 13. However, that note was dated long after the last prescription in the record for D.G. of October 15, 2014. *Id.* at 12.

raised multiple red flags including: "the type of medication, the strength of the medication, the distance traveled, and cash." Tr. 100. Further, she testified that the prescriptions from the practice in Orlando had the same red flags and that the patient was still traveling a distance.[33] *Id.* at 102. The Government's evidence includes a form letter with the patient, diagnosis and last MRI filled in from Dr. R. faxed on March 14, 2014. GX 8, at 26. Dr. Gordon testified that nothing in the file, including the letter, resolves the red flags. Tr. 105. She concluded that the prescriptions dispensed to E.H. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.*

f. S.1 and J.S.2

From February 12, 2014, to May 5, 2014, Respondent Pharmacy filled prescriptions for customers J.S.1 and J.S.2 written by Dr. R. GX 6, at 1-14. According to the prescriptions, J.S.1 and J.S.2 live at the same address in Palm Bay, Florida. RD, at 34 (citing Tr. 585); *compare* GX 6, at 1-2, *with* GX 6, at 5-6. The distance from the residence of J.S.1 and J.S.2 to Dr. R's office in Miami is 174 miles. GX 6; RD, at 35 (citing Stipulation 10). They lived 22 miles from Respondent Pharmacy. RD, at 35 (citing Stipulation 12). Dr. Gordon testified that the prescriptions to J.S.1 and J.S.2 raised the same red flags as the other patients including, "the type of medication, the strength is the highest strength of the medication, the distance

[33] One of the prescriptions includes a Rockledge address for the Orlando practice, which Dr. Gordon testified is still far away from E.H.'s home. Tr. 103-04.

traveled, and cash." Tr. 87, 113. The Government's evidence includes a form letter for J.S.2 with the patient, diagnosis and last MRI filled in from Dr. R. faxed on March 10, 2014. GX 6, at 16. Dr. Gordon testified that nothing in the file, including the letter, resolves the red flags. Tr. 113. No such letter is in the file for J.S.1. *See generally* GX 6. She concluded that the prescriptions dispensed to J.S.2[34] were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.* at 113-114. Dr. Gordon further testified that the fact that J.S.1 and J.S.2 reside at the same address raises an additional red flag, "because that shows that they're a group. They both live at the same address, they're getting the same type of chronically sought after narcotic from the same doctor, both traveling an hour or three hours south one way to get their medication, both have a similar diagnosis of back pain." *Id.* at 114.

Respondents' Owner and PIC stated that the majority of the prescriptions Respondent Pharmacy filled for J.S.1 and J.S.2 were filled by B.S, but that she had filled some of J.S.2's prescriptions. *Id.* at 586. She recalled having a conversation with J.S.2 about the distance driven and that it was "short-term" and "[h]e did tell me the diagnosis. I don't recall about the time." *Id.* at 588. She also testified that she had encouraged J.S.2 to find a local pain physician and he had found one in Orlando, which she considered

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[34] Dr. Gordon's testimony did not include a specific conclusion regarding corresponding responsibility for J.S.1 separate and apart from J.S.2; however, I find that the record is clear that the red flags for both of these patients were the same and therefore I draw the same conclusion for J.S.1 that I do for J.S.2.

to be local despite being 50 miles away, because "there weren't the availability of a lot of pain management doctors, period, but there were even less that had openings." Tr. 593-94.

g. C.C.

From December 28, 2013, to May 5, 2014, Respondent Pharmacy filled prescriptions for customer C.C. written by Dr. R. GX 11, at 1-12. C.C.'s address on the prescriptions is in Melbourne, Florida and the distance from Dr. R's office in Miami is 176 miles. GX 11; RD, at 36 (citing Stipulation 28). C.C.'s customer file also includes prescriptions filled from August 18, 2014, to March 30, 2015, written from a practice in Rockledge, Florida. GX 11, at 13-44; RD, at 36. Dr. Gordon testified that the prescriptions from Dr. R. to C.C. raised the same red flags as the other patients.[35] Tr. 123. Dr. Gordon also testified that even though the doctor in Rockledge was local to C.C., the prescriptions still raised red flags because the prescriptions were "still the short-acting opioid at the highest dose, the chronic back pain, and cash." *Id*. at 125; GX 11, 13-44. The Government's evidence includes a form letter for C.C. from Dr. R. with the patient name diagnosis and last MRI filled in by hand, which although undated, appeared to be received April 7, 2014, according to the notes in the Respondent Pharmacy's files. GX 11, at 45-46. Dr. Gordon testified that nothing in the file, including the letter, resolves the red flags for the prescriptions for C.C. Tr. 126-127. She concluded that

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[35] The Government noted that the fill sticker on one of the prescriptions gives an address in Boynton Beach for Dr. R., but Dr. Gordon said that although "it probably shaves off maybe an hour and a half drive," it still raises the same red flags. Tr. 123-24.

the prescriptions dispensed to C.C. from Dr. R.[36] were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.*

h. P.P.

From January 31, 2014, to April 10, 2014, Respondent Pharmacy filled prescriptions for customer P.P. written by Dr. R. GX 12, at 1-6. P.P.'s address on the prescriptions is in Palm Bay, Florida and the distance from Dr. R's office in Miami is 173 miles. GX 12; RD, at 36 (citing Stipulation 30). Dr. Gordon testified that the prescriptions from Dr. R. to P.P. raised the same red flags as the other patients for the strength, type of medication, "a highly sought after opioid," and the distance traveled. Tr. 128. She further stated that P.P. charged his insurance for some of the prescriptions, but paid cash for the prescription filled on February 18, 2014, which indicates a red flag when patients are "maybe trying to hide something from the pharmacist. They get it filled somewhere else and bill their insurance." *Id.* at 128. The Government's evidence includes a form letter for P.P. from Dr. R. with the patient name, diagnosis and last MRI filled in by hand, which was faxed on January 23,

[36] Although Dr. Gordon testified that the prescriptions from the physician in Rockledge raised red flags, she limited her opinion that Respondent had not fulfilled its corresponding responsibility or acted within the usual course of professional practice to the prescriptions to C.C. by Dr. R. I am limiting my findings to Dr. R's prescriptions, because most of the other prescriptions included a red flag of distance and Dr. Gordon did not explain how or whether the absence of that red flag in this instance might affect the pharmacist's corresponding responsibility and professional practice.

2014. GX 12, at 8; RX H, at 264. Dr. Gordon testified that nothing in the file, including the letter, resolves the red flags for the prescriptions for P.P. Tr. 129-130. She concluded that the prescriptions dispensed to P.P. prescribed by Dr. R. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.*

Although the letter of necessity from Dr. R. was included in the Government's evidence, there was no corresponding note of receipt in his patient file and there was no note that Respondent Pharmacy would not take out of county prescriptions.[37] GX 12, at 7. Respondents' Owner and PIC stated that no prescriptions were filled for patient P.P. after May 14, 2014, but the ALJ found, and I agree, that Respondents' own exhibits demonstrate that not to be the case. Tr. 633; RD, at 37; RX H, at 265 (showing that the last prescription filled for P.P. by Respondent Pharmacy was on September 22, 2016). Respondents' Owner and PIC also testified that the prescriptions for P.P. were filled by Pharmacist B.S.,[38] a former employee of Respondent Pharmacy. Tr. 632-33.

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[37] The ALJ noted, and I agree, that the Respondents' Owner and PIC testified that even though there was no notation, a pharmacist filling a prescription for P.P. could check the paper file for the letter of necessity; however, without a notation, a pharmacist would not know that the letter existed to know to check the paper file. RD, at 37 n.17 (citing Tr. 748-49)

[38] Although B.S. may have filled the prescriptions in the Government's evidence, it is noted that Respondents' evidence demonstrates that B.S. was terminated for potential diversion on April 23, 2016; therefore, a different pharmacist must have filled P.P.'s prescriptions following B.S.'s termination. RX G, at 5l; Tr. 564.

i. K.P.

From February 4, 2014, to April 8, 2014, Respondent Pharmacy filled prescriptions for customer K.P. written by Dr. R. GX 13, 11-16. Additionally, from April 22, 2013, to August 24, 2013, Respondent Pharmacy filled prescriptions for K.P. from a prescriber in Fort Lauderdale, Florida.[39] K.P.'s address on the prescriptions varies;[40] however, K.P.'s address on all of the fill stickers from Respondent Pharmacy indicates that he was located in Fort Lauderdale, Florida. GX 13, at 2, 4, 6, 8, 10, 12, 14, 16. The distance between K.P.'s address and Respondent Pharmacy is 164 miles. RD, at 38 (citing Stipulation 32). Dr. Gordon testified that these prescriptions raised numerous red flags including: "the type of medication, the highly sought out opioid, the strength of the medication, the distance to the pharmacy [. . .] and that the patient was paying cash." Tr. 132. The Government's evidence includes a form letter with the patient name, diagnosis and last MRI filled in from Dr. R. faxed on January 31, 2014. GX 13, at 18; RX H, at 273. There was no documentation of the letter in the notes section of the patient profile in Respondent Pharmacy's system, but there was an undated note stating not to fill any more "out of county physicians." GX 13, at 17; RD, at

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[39] One of the fill stickers for the Fort Lauderdale prescriber indicates a Miami address, but I find this to be irrelevant because the red flag for K.P. related to location is the distance he lived from the pharmacy. *See* GX 13, at 10; Tr. 133.

[40] A few of the prescriptions show addresses in Sunrise Florida, which is west of Fort Lauderdale. RD, at 38 n.18. Additionally, one of the prescriptions indicates that K.P. lives in Palm Bay, which Dr. Gordon testified "creates more of a red flag. Where does he live?" GX 13, at 11; Tr. 134-35.

38. There was no letter of necessity or other notes regarding the prescriber in Fort Lauderdale. *See generally* GX 13; RD, at 38. Dr. Gordon testified that nothing in the file, including the letter, resolves the red flags. Tr. 135-136. She concluded that the prescriptions dispensed to K.P. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id*. at 136.

Based on all of the record evidence, and the testimony of Dr. Gordon, which I credit, I find that the prescriptions issued by Dr. R. and other doctors for Dr. R.'s patients as detailed herein, raised red flags, including that customers arrived in groups, purchased prescriptions with cash, traveled long distances and because the prescriptions were for highly sought after controlled substances at highest strengths. I further find that the letters of medical necessity provided by Dr. R. did not resolve the multiple red flags on his prescriptions and that, even if these red flags were resolvable, there was no credible evidence in the record that Respondent Pharmacy resolved them before it filled the prescriptions. I conclude that the pharmacists filling the prescriptions did not fulfill their corresponding responsibility and the prescriptions were not dispensed in the usual course of professional practice.

2. Other Prescriptions Presenting Red Flags

a. J.C.

From approximately October 11, 2013, to January 16, 2015, Respondent Pharmacy filled prescriptions

for customer J.C. written by a prescriber in Fort Lauderdale, Florida. GX 10. Most of the prescriptions record only a street address for the patient without a city, but a few prescriptions list the city as Palm Bay, Florida.[41] *Compare, e.g.*, GX 10, at 1 *with* GX 10, at 71-82; RD, at 39. The address on all of the fill stickers states that J.C. lives in Indialantic, Florida, which is 158 miles from the prescriber's office in Fort Lauderdale. *See, e.g.,* GX 10, at 2; RD, at 39 (citing Stipulation 22). There is nothing in the record evidence that resolves the discrepancy between the addresses on the prescriptions and the address on the fill stickers. RD, at 39. The first five prescriptions in the Government's exhibit were all issued on January 3, 2014, and are all for varying strengths and amounts of the same controlled substance, Roxicodone, including two prescriptions for 10 milligrams and two prescriptions for 20 milligrams and one prescription for 5 milligrams. Tr. 115, 835; GX 10, at 1-10; RD, at 39. Dr. Gordon testified that the five prescriptions for Roxicodone "just screams red flags." Tr. 117. "Furthermore, the instructions for taking these five prescriptions for the same controlled substance suggested that J.C. could have been taking all of these medications at the same time." RD, at 39 (citing Tr. 834-35). On the same date, January 3, 2014, in addition to the five prescriptions for the Roxicodone, Respondent Pharmacy also filled a sixth prescription for J.C. for the highest available dosage of diazepam, or Valium, which "would now constitute a drug cocktail." Tr. 117; GX 10, at 175-76.

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[41] Dr. Gordon testified that even if the patient had lived in Palm Bay, it would be a 2 to 2.5 hour trip to Fort Lauderdale. Tr. 116.

Furthermore, the ALJ found, and I agree, that Respondent Pharmacy additionally filled this same drug cocktail of oxycodone and diazepam for J.C. on January 28, 2014 jr. 118-19; GX 10, at 11-20, 177-78); July 19, 2014 (GX 10, at 95-96, 193-194); September 3, 2014 (GX 10, at 111-14[42], 191-92); September 23, 2014 (GX 10, at 119-26, 193-94); December 22, 2014 (GX 10, at 141-44, 197-98); and January 16, 2015[43] (GX 10, at 145-48, 199-200).

Further, Respondent Pharmacy filled prescriptions for J.C. that , constituted early refills. Tr. 121. For example, the ALJ found, and I agree, that Respondent Pharmacy filled multiple prescriptions for J.C. on January 28, 2014 (Tr. 121, GX 10, at 11-19) and then again filled prescriptions on February 11, 2014, and February 26, 2014. GX 10, at 19-20, 21-26, 27-30. Dr. Gordon said this raised red flags because "[t]he patient already got like a ton of oxycodone, and this is just like twelve days later he just got a whole nother [sic] batch." Tr. 122. She further testified that nothing

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[42] It was not alleged by the Government and is therefore not being considered, but is noted that the Government's exhibit also demonstrates that J.C. filled prescriptions written on September 2, 2014 at Respondent Pharmacy on September 3, 2014, and September 5, 2014, and September 10, 2014. GX 10, at 114, 116, 118.

[43] The prescriptions for oxycodone and Diazepam were all prescribed on January 16, 2015, but Respondent Pharmacy dispensed them on January 16, 2015, January 19, 2015, and January 28, 2015. GX 10, at 145-152; 199-200. The evidence shows that Respondent Pharmacy dispensed prescriptions for oxycodone and diazepam, which , constituted a drug cocktail, on January 19, 2015. *Id.* at 148, 200.

in the patient records[44] is written to resolve the red flags for J.C.'s prescriptions. *Id.*

Respondents' Owner and PIC testified[45] that if J.C. paid cash for a prescription, the fill sticker stated "cash" and if he used insurance it would read "advance." Tr. 615. J.C. paid cash for his prescriptions 10 times. RD, at 40 (citing Tr. 613); *see e.g.*, GX 10, at 146. Respondents' Owner and PIC further testified that she knows J.C. and he was a customer for 10 years. Tr. 596, 740. She further testified that she had had a conversation with the prescribing doctor[46] "about the therapy because it is different, so I particularly wanted to know about the use of several different

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[44] The Patient profile includes a note that says that someone spoke with the prescriber and verified medical necessity on October 2, 2012. The notes also include a note on March 30, 2015, after several years of filling prescriptions, that the address on RX must match address on the driver's license and that there could be "no more credit." GX 10, at 201.

[45] Respondents' Owner and PIC also testified that she believed that the Government had not included all evidence from the patient memo in their exhibits, because she "knew this patient well." Tr. 612. Respondent did not offer additional evidence and the print out in her exhibits on J.C. contains the same information in the patient memo as the Government's print out. *Compare* RX H, at 145 *with* GX 10, at 201.

[46] Respondents' Owner and PIC testified that this doctor had a good reputation in the community. At first, Dr. Gordon testified that it is not within the standard of practice to rely on a physician's reputation to fill a prescription, but later amended her statement to allow that reputation "will come into play." Tr. 832, 838. I do not find this information particularly relevant, because there is nothing in the record documenting Respondents' Owner and PIC's belief that the physician's reputation resolved the multitude of red flags that these prescriptions presented.

strengths of oxycodone." *Id.* at 597. In speaking with the doctor, Respondents' Owner and PIC testified that "[J.C.] was on a very tightly tailored pain management treatment plan where as his pain fluctuated, he would use a different dose to use the minimal amount to relieve the pain." *Id.* at 610. Later, she changed the rationale for the multiple prescriptions, stating, "those were split scripts[47] so that if the patient either didn't have the funds or if it wasn't available because of shortages . . . so that he could get a partial here and there." Tr. 855.

Dr. Gordon testified that there were no instructions with these prescriptions about how to take them. *Id.* at 832-34. In order to address the prescriptions under the standard of practice, she said that a pharmacist would need to call to find out why the patient needs all of the prescriptions, "and is the patient supposed to take one at a time or can they take all four at the same time." *Id.* at 835, 837. She concluded that the prescriptions dispensed to J.C. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.* at 120

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[47] Some of the prescriptions did include a note indicating "split script;" however, I find Dr. Gordon more credible that this could not resolve the red flag of the need for all of the prescriptions or the instructions on how to take them. *See e.g.*, GX 10, at 161. Additionally, on March 20, 2015, Respondent Pharmacy filled all of the prescriptions that appeared to be duplicative on the same day, which undermines the notion that they were split scripts. *Id.* at 159-64.

b. M.B.

From October 3, 2013, to March 13, 2015, Respondent filled prescriptions for patient M.B., whose address on the prescriptions and fill stickers was listed in Palm Bay, Florida. GX 14, at 1-88. Dr. Gordon testified that these prescriptions raised multiple red flags. For example, the prescriptions filled for hydromorphone and lorazepam on December 30, 2013, constituted a drug cocktail. Tr. 137. Dr. Gordon noted many instances of drug cocktails dispensed to M.B., including Ativan and hydromorphone, MS Contin, or extended-release morphine. Tr. 138. The ALJ noted that beginning in December 2014, Respondent Pharmacy was filling two prescriptions for hydromorphone for M.B. at the same time it filled prescriptions for lorazepam for him. RD, at 41; GX 14, at 65-88. Dr. Gordon testified that a further red flag was the location of the physician in Sanford, which is about an hour away from M.B.'s residence in Palm Bay. *Id.* at 138. The records for patient M.B. demonstrate that M.B. paid for his prescriptions "cash for some things and insurance for others." Tr. 138; *compare* GX 14, at 10, *with id.* at 12.

The Government's Exhibit included a letter dated May 6, 2013, with a corresponding note in the patient profile from M.B.'s prescriber. GX 14, at 89-92. The letter included a diagnostic code and list of medications, but "provide[d] no information about why M.B. was making a 170 mile round trip to see" the prescriber. RD, at 41; GX 14, at 90-92. Dr. Gordon testified that nothing in the file, including the letter, resolved the red flags. Tr. 138-39. She concluded that the prescriptions dispensed to M.B.

were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id*. at 139-40.

Respondents' Owner and PIC testified that she spoke to M.B.'s prescriber and "had a general conversation, not patient specific." Tr. 640. She testified that "63 out of 91 [of M.B.'s] prescriptions" were paid by insurance, and that M.B.'s payment with cash "raised a red flag that was resolved," because "the insurance, if they won't pay for it, then we give them the option to pay cash."[48] *Id.* at 642. Respondents' Owner and PIC testified that M.B. had "presented with a prescription from a different physician," and that she had "faxed Dr. [C]'s office to see the reason for his discharge" and found out "that he had been discharged for cause," so she refused to fill further prescriptions for M.B. Tr. 643 (citing RX H, at 274 (found at 283)).

c. C.A.

From December 17, 2013, to February 10, 2014, Respondent Pharmacy filled prescriptions for patient C.A., whose address on the fill stickers was listed as Sebastian, Florida,[49] which was 86 miles from the

[48] I note that M.B.'s patient records demonstrate that he paid cash for most of his prescriptions for hydromorphone and the other prescriptions with insurance, which would support Respondents' Owner and PIC's testimony regarding the resolution of the red flag; however, he used insurance to pay for "hydromorphone 8 MG tablet" on March 13, 2015 (GX 14, at 86) and Respondents offered no explanation to resolve this discrepancy. More importantly, Respondents provided no documentation of the alleged resolution of this red flag or any other of the red flags for patient M.B.

[49] As the ALJ noted, the address listed for C.A. on the prescriptions had the same street address as the fill stickers, but listed the city

prescriber in Orlando. GX 15, at 1-7; RD, at 41 (citing Stipulation 35). Dr. Gordon testified that these prescriptions raised multiple red flags, including the type of medication, the distance traveled and that all of the prescriptions were paid for in cash. Tr. 141; GX 15, at 2, 4, 6. "Two of the three prescriptions that contain these red flags were filled by [Respondents' Owner and PIC]." RD, at 42 (citing Tr. 142; GX 15, at 1-2, 5-6). The patient's profile notes "must have letter of med nec for March 2014 fill Dr. Kuhn." GX 15, at 7. The exhibits included an undated letter. GX 15, at 8. From the date of the note, it appears that this letter must have arrived around the time of the March 2014 fill and after the three prescriptions in the exhibit. Dr. Gordon testified that nothing in the file, including the letter, resolves the red flags. Tr. 143. She concluded that the prescriptions dispensed to C.A. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.*

d. D.B.

From December 17, 2013, to March 26, 2015, Respondent Pharmacy filled prescriptions for patient D.B. GX 7, at 1-60. D.B.'s address on the fill stickers is in Port St. Lucie, Florida, which is 76 miles from Respondent Pharmacy; however, D.B.'s address on the prescriptions is in Jupiter, Florida. GX 7, at 1-60; RD, at 42 (citing Stipulation 27). The doctor's office in

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as Barefoot Bay, Florida instead of Sebastian, Florida. *Compare* GX 15, at 1, *with id.* at 2. The distance between these two cities is negligible and despite the Government trying to raise the difference as a red flag at the hearing, it does not appear to be relevant. Tr. 141.

Jupiter, Florida is 111 miles from Respondent Pharmacy. RD, at 42 (citing Stipulation 26).

Dr. Gordon testified that these prescriptions raised multiple red flags, including the type and strength of the medication, the distance traveled to the pharmacy and that many of the prescriptions were paid for with cash. Tr. 144. Additionally, many of the prescriptions filled were for drug cocktails. *Id*. at 144-47. For example, Respondent Pharmacy filled a drug cocktail of: oxycodone and the highest dose of Xanax (filled by Respondents' Owner and PIC six days after the oxycodone prescription) in December 2013. GX 7, at 1-3; Tr. 145-46; RD, at 42. Respondents' Owner and PIC filled a prescription for oxycodone, Percocet and Xanax, which included two immediate release opioids, on July 1, 2014. Tr. 148; GX 7, at 21-26. Respondent Pharmacy filled prescriptions for Percocet, Xanax and Ambien on February 21, 2015. Tr. 146-47; GX 7, at 51-56. Additionally, on October 24, 2014, Respondent Pharmacy filled two identical prescriptions for the highest dosage of oxycodone. Tr. 147; GX 7, at 35-38.

Further, the record demonstrates early fills, which constitute red flags. For example, on June 19, 2014, Respondent Pharmacy filled a prescription for a 30 day supply of Percocet and 30 day supply of oxycodone, and Respondents' Owner and PIC re-filled both for a 30 day supply on July 1, 2014, despite that 30 days had not passed. Tr. 726-27; GX 7, at 19, 20, 21-14. Respondents' Owner and PIC admitted that it was an early fill "as to counting the days." Tr. 727. She further responded "yes" to the question as to whether the early fill , constituted a red flag and admitted

that nothing in the patient profile or on the prescription resolved the red flag. Tr. 727.[50]

The patient memo box on D.B.'s patient profile includes a note from March 30, 2015, that "address on RX must match driver's license." GX 7, at 61; Tr. 733. Further, Respondents' Owner and PIC testified that she had resolved the red flag that he was traveling so far, because "he had a residence in Satellite Beach that he intended to move back to" and Respondents provided a copy of what appears to be a scanned prescription, dated March 24, 2015, with a handwritten note in Respondents' Owner and PIC's handwriting, stating, "Moving back to Sat Bch July." Tr. 619; RX H, at 192. However, the ALJ found, and I agree, that "the pharmacy had been filling D.B.'s prescriptions since December of 2013, yet all of the prescription addresses indicated that D.B. lived in Jupiter, Florida, while the fill stickers indicated he lived in Port St. Lucie." RD, at 43.

Dr. Gordon testified that nothing in the Government's evidence resolved the red flags on the prescriptions. Tr. 147-49. She concluded that the prescriptions dispensed to D.B. were not dispensed within the usual course of professional practice and the pharmacist

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[50] Respondents' Owner and PIC argued that the fact that the patient "consistently saw the same doctor who wrote subsequent scripts which seemed to legitimize" the prescriptions, because "that would suggest that a conversation was had about how much was used and why he was writing it yet again." Tr. 729. I reject the notion that a red flag that demonstrates that a prescription may be illegitimate is resolved because the practitioner who issued the initial potentially illegitimate prescription, issued another potentially illegitimate prescription.

did not fulfill his or her corresponding responsibility. *Id*. at 149.

e. J.D.

From October 18, 2013, to April 3, 2015, Respondent Pharmacy filled prescriptions for patient J.D. whose address on the prescriptions and most of the fill stickers[51] was listed as Cocoa Beach, Florida, which was 75 miles from the prescriber in Sanford, Florida. GX 16, at 1-72; RD, at 43 (citing Stipulation 36). Dr. Gordon testified that these prescriptions raised multiple red flags, including the type of medication, the fact that the Xanax and hydromorphone were at high dosages, the distance traveled, paying for prescriptions with cash, and drug cocktails of hydromorphone and Xanax. Tr. 152-54; RD, at 43. The ALJ found, and I agree, that the Government's evidence demonstrates that Respondent Pharmacy filled prescriptions for both hydromorphone, at its highest dosage, and Xanax on 16 different dates. RD, at 43-44 (citing GX 16, at 7-70). Furthermore, the ALJ found, and I agree, that Respondent Pharmacy provided J.D. with early refills on March 21, 2014, May 16, 2014, October 3, 2014, November 21, 2014, and January 9, 2015. RD, at 44 (citing GX 16, at 11-26, 39-62).

The patient's profile notes a May 14, 2013, letter of medical necessity from Dr. C., seven months after Respondent Pharmacy began filling J.D.'s prescriptions. GX 16, at 73. The letter provides a list of medications, a diagnosis code and the initial date of treatment, but

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[51] The first two prescriptions list an address of Titusville, Florida on the fill stickers and not the prescriptions, but the rest of the prescriptions list Cocoa Beach on both. GX, 16, at 1-4.

no explanation for the distance traveled, strength of the medication or the combination of medications. GX 16, at 74-75. Dr. Gordon testified that nothing in the file, including the letter, resolves the red flags. Tr. 154.[52]

f. K.B.3

From December 27, 2013, to January 23, 2015, Respondent Pharmacy filled prescriptions for patient K.B.3, whose address on the prescriptions and fill stickers was listed as Palm Bay, Florida, which was 88 miles from the prescriber, Dr. S., in Sanford, Florida. GX 17, at 1-27; RD, at 44 (citing Stipulation 37). Dr. Gordon testified that these prescriptions raised multiple red flags, including the type of medication, the fact that the hydromorphone was prescribed at its highest strength, the distance traveled to the prescriber, and paying for prescriptions with cash. Tr. 155-56; RD, at 44. The ALJ additionally noted that Respondents' Owner and PIC "filled prescriptions for K.B.3 for the maximum available dosage of hydromorphone on June 25, 2014, and July 22, 2014." RD, at 44 (citing GX 17, at 29-35). Respondents' Owner and PIC testified that she did not see any red flags related to the distance traveled or any other red flags related to K.B.3's prescriptions and that she "interacted with him regularly." Tr. 660.

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[52] Dr. Gordon's testimony did not include a specific conclusion regarding corresponding responsibility for J.D.; however, I find that the record is clear that the red flags are the same as the other patients' prescriptions and therefore I draw the conclusion that these were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility.

The patient's profile notes that on September 24, 2014, Respondent Pharmacy received a letter of medical necessity from Dr. S. GX 17, at 28. The Government's Exhibits include three different letters dated September 24, 2014, January 30, 2013, and September 2, 2013, explaining that K.B.3 had been under various doctors' care for back pain,[53] but they "don't address why the patient's paying cash, they don't address why the patient's going such a long distance to obtain these sought after opioids, desirable opioids." Tr. 157; GX 17, at 29-34. Dr. Gordon testified that nothing in the file resolves the red flags. Tr. 156-157. She concluded that the prescriptions dispensed to K.B.3 were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id*. at 157.

g. K.B.2

From October 21, 2013, to March 26, 2015, Respondent Pharmacy filled prescriptions for patient K.B.2, whose address on the prescriptions and fill stickers was listed as Melbourne, Florida, which was 67 miles from the prescriber in Orlando, Florida. GX 18, at 1-98; RD, at 45 (citing Stipulation 38). Dr. Gordon testified that these prescriptions raised multiple red flags, including the type of medication, the fact that the diazepam and hydromorphone were prescribed at its highest strength, the distance traveled to the prescriber, paying for prescriptions with cash. Tr. 158-64; RD, at 45. Dr. Gordon also testified that Respondent Pharmacy filled drug cocktails for K.B.2 consisting of

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[53] It is noted that one of the records contains a physical exam that notes that the patient's back is normal and does not identify any pain. GX 17, at 33.

diazepam, hydromorphone and morphine sulfate.[54] Tr. 159-61. The ALJ concluded that Respondent Pharmacy filled this drug cocktail for K.B.2 13 times between January 13, 2014, and March 26, 2014. RD, at 45 (citing GX 18, at 11-98). He further noted that "[a]lthough K.B.2 would normally receive his prescriptions for these three controlled substances on the same day, he would frequently present the prescriptions to the Pharmacy within a two or three day time frame." RD, at 45 (citing *e.g.*, GX 18, at 11-16, 17-22, 27-32, 33-38, 39-44, 45-50, 77-82, 93-98). Respondents' Owner and PIC also filled prescriptions for morphine sulfate and diazepam on June 10, 2014. RD, at 45 (citing GX 18, at 41-44).

The patient's profile notes that on April 15, 2013[55], Respondent Pharmacy received a letter of medical necessity from Dr. P. GX 18, at 99. The letter describes K.B.2's chronic pain and spine injuries and provides an MRI performed on July 30, 2012. *Id.* at 101. Dr. Gordon testified that nothing in the file, including the letter and MRI, resolves the red flags. Tr. 164-166. She stated, "It's the distance. Why is somebody

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[54] The ALJ noted, and I agree, that although the Government did not allege the drug cocktails in the OSC for K.B.2, they were noticed in the prehearing statement. RD, at 45 n.23; Govt Prehearing, at 16.

[55] The letter predates by several months any of the prescriptions in the Government's records; however, Respondent submitted evidence that it had been filling similar prescriptions for K.B.2 since November 2011. GX 18, at 100; GX 18, at 1; RX H, at 324.

taking a long-acting opioid, immediate-release acting opioid, and Valium driving so far?"[56] *Id.* at 165.[57]

h. A.G.

From December 20, 2013, to March 20, 2015, Respondent Pharmacy filled prescriptions for patient A.G., whose address on the fill stickers[58] was listed as Indian Harbor, Florida, which was 65 miles from the prescriber in Orlando, Florida. GX 19, at 1-68; RD, at 46 (citing Stipulation 39). Dr. Gordon testified that these prescriptions raised multiple red flags, including the fact that two immediate-release opioids were prescribed and dispensed at the same time, the distance traveled to the prescriber, and paying for prescriptions with cash. Tr. 167-168; RD, at 46. Respondents' Owner and PIC filled prescriptions for A.G. for oxycodone and hydromorphone on February 21, 2014. RD, at 46 (citing GX 19, at 9-12). The ALJ concluded that Respondent Pharmacy filled the two immediate-release

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[56] The ALJ found, and I agree, that there was no evidence demonstrating that the patients themselves were driving their cars, but whether or not the patient was driving the car, the distances had to be traveled by some mode of transportation in order to obtain the prescriptions. Tr. 165. Further, I credit Dr. Gordon's testimony that traveling a long distance with lower back pain is a red flag. Tr. 98.

[57] Dr. Gordon's testimony did not include a specific conclusion regarding corresponding responsibility for K.B.2; however, I find that the record is clear that the red flags are the same as the other patients' prescriptions and therefore I draw the conclusion that these were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility.

[58] There is no address on the prescriptions. GX 19.

opioids 17 times between December 20, 2013, and March 20, 2015. RD, at 46 (citing GX 19, at 1-68). The OSC alleged that A.G. presented both prescriptions every 28 days based on his 28-day prescription for hydromorphone, even though his prescription for 5 oxycodone tablets a day was for a 30-day supply.[59] OSC, at 8; RD, at 46 (citing GX 19, at 13-60). Therefore, the ALJ concluded, and I agree, that between March 21, 2014, and January 23, 2015, A.G. filled the oxycodone prescription early 11 times with 2 days of 5 tablets each amounting to 10 tablets extra each fill, and as a result, had received an extra 110 tablets of oxycodone over what had been prescribed. RD, at 46 (citing GX 19, at 19-20, 23-24, 27-28, 31-32, 34-36, 39-40, 43-44, 47-50, 55-58). Dr. Gordon testified that two days early she would let go, but she would not be willing to fill for a patient two days early repetitively. Tr. 233. Dr. Grant testified that "after a long period of time. . . . There would be a considerable amount. But I don't know until I have the conversation." Tr. 510. He further testified that repeatedly filling a prescription two days early would require a conversation first with the patient and then with the prescriber. Tr. 510. Therefore, I agree with the ALJ that the record supports that the repeated filling of these prescriptions , constituted an early refill and in accordance with the testimony of Respondents' Owner

[59] The oxycodone prescription was for 150 tablets of oxycodone 30 milligrams to be taken 5 times a day. GX 19, at 14. Therefore, filling the prescription in full every 28 days resulted in A.G. receiving two days extra of tablets of oxycodone.

and PIC, an early refill is a red flag. Tr. 727. There is no evidence that this red flag was resolved.[60]

The patient's profile notes a March 22, 2014, letter of medical necessity from Dr. K,[61] four months after Respondent Pharmacy began filling A.G.'s prescriptions. GX 19, at 69. The letter stated that it was necessary for A.G. to use this medication, but did not identify the type of medication. GX 19, at 70; RX H, at 334. Dr. Gordon testified that nothing in the file resolves the red flags and the treatment plan "does not address why there's two—why the need for two immediate-release opioids, because that doesn't make any pharmacological sense." Tr. 168-69; 171. Further, Dr. Gordon stated that the MRI that was included for A.G. raised additional questions, because it was from 2011 and was "dated." Tr. 305. She concluded that the prescriptions dispensed to A.G. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id*. at 169.

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[60] Although I agree with the ALJ that these early fills were a red flag, I find that the other red flags for A.G. were egregious enough to demonstrate that filling his prescriptions violated the pharmacist's corresponding responsibility.

[61] Dr. Gordon remarked that Dr. K's residency was an OB-GYN and that a pharmacist should look up a practitioner's credentials where there is a red flag. Tr. 168, 177. She further explained in relation to other patients of this doctor that she thought that the education of the doctor as an OB-GYN was a red flag, because she "didn't specialize in pain management." *Id.* at 177. Although I accept Dr. Gordon's rationale as to why the doctor's education is a red flag, her practice at the time of the prescriptions was clearly in pain management, and therefore, I am not relying on this possible red flag in my final determination. *See* GX 19, at 70.

i. K.B.1 and C.K.

Respondent Pharmacy filled prescriptions for patients K.B.1 and C.K., whose prescriptions lack addresses. GX 20. The address on fill stickers for K.B.1 was listed as Malabar, Florida, which is 73 miles from the prescriber in Orlando, and the address for C.K. is listed as Cocoa Beach, Florida, which is 51 miles from the same prescriber. GX 20, at 1-64; RD, at 47 (citing Stipulations 40 and 42). Dr. Gordon testified that these prescriptions raised multiple red flags, including the type of medication being a commonly sought-after opioid (oxycodone) of the highest dosage,[62] the distance traveled to the prescriber, and paying for prescriptions with cash. Tr. 172-175; RD, at 47. Furthermore, Dr. Gordon pointed out that these two patients obtained their prescriptions from the same provider on the same date, so it "seems this was a group, a small group of two going to the same doctor on the same date and filling similar prescriptions." Tr. 173. Further, on March 31, 2015, K.B.1 and C.K. filled a prescriptions for oxycodone prescribed on the same day from Dr. K. with sequential fill numbers. GX 20, at 29-30, 64-65; Tr. 173-174. The ALJ further found that Respondent Pharmacy filled prescriptions for "these two individuals on the same day 14 times between April 1, 2014, and March 31, 2015." RD, at 48; (citing GX 20, at 3-30, 37-64).[63]

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[62] The ALJ noted and I agree that initially the prescription for K.B.1 was for 15 mg of oxycodone, but it was increased to 30 mg on September 16, 2014. RD, at 47 n.25 (citing GX 20, at 3-4, 15-16).

[63] Although Respondents argued that the Government had not presented evidence that the two patients were visiting Respondent Pharmacy as a group, Respondents' Owner and PIC testified

Respondents' Owner and PIC filled two prescriptions for oxycodone for these two patients one minute apart on May 28, 2014, and November 11, 2014. RD, at 48 (citing GX 20, at 7-8, 41-42, 19-20, 53-54).

The patient's profile for C.K. notes an April 15, 2013, letter of medical necessity from Dr. K. GX 20, at 67. The letter seemed to be in response to a letter from Respondent Pharmacy requesting medical necessity, because it was attached to the letter, and it referred to an attached MRI, which was not in the file. GX 20, at 68-69. The patient's profile for K.B.1 notes receipt of a letter of medical necessity on April 1, 2014, which gives his diagnosis and does not identify the medication. *Id.* at 65. Dr. Gordon testified that nothing in the file resolves the red flags. Tr. 174-76. She concluded that the prescriptions dispensed to C.K. and K.B.1 were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility in dispensing these prescriptions. *Id.* at 175-76.

j. J.M. and M.M.

Respondent Pharmacy filled prescriptions for patients J.M. and M.M., whose prescriptions lack addresses, but the address on fill stickers for both patients was listed as Satellite Beach, Florida, which

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that "I don't know why they would come in at the same time. But in recollection, they do, I think they do know each other, but I don't know the relationship." Tr. At 671; Resp Posthearing, at 34. Respondents' Owner and PIC testified that she could resolve the red flag of coming in together "by handling them individually." Tr. 672. However, Dr. Gordon testified that the red flag was presented by the fact that they were a group—handling them individually would ignore the red flag entirely.

is about 65 miles from Dr. K., the prescriber, in Orlando. GX 21, at 1-42; RD, at 49 (citing Stipulations 46-47). Dr. Gordon testified that these prescriptions raised multiple red flags, including the medication, the distance traveled to the prescriber, drug cocktails of Xanax and oxycodone and carisoprodol and oxycodone and that the doctor's education was not in pain management, but OB-GYN.[64] Tr. 177-80; RD, at 49. The OSC also alleged and the evidence clearly supports that "M.M. always sought to pay cash for the prescriptions and J.M. occasionally sought to pay cash." OSC, at 8. Dr. Gordon also identified a red flag in that the records show a group of patients "going to the same doctor on the same day and then going to the pharmacy and getting their medications dispensed on the same day." Tr. 178. The ALJ further found that Respondent Pharmacy filled prescriptions for "these two individuals on the same day 15 times between January 7, 2014, and March 31, 2015." RD, at 49 (citing GX 21, at 3-30, 37-64). It is noted also that these individuals were coming in sequentially during the same timeframe as the C.K. and K.B.1 and all four were patients of Dr. K. The ALJ further found that "many times the prescriptions [sic] numbers on the fill stickers were sequentially only one number apart, and other times they were separated only by a few numbers, and the prescriptions were frequently picked up within minutes of each other." *Id.* (citing GX 21, at 1-12, 15-30, 33-36, 39-42, 57-60, 63-66, 69-76, 79-82, 85-88, 95-102, 105-116, 119-22, 129-32, 135-38; RX H, at 419). Respondents' Owner and PIC filled sequential prescriptions for oxycodone for these two patients on

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[64] As explained above, I am not considering the doctor's training as a red flag.

January 7, 2014, May 27, 2014, July 22, 2014, December 9, 2014, January 6, 2015, March 3, 2015, and March 31, 2015. RD, at 48 (citing GX 21, at 1-4, 23-26, 33-36, 63-66, 69-72, 79-82, 85-88, 109-12, 135-38.). These prescriptions were dropped off within minutes of each other and the fill numbers were in sequence in all but one instance. *Id.* Additionally, the majority of the prescriptions that Respondent Pharmacy filled for these two patients were for drug cocktails of oxycodone and Soma, and oxycodone and Xanax. RD, at 48-49. Respondents' Owner and PIC filled drug cocktail prescriptions for these two patients on January 7, 2014, May 27, 2014, July 22, 2014, December 9, 2014, January 6, 2015, March 3, 2015, and March 31, 2015. *Id.* (citing GX 21, at 3-4, 89-90, 25-26, 103-04, 33-34, 111-12, 35-36, 109-10, 63-64, 127-28, 65-66, 125-26, 69-70, 133-34, 79-80, 137-38, 81-82, 135-36, 87-88, 139-40).

The patient's profile for J.M. notes a March 29, 2013 letter of medical necessity from Dr. K. GX 21, at 143. The letter states that Dr. K. "feels it medically necessary to prescribe Roxicodone 15 mg" and attaches an MRI stating Lumber IVD degeneration. *Id.* at 144-45. The patient's profile for M.M. notes receipt of a letter of medical necessity on March 14, 2013, which gives his diagnosis and attaches an MRI of his ankle showing mild-to-moderate arthritis and mild synovitis/arthritis in his elbow. *Id.* at 147-49. Dr. Gordon testified that nothing in the file resolves the red flags. Tr. 181-82. She testified that the file contained a drug test for M.M., "which is "[g]etting better," but the ALJ noted, and I agree, that it is unclear what the drug test indicates as a "pass." *Id.* Dr. Gordon concluded that the prescriptions dispensed to J.M

and M.M. were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility. *Id.* at 183-84.

k. H.B.

From November 27, 2013, to March 31, 2015, Respondent Pharmacy filled prescriptions for patient H.B. whose address on some of the fill stickers[65] was listed as Melbourne, Florida, which was approximately 54 miles from multiple prescribers in Orlando, Florida.[66] GX 22, at 1-122; RD, at 51 (citing Stipulation 48). Dr. Gordon testified that these prescriptions raised multiple red flags. Tr. 185-190. She testified

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[65] As the ALJ remarked, "[i]t is unclear where H.B. actually lived, because [GX] 22 reports several different addresses;" however, the OSC did not contain any allegations regarding H.B.'s address. RD, at 51; *see* GX 22.

[66] Respondents noted that, "[O]n February 3, 2015, the patient transferred to another provider" who prescribed the same medication and whose office was within Respondent Pharmacy's county. Resp Posthearing, at 37 (citing GX 22, at 109). It is noted that the prescriptions written on February 3, 2015, March 3, 2015, March 31, 2015, appear to be written from a different physician in Merritt Island, FL, which does not pose the same distance concern from the pharmacy or residence. (GX 22, at 109, 111, 113). Respondents note that the new doctor prescribed H.B. Oxycodone 30 mg., "the same medication prescribed by Dr. [S.] on previous occasions;" however, Dr. S. notably did not prescribe the duplicative prescriptions of oxycodone that H.B. had received previously. RX H, at 435; Resp Posthearing, at 37. Furthermore, although I find that the prescriptions on March 3, 2015, and March 31, 2015, do not present the red flag of distance traveled or therapeutic duplication, the red flag of drug cocktail remained unresolved, and the February 3, 2015 prescriptions were for a drug cocktail and one was refilled early.

that H.B. was receiving "uppers and downers" including Adderall, which is an amphetamine and central nervous system (hereinafter, CNS) depressant, and a red flag was "the necessity for Ambien and Xanax at the same time. Both suppress the CNS system." *Id.* at 185. She stated that the combination of an amphetamine with a depressant is contraindicated, "because one suppresses the central nervous system and one stimulates the central nervous system. They're working against each other." *Id.* at 189. Further, Dr. Gordon noted that a doctor in Orlando was prescribing H.B. oxycodone and the distance traveled was a red flag. *Id.* at 186. H.B. was also obtaining prescriptions for both 15 mg. and 30 mg. of oxycodone at the same time, which Dr. Gordon testified is "called therapeutic duplication." *Id.* at 186-87. Dr. Gordon testified that H.B. was also receiving the highest dose of Ambien, "[s]o on top of the Xanax and on top of the oxys, it's just a dangerous combination. Cocktail." *Id.* at 187. The ALJ found that Respondents' Owner and PIC filled prescriptions constituting therapeutic duplication on July 1, 2014, and one[67] of the two prescriptions constituting therapeutic duplication on September 23, 2014. RD, at 51 (citing GX 22, at 15-26, 49-52, 71-72). She also filled one of the two prescriptions constituting therapeutic duplication on May 8, 2014—the other was dispensed on May 7, 2014. GX 22, at 41 and 40.

I agree with the ALJ's findings that Respondent Pharmacy filled multiple drug cocktails for H.B.

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[67] The ALJ noted and I agree that it appears that B.S. filled the other duplicative prescription. RD, at 51 n.32.

between February 12 and February 20, 2014, for oxycodone, Xanax, and Ambien, on March 12, 2014, for two prescriptions of oxycodone and one of Adderall, and on February 3, 2015, for oxycodone and Soma. RD, at 52 (citing Tr. 187-90; GX 22, at 15-18, 21-26, 28-32, 109-112).

The OSC alleged that H.B. also received early refills. OSC, at 9. The ALJ found, and I agree, that H.B. received early refills: on February 12, 2014, for Adderall, after having received a 30-day supply on January 31, 2014; on February 20, 2014, for alprazolam, after having received a 30-day supply on February 12, 2014; and on February 3, 2015, after having received a 30-day supply on January 13, 2015. RD, at 51-52 (citing GX 22, at 13-14, 19-20, 21-22, 25-26, 107-10). Respondents' Owner and PIC admitted that a fill with a similar timeframe was an early fill and that an early fill was a red flag. *See supra* Section II(G)(2)(k) (citing Tr. 727).

The records for H.B. include two letters of medical necessity for H.B. GX 22, at 124-25. The letter from Mid Florida Health stated that it was necessary for H.B. to have her medications, but did not identify the type of medication, nor was it clear which prescriptions in H.B.'s file originated from this practice. GX 22, at 124. The other letter is an unsigned form letter from Dr. S. describing office diversion protections with H.B.'s name and her diagnosis as a "lumber tear" and "lumbago," but does not, as the ALJ pointed out, explain why it was necessary to have the medications or what they were. Dr. Gordon testified that nothing in the file resolved the red flags. Tr. 190. Dr. Gordon also stated that she "didn't see any documentation that showed that the pharmacy contacted one doctor

and told them what was going on with the other doctor," which would be done under the normal standard of practice. *Id.* at 189.[68]

Based on all of the record evidence, I find that the prescriptions for J.C., M.B., C.A., D.B., J.D., K.B.3, K.B.2, A.G., K.B.1, C.K, J.M., M.M., H.B. raised red flags, because customers arrived in groups, purchased prescriptions with cash, traveled long distances, refilled their prescriptions early, and because the prescriptions were for highly sought after controlled substances at highest strengths. I further find that the letters of medical necessity in Respondents' files did not resolve the multiple red flags on these prescriptions and that, even if these red flags were resolvable, Respondent Pharmacy produced no contemporaneous documentary evidence to support its claim that it resolved them before it filled the prescriptions.

H. Relationship Between Respondent Pharmacy and Respondent LLC

The OSC was addressed to both Respondent Pharmacy and Respondent LLC, but the allegations in the OSC relate only to the actions of Respondent Pharmacy, and not Respondent LLC.[69] OSC, at 1;

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[68] Dr. Gordon's testimony did not include a specific conclusion regarding corresponding responsibility for H.B.; however, I find that the record is clear that the red flags are the same as the other patients' prescriptions and therefore I draw the conclusion that these were not dispensed within the usual course of professional practice and the pharmacist did not fulfill his or her corresponding responsibility.

[69] Respondents also argue that the claims against Respondent LLC should be "dismissed as a matter of law for lack of notice." Resp Posthearing, at 77. The OSC clearly is addressed to both

RD, at 100; Resp Posthearing, at 77. However, the ALJ found, and I agree, that Respondents are "essentially one and the same." RD, at 100. In particular, Respondent Pharmacy and Respondent LLC share the same Owner and PIC.[70] RD, at 52 (citing Tr. 337-43; 345-46; 348-52, 356; GX 27[71], 28). The DI testified that, although Respondents have separate doors, they share a lobby entrance, entering either door allows access to either business, and they are "separated by a partition wall which comes approximately three-quarters of the way up through the business but stops just shy of the lobby." Tr. 347; RD, at 52. Further he testified that "the offices in the back seem to be collocated," and that "during the execution of the admin warrant, the computer that [DEA was] using to access [Respondent Pharmacy's] data was located

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Respondents and the hearing proceeded with the consent of the Respondents to consolidate the two cases; therefore, I find this argument meritless.

[70] Records from the Florida Health Department show Respondents' Owner and PIC as the Supervising Pharmacist for both Respondents. GX 27, at 8-9; GX 28, at 8-9; Tr. 350-51. Additionally, she is listed as the point of contact on both DEA registrations. GX 27, at 1; GX 28, at 1; Tr. 338-39.

[71] Respondents' counsel objected to Page 2 of GX 27, because he noted that it cannot be considered a business record due to its inclusion of notes related to the investigation. Tr. 363. This part of the exhibit was produced only to demonstrate that Respondents' Owner and PIC was listed as the point of contact for both DEA registrations. Respondents' Owner and PIC testified that she was "the sole owner of both;" and the record does not reflect that there is any dispute of fact about the Respondents' Owner and PIC's ownership of both entities, to which she, herself, attested. Tr. 529.

on the [Respondent LLC] side of the wall in an office." Tr. 347.

The DI testified that he had confirmed through Florida Department of Revenue that M.P. was the only employee of Respondent LLC during the last two quarters of 2016. Tr. 354-55; RD, at 53. M.P. testified that he is the Manager of Respondent LLC and his boss is Respondents' Owner and PIC. Tr. 409-410. M.P. also handles human resources, discipline, interviewing, and payroll for Respondent Pharmacy, but he considers himself to be employed by Respondent LLC, because he is paid out of its funds.[72] *Id.* at 395, 404, 410; RD, at 53. Additionally, M.P. has been engaged in "managing marketing, and developing [Respondent Pharmacy] for over nine years" and he is the senior individual in both Respondents other than the Respondents' Owner and PIC. GX 30, at 8; Tr. 395, 416.

The DI testified that he inquired with Respondents' supplier and Respondent LLC had never purchased any controlled substances under its DEA registration;

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[72] M.P. testified that he had "never been employed by Respondent Pharmacy," but to the extent that his statements were intended to demonstrate that he lacked authority over Respondent Pharmacy or support the notion that the two entities were distinct, I do not find his testimony to be credible. Tr. 395. He admitted that he was basing his definition of employment only on the origin of his paycheck. *Id.* He also admitted that he identified himself as the manager of Respondent Pharmacy on the Notice of Inspection. *Id.* at 320; GX 32. I do not find that the information related to which of Respondents employed M.P. to be relevant to the underlying issues in this case, because I do not find that the Government unlawfully searched Respondent Pharmacy. *See infra* III(B)(1).

therefore, the ALJ concluded, and I agree, that Respondent LLC "does not handle controlled substances." RD, at 53; Tr. 356.

III. Discussion

A. Allegation that Respondents' Registrations Are Inconsistent with the Public Interest

Under Section 304 of the Controlled Substances Act (hereinafter, CSA), "[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. § 824(a)(4). In the case of a "practitioner," defined in 21 U.S.C. § 802(21) to include a "pharmacy," Congress directed the Attorney General to consider the following factors in making the public interest determination:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing . . . controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the . . . distribution[] or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823(f). These factors are considered in the disjunctive. *Robert A. Leslie, M.D.*, 68 Fed. Reg. 15,227, 15,230 (2003).

According to Agency decisions, I "may rely on any one or a combination of factors and may give each factor the weight [I] deem[] appropriate in determining whether" to revoke a registration. *Id.*; *see also Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi v. Drug Enf't Admin.*, 841 F.3d 707, 711 (6th Cir. 2016); *MacKay v. Drug Enf't Admin.*, 664 F.3d 808, 816 (10th Cir. 2011); *Volkman v. U. S. Drug Enf't Admin.*, 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie v. Drug Enf't Admin.*, 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I "need not make explicit findings as to each one." *MacKay,* 664 F.3d at 816 (quoting *Volkman*, 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482. "In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct." *Jayam Krishna-Iyer, M.D.*, 74 Fed. Reg. 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

Under DEA's regulation, "[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied." 21 C.F.R. § 1301.44(e). In this matter, while I have considered all of the factors, the

Government's evidence in support of its *prima facie* case is confined to Factors Two and Four.[73] I find that the Government's evidence with respect to Two and Four satisfies its *prima facie* burden of showing that Respondents' continued registrations would be "inconsistent with the public interest." 21 U.S.C. § 824(a)(4). I further find that Respondents failed to produce sufficient evidence to rebut the Government's *prima facie* case.

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[73] Respondents note that the Florida Board of Pharmacy has not made a recommendation in this matter, nor have the Respondents been convicted of any state or federal crimes related to controlled substances. Resp Posthearing, at 50. As Respondents have noted, the record in this case contains no evidence of a recommendation regarding Respondent Pharmacy's privilege to operate as a pharmacy by the relevant state licensing board or professional disciplinary authority or any action by the state licensing board that demonstrates that it has considered the same facts in relation to Respondent Pharmacy's continued licensure. *See John O. Dimowo*, 85 Fed. Reg. 15,800, 15,809 (2020). Prior Agency decisions have found that where the record contains no evidence of a recommendation by a state licensing board, that absence does not weigh for or against revocation. *See, e.g.*, *Ajay S. Ahuja, M.D.*, 84 Fed. Reg. 5479, 5490 (2019) (finding that "where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation."); *Holiday CVS LLC dba CVS Pharmacy Nos 219 and 5195*, 77 Fed. Reg. 62,316, 62,340 (2012); *Roni Dreszer, M.D.*, 76 Fed. Reg. 19,434, 19,444 (2011). Accordingly, I agree with the ALJ's finding that Factor One does not weigh for or against revocation in this matter. RD, at 61. I also agree with the ALJ that, because there is no evidence related to any convictions "relating to the manufacture, distribution, or dispensing of controlled substances," Factor Three does not weigh for or against revocation in this case. RD, at 61 (citing 21 § U.S.C. 823(f)(3)).

1. Factors Two and Four–The Respondents' Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

Under the CSA, it is "unlawful for any person knowingly or intentionally . . . to . . . distribute[] or dispense, or possess with intent to . . . distribute[] or dispense, a controlled substance" "except as authorized" by the Act. 21 U.S.C. § 841(a)(1). A pharmacy's registration authorizes it to "dispense," or "deliver controlled substance to an ultimate user . . . by, or pursuant to the lawful order of . . . a practitioner." 21 U.S.C. § 802(10).

(a) Allegations Regarding Respondent Pharmacy's Failure to Exercise Its Corresponding Responsibility

According to the CSA's implementing regulations, an effective controlled substance prescription is one that is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). While the "responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, . . . a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.* The regulations establish the parameters of the pharmacy's corresponding responsibility.

> An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of . . . 21 U.S.C. § 829 . . . and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Id. "The language in 21 C.F.R. § 1306.04 and caselaw could not be more explicit. A pharmacist has his own responsibility to ensure that controlled substances are not dispensed for non-medical reasons." *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy*, 55 Fed. Reg. 4729, 4730 (1990) (citing United *States v. Hayes*, 595 F.2d 258 (5th Cir. 1979), *cert. denied*, 444 U.S. 866 (1979); *United States v. Henry*, 727 F.2d 1373 (5th Cir. 1984) (reversed on other grounds)). As the Supreme Court explained in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, "the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006).

The evidence in this case demonstrates that Respondent Pharmacy filled prescriptions from a group of Dr. R's patients repeatedly "at approximately the same time, one after the other." RD, at 71; *supra* Section (II)(G)(1)(a). Dr. Gordon testified that these red flags are not resolvable and she would not have filled the

prescriptions. *Id.*; Tr. 111. The record demonstrates numerous red flags associated with the prescriptions issued to patients of Dr. R. For example, S.P. and E.H. made a 340 and 350 mile-round trip respectively to see Dr. R. and received the highest dosage of opioids and paid cash. RD, at 72; *supra* Section (II)(G)(1)(a), (e). In addition, J.S.1 and J.S.2 lived at the same address, received their prescriptions often on the same day for highly diverted and abused controlled substances, and travelled long distances. RD, at 75. In accordance with the testimony of Dr. Gordon, these prescriptions should not have been filled and Respondent Pharmacy violated its corresponding responsibility in filling them. Further, the ALJ found, and I agree, that nothing in Respondent Pharmacy's files resolved any of the red flags for the prescriptions for the patients of Dr. R., where they may have been resolvable, and Respondent Pharmacy violated its corresponding responsibility by filling the prescriptions in the Government's evidence for Dr. R.'s patients. RD, at 71-80; *supra* Section (II)(G)(1).

Further, the evidence shows that Respondent Pharmacy filled prescriptions written by other physicians that contained multiple red flags indicating that the prescriptions were not issued for a legitimate medical purpose. J.C. presented five prescriptions for the same short-acting opioid and the doctor's instructions allowed J.C. to be taking all of them at once. Dr. Gordon testified that she would not have filled these prescriptions. Respondents' Owner and PIC offered two different justifications for filling them. There is nothing in Respondent Pharmacy's records that resolves the red flags and Respondents' post-hoc justification is inconsistent, which clearly demonstrates that her memory

of events is not adequate to determine whether the red flags were resolved. Section (II)(G)(2)(a). The prescriptions that Respondent Pharmacy filled for M.B. raised unresolved red flags for highly abused opioids and cocktails, payment by cash, long distances to obtain and fill prescriptions, and high dosages. Finally, the ALJ found, and I agree, that Respondent Pharmacy filled prescriptions for C.A., D.B., J.D., K.B.3, K.B.2, and A.G. in violation of its corresponding responsibility and outside the course of professional practice of pharmacies, because the numerous red flags of highly diverted and abused controlled substances, distance travelled, cash payments, early refills, and cocktails were unresolved.

To prove a pharmacist violated his corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. *See* 21 C.F.R. § 1306.04(a) ("[T]he person *knowingly* filling [a prescription issued not in the usual course of professional treatment] . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.") (emphasis added). DEA has also consistently interpreted the corresponding responsibility regulation such that "[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription." *Bertolino*, 55 Fed. Reg. at 4730 (citations omitted); *see also JM Pharmacy Group, Inc. d/b/a Pharmacia Nueva and Best Pharmacy Corp.*, 80 Fed. Reg. 28,667, 28,670-72 (2015) (applying the standard of willful blindness in assessing whether a pharmacist acted with the requisite sci-

enter). Pursuant to their corresponding responsibility, pharmacists must exercise "common sense and professional judgment" when filling a prescription issued by a physician. *Bertolino*, 55 Fed. Reg. at 4730. When a pharmacist's suspicions are aroused by a red flag, the pharmacist must question the prescription and, if unable to resolve the red flag, refuse to fill the prescription. *Id.*; *Medicine Shoppe-Jonesborough*, 300 F. App'x 409, 412 (6th Cir. 2008) ("When pharmacists' suspicions are aroused as reasonable professionals, they must at least verify the prescription's propriety, and if not satisfied by the answer they must refuse to dispense.").

In this matter, the Government did not allege that Respondent dispensed the subject prescriptions having actual knowledge that the prescriptions lacked a legitimate medical purpose. Instead, the Government alleged that Respondent violated the corresponding responsibility regulation as evidenced by it "repeatedly distribut[ing] controlled substances pursuant to prescriptions that contained one or more unresolved red flags for diversion." Govt Posthearing, at 41.

As I already found, many prescriptions from Respondent Pharmacy presented multiple, red flags including long distances, cash payments, drug cocktails, high doses/quantities of high-alert controlled substances, patients with the same address presenting the same prescription within a short period of time, patients sequentially presenting prescriptions prescribed by the same doctor on the same day, therapeutic duplication (two drugs in the same class prescribed together), and early refills. Agency decisions have consistently found that prescriptions with the same red flags at issue here were so suspicious as to support

a finding that the pharmacists who filled them violated the Agency's corresponding responsibility rule due to actual knowledge of, or willful blindness to, the prescriptions' illegitimacy. 21 C.F.R. § 1306.04(a); *see, e.g., Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy*, 83 Fed. Reg. 10,876, 10,898, *pet. for rev. denied*, 789 F. App'x 724 (11th Cir. 2019) (long distances; pattern prescribing; customers with the same street address presenting the same prescriptions on the same day; drug cocktails; cash payments; early refills); *Hills Pharmacy*, 81 Fed. Reg. 49,816, 49,836-39 (2016) (multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting similar prescriptions on the same day; long distances; drug cocktails); *The Medicine Shoppe*, 79 Fed. Reg. 59,504, 59,507, 59,512-13 (2014) (unusually large quantity of a controlled substance; pattern prescribing; irregular dosing instructions; drug cocktails); *Holiday CVS*, 77 Fed. Reg. 62,316, 62,317-22 (2012) (long distances; multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting virtually the same prescriptions within a short time span; payment by cash); *East Main Street Pharmacy*, 75 Fed. Reg. 66,149, 66,163-65 (2010) (long distances; lack of individualized therapy or dosing; drug cocktails; early fills/refills; other pharmacies' refusals to fill the prescriptions). Dr. Gordon credibly testified as to the presence of red flags on the prescriptions that Respondent Pharmacy filled. Respondents' Owner and PIC also testified that she recognized red flags on the prescriptions.

I agree with the ALJ that Respondent Pharmacy "repeatedly filled numerous prescriptions for highly abused and diverted controlled substances in the face of blatant red flags. The Pharmacy did little to nothing to resolve these numerous red flags, but instead relied on 'rubber stamped' types of letters of medical necessity that were often not tailored towards a particular patient, and were obviously missing information." RD, at 97. When asked by Respondents' counsel if she "believe[d] pharmacists can make decisions about the treatment of patients' medical conditions," Dr. Gordon testified, "Pharmacists are part of the medical care team. We're there, we're the stop gate to make sure that that patient is safe and taking a medication that's appropriate for them." Tr. 217. The evidence in this case shows that Respondent Pharmacy failed at the responsibility described by Dr. Gordon.

Dr. Gordon credibly testified that a Florida pharmacist should have recognized these red flags and that a Florida pharmacist exercising his or her corresponding responsibility would not dispense controlled substances without investigating, documenting the investigation, and resolving any red flags. Respondents' Owner and PIC also admitted during her testimony that she had actual knowledge of some of the red flags on the prescriptions, but that she felt like she had resolved them.

I have considered and reject Respondent Pharmacy's claim that it investigated and resolved the red flags on the subject prescriptions before they were filled and therefore complied with its corresponding responsibility. Tr. 796. Respondents' Owner and PIC testified that she relied on written policies

and procedures that she stated Respondent Pharmacy had in place, which by virtue of being followed would have resolved the red flags prior to dispensing; however, Respondent Pharmacy produced neither the procedures themselves[74] nor any evidence that, if they had been in place, they had been followed. For example, she stated that payment of cash is not a red flag because Respondent Pharmacy's policy was to ask for insurance from every customer, and then concluded that if a customer paid cash, it was a result of a negative answer regarding insurance, thereby resolving the red flag. Tr. 719. She stated that she is not assuming it happened, because "it is the policy." *Id.* However, despite the policies that she so strongly asserted were in place, according to her testimony, B.S. filled dozens of prescriptions in violation of those policies and had to be counseled. *Id.* at 560, 770. In addition, she admitted to making exceptions to the policies herself without documenting her rationale for the departures. Tr. 773. The pre-

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[74] Respondents contest that requiring them to document their resolutions of red flags is inappropriately "requiring Respondents to prove their innocence." Resp Exceptions, at 17. The Government in this case demonstrated that the standard of practice in Florida required documentation of the resolution of red flags and Respondent Pharmacy did not document. The Government proved that Respondent Pharmacy repeatedly filled multiple prescriptions with red flags demonstrating that Respondent Pharmacy had violated its corresponding responsibility and that Respondent Pharmacy's registration is inconsistent with the public interest. The burden shifts to the Respondents to show why they can be entrusted with the responsibility carried by their registrations. *Garrett Howard Smith, M.D.*, 83 Fed. Reg. 18,882, 18,910 (2018) (citing *Samuel S. Jackson*, 72 Fed. Reg. 23,848, 23,853 (2007)).

scriptions or patient profiles from Respondent Pharmacy do not contain pharmacist remarks regarding the resolution of red flags on the prescriptions, and Dr. Gordon testified that the letters from the prescribers, which were often issued after controlled substances had already been dispensed, did not adequately resolve the red flags. *See United States v. Hayes*, 595 F.2d at 260 ("Verification by the issuing practitioner on request of the pharmacist is evidence that the pharmacist lacks knowledge that the prescription was issued outside the scope of professional practice. But it is not an insurance policy against a fact finder's concluding that the pharmacist had the requisite knowledge despite a purported but false verification. . . . What is required by [a pharmacist] is the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute because he knows that the issuing practitioner issued it outside the scope of medical practice."). Furthermore, Dr. Gordon credibly testified that some of the prescriptions, particularly to groups of Dr. R.'s patients, contained red flags that were not resolvable and the prescriptions should not have been filled. *Id.* at 110-11. Finally, I agree with the ALJ that Respondents' Owner and PIC's testimony was not always credible, particularly where she exaggerated her relationship with her customers in order to suggest that she had resolved red flags. RD, at 13-14.

Respondents further contest that when Respondents' Owner and PIC was confronted with one employee, B.S., who "exercised his own independent judgment and filled prescriptions from South Florida, she halted the practice and counseled the employee."

Resp Posthearing, at 52. Although Respondents' Owner and PIC stated that, although she had no personal knowledge that the prescriptions were legitimate, she thought that Dr. R. was legitimate, but she also stated that she had counseled B.S., "because we don't want the scrutiny of it." *Id.* at 560, 770, 557; RX H, at 62. She clearly understood that there was a high probability that the prescriptions were illegitimate due to the red flags that they presented and that they suggested the need for "scrutiny." Yet in filling the prescriptions, neither she nor B.S. provided any documentation regarding the "scrutiny" that the prescriptions presented. As stated above, she also testified that she, herself, filled Dr. R.'s prescriptions twice. Tr. 771; 560.

Further, I reject the insinuation that Respondent Pharmacy should not be held responsible for the actions of its pharmacist B.S. When considering whether a pharmacy has violated its corresponding responsibility, the Agency considers whether the entity, not the pharmacist, can be charged with the requisite knowledge. *See Pharmboy Ventures Unlimited, Inc.*, 77 Fed. Reg. 33,770, 33,772 n.2 (2012) ("DEA has long held that it can look behind a pharmacy's ownership structure 'to determine who makes decisions concerning the controlled substance business of a pharmacy.'"); *S&S Pharmacy, Inc.*, 46 Fed. Reg. 13,051, 13,052 (1981) (the corporate pharmacy acts through the agency of its PIC). Knowledge obtained by the pharmacists and other employees acting within the scope of their employment may be imputed to the pharmacy itself.

At times during her testimony, Respondents' Owner and PIC stated that she relied on the personal judgment of her pharmacists, while also stating that

the pharmacy's policy is "updated regularly, but it's generally just a day-to-day hands-on training. I'm there all the time." Tr. 709. Ultimately, as the Owner and PIC, she is responsible for the actions of Respondents, and her own statements support that notion. She chose to hire someone while knowing that he had a criminal history and Board of Pharmacy disciplinary history, she had the means to meaningfully supervise his work because she was present at Respondent Pharmacy "all the time," and further, as the individual responsible for the entity, she had a duty[75] to ensure that the pharmacists she employed, while acting in the scope of their employment, were

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[75] I reject Respondents' claim that imposing a duty on its pharmacists to ensure that they were meeting their corresponding responsibility would violate Florida Rule 64B16-27.831(2)(a), which provides that "'[w]hen validating a prescription, neither a person nor a licensee shall interfere with the exercise of the pharmacist's independent professional judgment.'" Resp Posthearing, at 69 (quoting Fl. Admin Code Ann. r. 64B16-27.831(2)(a)). There is no evidence that the State of Florida's provision would prevent an employer from ensuring that an employee was resolving and documenting red flags. The judgment in question is resolving "any concerns about the validity of the prescription," not complying with pharmacy policies, to include documenting the pharmacist's rationale for deciding to fill a prescription whose legitimacy was in question. *Id.* In fact, the regulation itself requires that the pharmacist resolve the concerns. *Id.* I decline to permit Respondent Pharmacy to hire an employee, whom it knew to have disciplinary issues and a criminal record, to fill dozens of prescriptions whose legitimacy was in question and then to relinquish all responsibility for that pharmacist's actions. The DEA registration is issued to the pharmacy, not the individual pharmacist, and the pharmacy has responsibility under federal law to ensure compliance with the law in order to maintain its registration.

following her policies and the law. Finally, the violations of corresponding responsibility and standard of practice in this case are not limited to the actions of B.S. The Government's evidence clearly demonstrates that Respondents' Owner and PIC herself filled prescriptions with multiple red flags herself for customers such as H.B., C.A., D.B., K.B.2, and J.S.2.

I have also considered and reject Respondents' argument that Dr. Gordon relied only on DEA decisions to identify red flags. Resp Exceptions, at 7. Dr. Gordon testified that "[r]ed flags is just a term . . . that the lawyers and the Courts have come up with, but . . . there's always been red flags, since inception of pharmacy." Tr. 209-10. She further stated that "[t]he Courts called it red flags. Pharmacists just call it checking to make sure that that medication is safe or legitimate." *Id.* at 211. Dr. Gordon's testimony is further supported by Respondents' Owner and PIC's testimony, that she was aware that when a pharmacist spots a red flag for a prescription, that she must "resolve it, and if [she] cannot resolve it, not to fill it." Tr. 566; RD, at 24. Respondents' Owner and PIC also testified that she understands the concept of red flags and that she recognized that there are red flags in Respondent Pharmacy's prescriptions. Tr. 796. There is no evidence that the Agency has set a standard independent of pharmacy practice as Respondents have contended. Resp Exceptions, at 9. Dr. Gordon testified repeatedly that documentation was "the standard of practice, if there's something questionable about a prescription, you document it after you speak with the patient or the doctor," and further, she gave a credible rationale as to why it was the standard of practice, "so that you can let other pharmacists know what happened

the time before." Tr. 215, 44-45. If there were red flags on a prescription, which were necessary to be resolved in order to confirm the prescription's legitimacy, it is unclear how another pharmacist filling a subsequent prescription would know that they had been resolved without documentation. Dr. Gordon's testimony is supported by the facts in this case, because Respondents' Owner and PIC blamed B.S. for filling prescriptions not in accordance with policy, but then filled prescriptions for the same patients with the same red flags. Without documentation of the resolution of the red flags, there was no way for her to know whether B.S. had resolved them, or in fact, whether she had resolved them. Her memory of her own conversations with customers that supposedly resolved the red flags did not always prove to be reliable. *See e.g.*, Tr. 596, 671, 673, 716, 720.

Respondents argue in their Exceptions that DEA is acting outside of its statutory authority in determining that the course of professional practice in Florida requires a pharmacist to resolve and document red flags. Resp Exceptions, at 8-10. Part of Respondents' argument is that the Florida statutes cited by the Government do not require the documentation of red flags. *Id.* at 10. Respondents admit that under Florida law, "if a pharmacist identifies one of the enumerated 'red flags' in the regulations, 'the pharmacist shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber.'" Resp Exceptions, at 11 (quoting Fla. Admin. Code Ann. r. 64B16-27.810.) However, Respondents argue that the regulations do not require the documentation of the resolution of such red flags. *Id.*

The Florida Board of Pharmacy requires a pharmacist to conduct prospective drug use review on each prescription and identify such issues as "[o]ver-utilization," "[d]rug-drug interactions," "[i]ncorrect drug dosage," and "[c]linical abuse/misuse," and shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber. Fla. Admin. Code Ann. r. 64B16-27.810 (2020). A preceding section of the regulations states that "a patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing." Fla. Admin. Code r. 64B16-27.800(1). The regulation further states that among the information required to be maintained in the patient records is the "pharmacist comments relevant to the individuals' drug therapy, including any other information peculiar to the specific patient or drug." *Id.* at (1)(f). Respondents argue that "there is no definition available as to what constitutes 'peculiar' information" and that it "should be read to mean peculiar information relevant to treatment." Resp Exceptions, at 11. The Government argued, and the ALJ found, that Florida law requires not only the resolution of red flags, but also a "pharmacist is required to maintain a patient record, allowing for immediate retrieval of information relative to previously dispensed drugs and those records are to include comments peculiar to the patient, and information provided by a licensed health care provider." RD, at 65.

Agency decisions have examined whether the resolution of red flags is required by these provisions

of Florida law. *See Trinity Pharmacy II*, 83 Fed. Reg. 7304, 7329-30 (2018); *Superior Pharmacy I and II,* 81 Fed. Reg. 31,310, 31,336 (2016) (stating that the regulation required documentation of the prospective drug review in the patient profiles). The Respondents do not argue that the drug review provision is inapplicable, merely that the documentation requirement is more appropriately read to require documentation of information "relevant to treatment." Resp Exceptions, at 11. The drug review in Florida law appears to be an affirmative obligation on the part of the pharmacist, and therefore, it would be consistent with such an affirmative obligation to read the preceding section of the regulation to require documentation of the prospective drug review. As stated above, the documentation requirements in this section "shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing." Fla. Admin. Code r. 64B16-27.800(1). In its Posthearing Brief, the Government cited to these regulatory provisions, not as an individual violation of Florida law,[76] but as further evidence that Respondent Pharmacy filled prescriptions for controlled substances outside the usual course of practice in Florida. Gov Posthearing, at 44-45. I ultimately do not find it necessary to find a violation of this regulation in this case, because the Government has proven by substantial evidence that Respondent Pharmacy violated its corresponding responsibility

[76] The Order to Show Cause alleged that in filling prescriptions with multiple red flags and not documenting their resolution, Respondent Pharmacy violated Fla. Admin. Code Ann. r. 64B16-27.800 and 64B16-27.810. OSC, at 10.

and filled prescriptions outside the standard of practice in Florida by not documenting the resolution of the red flags through credible expert testimony. I do consider this regulation to further support the testimony of Dr. Gordon regarding the importance of documentation in the standard of practice of pharmacy in Florida.

Dr. Gordon testified repeatedly that the standard of practice of pharmacy in Florida required documentation of the resolution of red flags. When Respondents' counsel summarized her testimony and asked if she was stating that documentation was "a requirement for pharmacists in the State of Florida to document red flags," she stated, "Yes. To show that—for each red flag, if there was a specific situation where you felt that the medication was for a legitimate medical purpose, that should be documented." Tr. 206. Dr. Gordon is not a lawyer and is not an expert in the details of state law, but she is required as a pharmacist to understand what conduct is outside of the usual course of professional practice in her state, whether that is derived from state law, mandatory training, standards of care or otherwise. Respondents imply that Dr. Gordon's inability to draw a solid conclusion as to where the requirement to document the resolution of red flags is written somehow demonstrates that there is no such requirement in the standard of practice. Resp Exceptions, at 10. I reject such fallacious reasoning. In this case, I find that Florida state law can be reasonably interpreted to support Dr. Gordon's testimony, but that her testimony is independently credible that documentation of the resolution of red flags is a requirement of the practice of pharmacy in the State of Florida.

Accordingly, in summary, I agree with the ALJ's finding in the RD that the Government has proven by substantial evidence that Respondent filled prescriptions for controlled substances that the pharmacists knew were not prescribed for legitimate medical purposes, or were willfully blind to such, in violation of their corresponding responsibility under 21 C.F.R. § 1306.04(a) and outside the usual course of professional practice in violation of 21 C.F.R. § 1306.06. I find these violations of federal law and negative dispensing experience to weigh against the Respondents' continued registrations under Factors Two and Four.

I further find that the Government has demonstrated that pharmacists at Respondent Pharmacy violated Fla. Stat. § 893.04(2)(a) (2009). During the time period covered by the Show Cause Order, Florida law required that a pharmacist, before dispensing a controlled substance listed in schedules II through IV, first determine "in the exercise of her or his professional judgment . . . that the order is valid." Fla. Stat. § 893.04(2)(a) (2009); *see also* Fla. Stat. § 893.02(22) (2011) (defining a "prescription" as an order for drugs "issued in good faith and in the course of professional practice . . . and meeting the requirements of s. 893.04."). In this case, I have found that the Government established by substantial evidence that pharmacists at Respondent Pharmacy filled prescriptions outside the usual course of professional practice of pharmacy. I find that the pharmacists did not exercise their professional judgment in acting outside of the usual course of practice and that this is evidence of Respondent Pharmacy's noncompliance with state law, which I consider under Factor Four and weigh against Respondents' continued registrations.

(b) Allegation that Respondent Pharmacy Filled Prescriptions Written for "Office Use" in Violation of 21 C.F.R. § 1306.04(b)

DEA regulations state that "[a] prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients." 21 C.F.R. § 1306.04(b). As I found above, Respondent Pharmacy dispensed testosterone to Dr. I's office on eight occasions and Dr. A's office once, between September 23, 2014, and January 28, 2015. GX 3; RD, at 29; *supra* Section II(F). As I also found above, the Government's expert witness testified that the fact that the prescriptions were labeled "for office use," assigned a prescription number, issued fill stickers, and included the office name in the place of a patient's name demonstrated that the prescriptions were issued outside of the usual course of professional practice. Tr. 64-65.

The Government's expert testified that "if there were an invoice and the prescription was issued to a practitioner," it would have resolved the issue, but clarified that it was not within the acceptable standard of practice to order controlled substances from a pharmacy to be distributed to a dispensing practitioner and then report it to the Florida Prescription Drug Monitoring Program (E-FORCSE). *Id.* at 278-79; 288-89. Respondents' Owner and PIC maintained that these were "wholesale transactions" and not prescriptions. Tr. 697. She maintained that Dr. I. was registered as a dispensing practitioner. Tr. 578. Respondents

also argued that Dr. I. was administering the controlled substances to patients in the office.[77] Resp Posthearing, at 10. The Government argued that these claims were based solely on conjecture and that the clear evidence was that prescriptions with fill stickers were dispensed "for office use." Govt Exceptions, at 1-2; *id.* at 2 n.1.

The ALJ did not sustain the 21 C.F.R. § 1306.04(b) violation, because he found that in order to prove such a violation, "it was incumbent upon the Government to prove that Drs. [I and A] were going to be dispensing the controlled substances to patients." RD, at 69. He noted that the prescriptions stated that they were "for office use" and that was consistent with Respondents' Owner and PIC's testimony that the practitioners were administering the testosterone and not dispensing it and that therefore, the prescriptions fell into an exception to the regulatory requirement. *Id.* at 69-70. The Government argued in its Exceptions that the ALJ had applied an exception to the regulation that does not exist and that the ALJ's reasoning related to his finding under 1306.04(b) incorrectly implied that it was "incumbent upon the Government to prove that [the practitioners] were going to be dispensing the controlled substances to patients." RD, at 69; Govt Exceptions, at 3-4. The Government further argued that the ALJ's analysis of the "office use" prescriptions under Section 1306.04(b) was inconsistent with the Agency's decision in *Roberto Zayas, M.D.*, 82 Fed. Reg. 21,410, 21,424 (2017). Govt Exceptions, at 2.

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[77] It is noted that these two theories seem to contradict each other.

Dr. Gordon clearly testified that if the purpose was to transfer the controlled substances, there was a lawful way in which to conduct such transactions, but issuing and dispensing pursuant to a prescription, using fill stickers and reporting to E-FORCSE was not within the usual course of professional practice of pharmacy in Florida. If Respondent Pharmacy had intended these documents to be invoices, they facially did not appear to be so, and Respondent did not produce any additional documentation that justified the filling of these prescriptions issued for "office use.[78]" I agree with the Government that the prescriptions themselves appeared to violate 21 C.F.R. § 1306.04(b). *See Roberto Zayas, M.D.*, 82 Fed. Reg. 21,410, 21,425 (2017) (holding that prescriptions written "for office use" violated 21 C.F.R. § 1306.04(b) and holding the prescriber responsible for calling in the prescriptions).

In this case, the Government initially stated that Dr. Gordon would testify that these prescriptions raised red flags that were not resolved. Govt Prehearing, at 8. The Government's expert did not discuss red flags related to these prescriptions, but did conclude

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[78] Respondents claim that in November 2014, Respondent Pharmacy started using invoices in lieu of prescription pads. Resp Posthearing, at 64 (citing GX 3, at 5-13). The documents in question appear different from the other pages of the exhibit, with the exception of GX 3, at 11, but they state "Prescription Form" at the top. The Respondents have not adequately explained the difference between the different forms and there are fill stickers associated with all of them. However, ultimately, I have not sustained this allegation, so I find it unnecessary to determine the accuracy of Respondents' unexplained claim that some of the exhibits may have been invoices.

that they were issued outside the usual course of professional practice. Tr. 65-66. In its Posthearing Brief, the Government argued that the prescriptions were issued in violation of 1306.04(b) "and accordingly were not dispensed in the usual course of professional practice." Govt Posthearing, at 9. However, the Government did not allege a violation of 21 C.F.R. § 1306.06[79] for these prescriptions, nor did it sufficiently establish through its expert witness that these prescriptions were dispensed in violation of Respondent Pharmacy's corresponding responsibility in violation of 21 C.F.R. § 1306.04(a), and even if the Government had established this, it appeared to abandon this theory in its Posthearing Brief. Therefore, I will not consider the allegation related to the prescriptions issued for "office use," because the Government has not adequately established a legal basis for my finding of a violation for Respondent Pharmacy's *filling* "office use" prescriptions in this case. *Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy*, 83 Fed. Reg. 10,876, 10,900 (2018) (noting that 21 C.F.R. § 1306.04(b) only prohibits the *issuance* of a prescription).

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[79] Although the Government had alleged generally that Respondent Pharmacy acted outside the usual course of professional practice in the Order to Show Cause, the Government did not adequately notice a violation of 1306.06 in the context of the 1304.04(b) violation. I have reviewed the Respondents' filings on this matter and I do not find evidence that they were on notice of this theory regarding the 1306.06 violation in order to have litigated the issue by consent. *See Farmacia Yani*, 80 Fed. Reg. 29,053, 29,059 (2015).

(c) Allegation that Respondent Pharmacy filled prescriptions that were issued by a practitioner to himself in violation of Fla. Stat. § 458.331(1)(r)

The Order to Show Cause alleged that Respondent Pharmacy filled prescriptions for controlled substances "despite unresolved red flags includ[ing]. . . . prescriptions [] written in violation of Florida law, Fla. Stat. 458.331(1)(r)." The ALJ found that "the Pharmacy violated its corresponding responsibility by filling prescriptions that J.S.3 wrote to himself. . . . " RD, at 68. Respondents argued that the ALJ incorrectly interpreted Florida state law relating to Respondent Pharmacy's filling of J.S.3's prescriptions to himself. Resp Exceptions, at 5.

Respondents' primary argument is that "[a] plain reading of the statute holds that a physician can prescribe to himself, so long as he is not the one dispensing the medication." Resp Exceptions, at 5. In making this argument, Respondents state that "the statute prohibits a physician from prescribing to himself, unless another practitioner 'prescribed, dispensed, or administered' the controlled substances," [80] [81] *Id.*

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[80] The prescriptions to J.S.3 involved testosterone and oxycodone, which are controlled substances under Fla. Stat. § 893.03.

[81] The ALJ found that the Respondents' evidence included multiple documents that indicated that J.S.3 had not been treated by another doctor, but had been self-prescribing. RD, at 68 (citing RX H, at 2-3, 15-22, 40-41). I agree with the ALJ on this point. Respondents clarify in their Exceptions that their argument is not that there was another practitioner involved in the prescribing or treatment, but that Respondent Pharmacy itself created the exception by dispensing the controlled substances. Resp Exceptions, at 5.

(citing Fla. Stat. § 458.331(1)(r) (emphasis added by Respondents). Although the basis of the Respondents' argument that the term "or" would permit a physician to prescribe to himself as long as a different practitioner dispensed the controlled substance is well-grounded in canons of statutory construction, Respondent submitted, and I can find, no evidence that the State of Florida permits such a loophole in its prohibition against self-prescribing.[82] If Respondents were correct in this interpretation, it would appear that a practitioner could only violate this law if he prescribed to himself and also dispensed the prescription to himself. Further, the testimony of Respondents' witnesses contradicts this reading of Florida law. D.M. and Respondents' Owner and PIC testified that the Board of Pharmacy visited in 2015 and told Respondents' Owner and PIC "that it was not lawful" to fill a prescription that a doctor had written for himself, after which D.M. changed his advice and Respondent Pharmacy did not fill any further prescriptions. Tr. 573; Tr. 809-10; *supra* Section (II)(E)(1). Therefore, the record contradicts Respondents' argument that the Florida Board of Pharmacy interprets the statute in the manner that Respondents suggest. However, as explained below, I do not believe that

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[82] For example, there is no indication or discussion of a distinction made on Respondents' alleged exception in this Florida disciplinary case on point, just that he violated Fla. Stat. § 458.331(1)(r). *Department of Health vs. Nader W. Said, M.D.*, DOH Case No. 2014-08153 (December 19, 2016), at 19. *Available at* https://appsmqa.doh.state.fl.us/MQASearchServices/Document/Mjk1Nzc5ODY%3D. If the statute were as limited as Respondents argue, then it would seem that a charge would necessitate including self-dispensing as well or additional facts related to the dispensing of the prescriptions.

whether the law was or was not actually violated by J.S.3's self-prescribing is essential to a finding that Respondent Pharmacy violated its corresponding responsibility for these prescriptions.

The second argument that Respondents proffered is that Fla. Stat. § 458.331(1)(r) is only grounds for discipline of physicians, not pharmacists. The Florida statute specifically provides that its provisions do not apply to "[o]ther duly licensed health care practitioners acting within the scope of their practice." Fla. Stat. § 458.303(1)(a); Resp Exceptions, at 4. Fla. Stat. § 456.001(4) includes pharmacists in the definition of "health care practitioners." However, as established herein, Florida law clearly requires that a pharmacist, before dispensing a controlled substance listed in schedules II through IV, first determine "in the exercise of her or his professional judgment . . . that the order is valid." Fla. Stat. § 893.04(2)(a) (2009). Additionally, as found above, Dr. Gordon credibly testified that "[a] pharmacist should not have filled any prescription written by a physician that wrote it for himself, a controlled substance" and concluded that these prescriptions were not filled within the standard of practice of pharmacy in Florida. Tr. 62. Therefore, based on Dr. Gordon's testimony, I find that a pharmacist filling these prescriptions could not have been acting within the scope of his or her practice in order to meet the exception set forth in Fla. Stat. § 458.303(1)(a), and the exception would not apply.

Most importantly, the Government's legal theory about these prescriptions was not that Respondent Pharmacy had directly violated this Florida statute in filling these prescriptions, but instead that J.S.3 wrote the prescriptions in violation of the law and the

prescriptions raised red flags, which Respondent failed to resolve, resulting in a violation of its corresponding responsibility. OSC, at 4; Govt Prehearing, at 8; Govt Posthearing, at 7-8. *See supra* II(E)(1).

As to the testimony of D.M. that he had provided legal advice to Respondents' Owner and PIC in which he maintained that a physician could prescribe controlled substances to himself as long as a pharmacist dispensed the prescription, I do not find that this alleged advice resolved the red flags that were presented by these prescriptions for several reasons. First, Respondent did not produce documentation of the advice. Second, per D.M.'s testimony the advice was general and did not pertain to the particular circumstance of J.S.3's prescriptions. *Supra* II(E)(1). Most importantly, D.M. testified that at the time he used the word "scrutiny" in lieu of the term red flag, and that his advice was that "it wasn't prohibited and it was permissible but required scrutiny." *Id.*; Tr. 810. Dr. Gordon testified that the usual course of professional practice in Florida required that the red flags be resolved prior to the pharmacists' dispensing of the prescriptions and that those resolutions be documented. There is no evidence of Respondent Pharmacy's documentation regarding this red flag. As D.M. testified, the fact that there was even a question about whether the prescriptions violated Florida law presented such "scrutiny" or a red flag, and the record evidence demonstrates that Respondent Pharmacy was advised by its attorney that this scrutiny was "required." Therefore, I find that Res-

pondent Pharmacy violated its corresponding responsibility[83] in dispensing prescriptions to J.S.3 without resolving the red flag due to Fla. Stat. § 458.331(1)(r), and that the filling of these prescriptions is appropriately considered under Factor Four as evidence that Respondent Pharmacy was not in "compliance with applicable State, Federal or local laws relating to controlled substances." 21 U.S.C. § 823(f)(4).

(d) The Legitimacy of the Prescriptions

Respondents cited,[84] and the ALJ applied, a clause written by one of my predecessors as part of a footnote in a prior Agency decision (hereinafter, the *Hills* footnote). *Hills Pharmacy, LLC,* 81 Fed. Reg. 49,816, 49,836 n.33 (2016) ("[I]t is true that a pharmacist cannot violate his corresponding responsibility if a prescription was nonetheless issued for a legitimate medical purpose."). The clause is footnoted in one other subsequent Agency decision. *Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy*, 83 Fed. Reg. 10,876, 10,899 n.36 (2018), *pet. for review den.*, 789 F. App'x 724 (11th Cir. 2019).

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[83] Respondents' final argument is that the Government did not demonstrate that the prescriptions to J.S.3 "lack[ed] a legitimate medical purpose." Resp Exceptions, at 6. The Respondents cite to the footnote in *Hills Pharmacy, LLC*, 81 Fed. Reg. 49,816, 49,836 n.33 to support this notion, which is further discussed *infra* Section III(A)(1)(d). I reject this argument the reasons discussed in relation to *Hills* below.

[84] Respondents argued that the Government must prove that the prescriptions Respondent Pharmacy filled lacked a legitimate medical purpose in order to show that Respondent Pharmacy violated its corresponding responsibility based on the language of the *Hills* footnote. Resp Exceptions, at 7.

Although the sentence containing the clause is not entirely clear, the clause itself states as "true" that a pharmacist may not be found to violate his corresponding responsibility unless the prescription at issue violates 21 U.S.C. § 829. The concept labeled "true" directly conflicts with DEA regulations and decades of Agency decisions interpreting those regulations.

I unequivocally reject the clause and the notion that a pharmacist may not be found to violate his corresponding responsibility unless the prescription at issue violates 21 U.S.C. § 829. I affirm the part of the footnote rejecting the respondent's argument, which stated, "Respondent argues that the Government cannot establish that a pharmacist has violated his corresponding responsibility unless it first establishes that the prescription lacked a legitimate medical purpose. . . . Respondent is mistaken."

A pharmacist's corresponding responsibility is to assess prescriptions according to the applicable standard of practice, which typically requires the pharmacist to recognize and resolve red flags on the prescriptions prior to filling them, and to act on that assessment by filling or declining to fill the prescription.

> The language in 21 C.F.R. § 1306.04 and relevant caselaw could not be more explicit. A pharmacist has his own responsibility to ensure that controlled substances are not dispensed for non-medical reasons. *See, United States v. Hayes,* 595 F.2d 258 (5th Cir. 1979) *cert. denied*, 444 U.S. 866 (1979); *United States v. Henry,* 727 F.2d 1373 (5th Cir. 1984) (reversed on other grounds). A pharmacist

> must exercise professional judgment when filling a prescription issued by a physician.

Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy, 55 Fed. Reg. 4729, 4730 (1990). Respondents have presented no good reason for me to depart from DEA's decades-long statement of a pharmacist's corresponding responsibility, and I decline to do so.[85]

B. Other issues

1. Unlawful Search Allegation

Respondents alleged that many of the records in the Government's case were obtained as a result of an unlawful search. Resp Posthearing, at 77-78. As found above, the first inspection occurred on September 18, 2013, during which M.P. signed a DEA Form 82, identifying himself as the "manager" and consenting to the search. GX 32. Respondents objected to this search claiming that "21 C.F.R. § 880 mandates that the 'owner, operator, or agent' in charge of such

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[85] In fact, I find compelling reasons to reject Respondents' proposed interpretation. For example, if I were to interpret a pharmacist's corresponding responsibility in the manner in which Respondents suggest, not only would it be a departure in the Agency position, but the administrative hearings would be mired in irrelevant complexity that is unnecessary given that a pharmacy must exercise its corresponding responsibility prior to the filling of a prescription in order to preserve the CSA's purpose of preventing addiction and abuse. *See Cove Inc. D/B/A Allwell Pharmacy*, 80 Fed. Reg. 29,037, 29,049 (2015) (finding that "[t]he obligations are referred to as 'corresponding responsibilities,' as they impose duties on pharmacies and pharmacists that correspond with those of the treating sources.")

premises must receive notice of the inspection."[86] Resp Posthearing, at 77. Respondents contest that DEA's service was improper because: M.P. was not an employee of Respondent Pharmacy;[87] M.P. testified that he was never given authorization to sign the DEA Form 82; and Respondents' Owner and PIC confirmed that she did not authorize him to do so. *Id.* at 78 (citing Tr. 395; 541); *see also* Tr. 402. The ALJ rejected Respondents' argument, because the ALJ did "not find the testimonies of [Respondents' Owner and PIC] and [M.P.] to be credible that [Respondents' Owner and PIC] did not give [M.P.] authority to sign the Notice of Inspection on September 18, 2013." RD, at 60 n.36. The ALJ further noted that Respondents' Owner and PIC arrived at Respondent Pharmacy shortly after M.P.'s signature and told the agents that she would provide copies of the pharmacy's records to them later, after which M.P. brought the records to the DEA Orlando District Office on September 23, 2013. *Id.*; GX 33 (DEA Form 12, Receipt for Cash or Other Items, signed by M.P.). I agree with the ALJ's determination that "it strains credulity[88]

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[86] I have assumed that Respondents intended to cite to 21 U.S.C. § 881.

[87] Although, M.P. stated, "I do work for [Respondent] Pharmacy," Respondents' Counsel clarified with him that the work he does for Respondent LLC overlaps. Tr. 404.

[88] I agree with the ALJ that Respondents' argument strains credulity, because Respondents' Owner and PIC provided copies voluntarily five days later. I also find that the argument strains credulity, because M.P. signed the DEA Form 82 writing in the word "Manager" in the blank in the statement "I hereby certify that I am the ____ for the premises described in this Notice of Inspection," and further stating that "I have the authority to act in this matter and have signed this Notice of Inspection pursuant

to suggest that [Respondents' Owner and PIC] did not willingly consent to delivering the documents to the DEA five days later." RD, at 60 n.36

The second inspection was conducted as a result of an Administrative Inspection Warrant pursuant to 21 U.S.C. § 880(d) in April of 2015, which the DI testified was obtained after Respondents' attorney D.M. failed to timely comply with a subpoena. *Supra* (II)(B)(2). Respondents did not appear to make any arguments related to the lawfulness of the second inspection.[89] *See generally* Resp Posthearing. I agree with the ALJ and reject Respondents' allegations regarding the legitimacy of the consent in the first DEA inspection. Respondents' Owner and PIC had five days to withdraw consent to the first inspection or refuse to provide copies of the documents, but nevertheless, she voluntarily chose to provide the

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to my authority." GX 32 (DEA Form 82). M.P. admitted that he spoke with Respondents' Owner and PIC after DEA arrived and that he did not refuse entry or request that DEA "strike his signature." Tr. 408. M.P. also signed two DEA Forms 12 on September 23, 2013, and October 14, 2016, in which he listed his title as "Manager." GX 33, 34. The record evidence shows that M.P. held himself out on numerous occasions to have the authority to act on behalf of both Respondents as its agent within the meaning of 21 U.S.C. § 880(c).

[89] Respondents seem to conflate the facts surrounding the two inspections, alleging that the DI "presented the DEA Form 82 directly to [Respondent Pharmacy] rather than go through the pharmacy's counsel" and that the DI admitted to not knowing whether M.P. was authorized to sign the form. Resp Posthearing, at 78. However, the DI testified that he was not even present at the administrative inspection that occurred on September 18, 2013, so whether he knew about the status of M.P.'s authorization back in 2013, when he served the administrative warrant in April 2015 is irrelevant. Tr. 317-18.

documents using the same agent who had signed the initial consent form to deliver them.

2. Respondents' Integrated Enterprise

Respondents argue that DEA has not alleged a single violation against Respondent LLC, and therefore it is inappropriate to revoke Respondent LLC's registration "simply because both companies share common ownership." Resp Posthearing, at 77. The ALJ found, and I agree, that "Respondents' arguments ignore the obvious, that the Pharmacy and Suntree Medical are essentially one and the same." RD, at 100. Agency decisions "treat[] two separately organized business entities as one integrated enterprise . . . based on the overlap of ownership, management, and operations of the two entities." *Jones Total Health Care Pharmacy, L.L.C., and SND Health Care, L.L.C.*, 81 Fed. Reg. 79,188, 79,222 (2016) (citing *MB Wholesale, Inc.*, 72 Fed. Reg. 71,956, 71,958 (2007) (citing *MB Wholesale, Inc.*, 72 Fed. Reg. 71,956, 71,958 (2007)). "[W]here misconduct has previously been proved with respect to the owners, officers, or key employees of a pharmacy, the Agency can deny an application or revoke a registration of a second or subsequent pharmacy where the Government shows that such individuals have influence over the management or control of the second pharmacy." *Superior Pharmacy I and Superior Pharmacy II*, 81 Fed. Reg. 31,310, 31,341, n.71 (2016). Further, the Agency may revoke a registration, even if there is no misconduct that can be attributed to the registration, if the Agency finds that the registrant committed egregious misconduct under a second registration. *Roberto Zayas, M.D.*, 82 Fed. Reg. 21,410, 21,430 (2017) (revoking physician's

DEA registration in Florida due to conduct attributed to a Texas registration that had expired).

Respondents argue that the terms of the CSA in requiring separate registrations for each entity or person and each principal place of business should be read to "suggest two (2) separate entities are not to be considered as one (1)." Resp Exceptions, at 18 (citing 21 U.S.C. §§ 802(49)(a), 802(38), and 822(e)). When a practitioner registrant acts in a manner inconsistent with the public interest, in determining whether to revoke, DEA looks to whether the practitioner can be entrusted with a registration. *See e.g., Arvinder Singh, M.D.*, 81 Fed. Reg. 8247, 8248 (2016). If a practitioner holding multiple registrations cannot be entrusted with one, it would be difficult to justify entrusting the same practitioner with another in a separate location. Similarly, if a corporate entity is owned and operated by the same individuals, who have acted inconsistently with the public interest, I cannot ignore the fact that these same individuals have used one of their registrations not in accordance with the law. Respondents quoted the DI stating that Respondent LLC "'has never purchased any controlled substances under that DEA registration'" and that the two entities "were two (2) separate businesses, one (1) supplying medication including controlled substances, the other involved in the sale of medical equipment;" however, the lack of Respondent LLC's past use of the registration does not prevent it from using its registration in the future. Resp Exceptions, at 19-20.

The lens through which Congress has instructed me to assess each registration is whether or not such registration is inconsistent with the public interest. 21

U.S.C. § 823(f). In this case, if Respondents were allowed to simply shift their operations to an entity with the same owner and essentially the same employees, the effect of the violations found herein against Respondent Pharmacy would be a nullity, and there would be nothing to prevent Respondent LLC from continuing to act in a manner inconsistent with the public interest. Contrary to Respondents' contention, it would be inconsistent with the intent of the CSA to permit such an easily implementable loophole, and it is consistent with Agency decisions to close the loophole by treating the two overlapping entities as one integrated enterprise for purposes of sanction.

Therefore, I agree with the ALJ that "[b]ecause of the obvious commonality of ownership, management and operations, it is abundantly clear" that if I revoke Respondent Pharmacy's registration, Respondent LLC "could pick up where the Pharmacy left off without missing a beat. Accordingly, due to that commonality, it is appropriate to treat the [Respondent] Pharmacy and [Respondent LLC] as one integrated enterprise." RD, at 101.

Finally, Respondents argue that they were given no notice as to the charges against Respondent LLC and therefore a finding against Respondent LLC would violate Constitutional due process. I reject this argument, because the grounds for revocation of Respondent LLC's registration are the precise grounds that form the basis of the revocation of Respondent Pharmacy's registration, and Respondent Pharmacy has been afforded due process of law through this proceeding. Furthermore, the OSC was clearly issued to both Respondent LLC and Respondent Pharmacy. *See* OSC, at 1. Each was initially docketed separately,

but prior to the hearing, the ALJ ordered that the two cases would be consolidated, to which the Respondents consented. ALJX 14 (Prehearing Ruling). Respondents simply cannot argue that they did not know that the adjudication of the alleged violations committed by Respondent Pharmacy were also being adjudicated against Respondent LLC.

C. Summary of the Public Interest Factors

As found above, Respondent Pharmacy filled hundreds of controlled substance prescriptions in violation of its corresponding responsibility and Florida law and outside the usual course of professional practice. Thus, I conclude that Respondent Pharmacy has engaged in misconduct which supports the revocation of its registration, and as explained above, it would be inconsistent with the public interest to permit Respondent LLC to maintain its registration given that Respondents are an integrated enterprise. I therefore find that the Government has established a *prima facie* case that Respondents' continued registrations "would be inconsistent with the public interest." 21 U.S.C. § 823(f).

IV. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that the Respondents' continued registration is inconsistent with the public interest due to their violations pertaining to controlled substance dispensing, the burden shifts to the Respondents to show why they can be entrusted with the responsibility carried by their registrations. *Garret Howard Smith, M.D.*, 83 Fed. Reg. 18,882, 18,910 (2018) (citing *Samuel S. Jackson*, 72 Fed. Reg. 23,848,

23,853 (2007)). The CSA authorizes the Attorney General to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter." 21 U.S.C. § 871(b). This authority specifically relates "to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute." *Gonzales v. Oregon*, 546 U.S. at 259. A clear purpose of this authority is to "bar[] doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking." *Id.* at 270. In efficiently executing the revocation and suspension authority delegated to me under the CSA for the aforementioned purposes, I review the evidence and argument Respondents submitted to determine whether or not they have presented "sufficient mitigating evidence to assure the Administrator that [they] can be trusted with the responsibility carried by such a registration." *Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. 23,848, 23,853 (2007) (quoting *Leo R. Miller, M.D.*, 53 Fed. Reg. 21,931, 21,932 (1988)). "'Moreover, because "past performance is the best predictor of future performance," *ALRA Labs, Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.'" *Jayam Krishna-Iyer*, 74 Fed. Reg. 459, 463 (2009) (quoting *Medicine Shoppe*, 73 Fed. Reg. 364, 387 (2008)); *see also Jackson*, 72 Fed. Reg. at 23,853; *John H. Kennnedy, M.D.*, 71 Fed. Reg. 35,705, 35,709 (2006); *Prince George Daniels, D.D.S.*, 60 Fed. Reg. 62,884, 62,887 (1995). The issue of trust is necessarily a fact-dependent determination based

on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.*, 81 Fed. Reg. 8247, 8248 (2016).

Regarding all of these matters, I agree with the analyses and conclusions contained in the Recommended Decision. RD, at 101-04. I agree with the ALJ that there is nothing in the record that suggests Respondent Pharmacy has accepted responsibility for its actions. In fact, as the ALJ found, "the evidence is clear in this case that the Pharmacy has taken no responsibility for its egregious and repeated failure to fulfill its corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances. The evidence is clear because the Pharmacy has specifically denied responsibility." RD, at 101. In fact, Respondents' attorney made very clear that Respondents were not accepting any responsibility. He stated, "I'm well aware that I can't go into remediation unless we were to accept responsibility, Your Honor. And we won't unless we do." Tr. 567; RD, at 99. Further, even after the Florida Board of Pharmacy had told Respondents' Owner and PIC that a practitioner could not prescribe to himself, Respondents maintained that the law permitted them to fill those prescriptions. *See* Resp Exceptions; Tr. 573, 809-10. Respondent Pharmacy did cease filling the prescriptions as a result of the Board of Pharmacy's in-

structions; however, the fact that Respondent Pharmacy relied on an interpretation involving a legal loophole to fill the prescriptions in the first place, and then continued to argue that the behavior was lawful in spite of the state's assertions to the contrary, not only demonstrates no remorse, but also demonstrates a willingness to push the boundaries of the law to maximize business. Such a willingness does not inspire optimism about Respondents' future compliance with the CSA.

I agree with the ALJ that the egregiousness of Respondent Pharmacy's conduct and the interests of specific and general deterrence support a sanction of revocation. RD, at 99. "Specifically, pharmacists employed by the Pharmacy, as well as [Respondents' Owner and PIC], dispensed numerous prescriptions of controlled substances in violation of their corresponding responsibility." *Id.*

There is nothing in the record that lends support to the proposition that Respondent Pharmacy's future behavior will deviate in any positive respect from its past behavior. Due to the fact that Respondent Pharmacy has accepted no responsibility nor offered any remedial measures, it has given me no reassurance that I can entrust it with a registration and no evidence that it will not repeat its egregious behavior.

Regarding general deterrence, the Agency bears the responsibility to deter similar misconduct on the part of others for the protection of the public at large. *David A. Ruben*, 78 Fed. Reg. at 38,385. Based on the number and egregiousness of the established violations in this case, a sanction less than revocation would send a message to the regulated community that

compliance with the law is not a condition precedent to maintaining registration.

A balancing of the statutory public interest factors, coupled with consideration of Respondent Pharmacy's failure to accept responsibility, the absence of any evidence of remedial measures to guard against recurrence, and the Agency's interest in deterrence, support the conclusion that Respondent Pharmacy should not continue to be entrusted with a registration. Further, the ALJ found, and I agree, that if I revoke Respondent Pharmacy's registration, Respondent LLC "could pick up where the Pharmacy left off without missing a beat. Accordingly, due to that commonality, it is appropriate to treat the Pharmacy and Suntree Medical as one integrated enterprise." RD, at 101. Due to the commonality of ownership and procedures, I cannot entrust Respondent LLC with a registration any more than I can entrust Respondent Pharmacy with one.

Therefore, I shall order the sanctions the Government requested, as contained in the Order below.

V. Order

Pursuant to 28 C.F.R. § 0.100(b) and the authority vested in me by 21 U.S.C. § 824(a), I hereby revoke DEA Certificates of Registration Nos. BS7384174 and FS2 l 94289 issued to Suntree Pharmacy and Suntree Medical Equipment LLC. Further, pursuant to 28 C.F.R. § 0.100(b) and the authority vested in me by 21 U.S.C. § 823(f), I hereby deny any pending application of Suntree Pharmacy and Suntree Medical Equipment to renew or modify these registrations, as well as any other pending application of Suntree

Pharmacy and Suntree Medical Equipment for registration in Florida. This order is effective [INSERT DATE THIRTY DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

/s/ Timothy J. Shea
Acting Administrator

Date: November 9, 2020

Subsequently entered into the Federal Register as
[FR Doc. 2020–25531 Filed 11–18–20; 8:45 am]
BILLING CODE 4410–09–P

RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION (AUGUST 15, 2017)

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTERS OF
SUNTREE PHARMACY AND SUNTREE MEDICAL EQUIPMENT LLC

Docket No. 17-09 and Docket No. 17-10

Before: Charles WM. DORMAN, Administrative Law Judge.

The Drug Enforcement Administration ("DEA" or "Government") served Suntree Pharmacy ("Pharmacy") and Suntree Medical Equipment LLC ("Suntree Medical") (collectively "Respondents") with an Order to Show Cause ("OSC"), seeking to revoke DEA Certificates of Registration ("CORs"), Numbers BS7384174 and FS2194289. Administrative Law Judge Exhibit ("ALJ-") 1. In response to the OSC, the Respondent requested a hearing before an Administrative Law Judge. ALJ-6. The hearing in this matter was held in Daytona Beach, Florida, from April 24-26, 2017.[1]

[1] While the Government only issued one OSC, this matter was assigned two different DEA docket numbers (Suntree Pharmacy was assigned No. 17-09 and Suntree Medical Equipment LLC was assigned No. 17-10). Considering that the matters of Suntree

The issue before the Administrator is whether the record as a whole establishes that the Respondents' CORs should be revoked, and any pending applications be denied, because the Respondents' registrations would be inconsistent with the public interest under 21 U.S.C. §§ 824(a)(4) and 823(f).

This Recommended Decision is based on my consideration of the entire administrative record, including all of the testimony, admitted exhibits, and the oral and written arguments of counsel.

ALLEGATIONS[2]

Between October 2013 and March 2015, the Pharmacy failed to comply with various federal and state laws related to controlled substances and engaged in conduct that demonstrates negative experience in its dispensing with respect to controlled substances, in violation of 21 U.S.C. § 823(f)(2), (4). ALJ-1, at 3. Specifically, the Pharmacy failed to exercise its corresponding responsibility regarding the proper prescribing and dispensing of controlled substances, in violation of 21 C.F.R. § 1306.04(a), Fla. Stat. § 893.04, and Fla. Admin. Code r. 64B16-27.800 and r. 64B16-27.810, during the following occasions:

Pharmacy and Suntree Medical Equipment LLC involve common issues of law and fact, both parties consented to the consolidation of these matters during the January 30, 2017 Prehearing Conference. ALJ-14, at 1.

[2] The Government withdrew the allegations concerning patients R.A., E.A., and A.B. during the hearing. Tr. 689-90. Although these allegations are included in paragraphs 10(t), (u), (v) of the Government's OSC, paragraph 8 was inadvertently referenced during the hearing. Tr. 690.

1. Between March 2014 and December 2014, the Pharmacy dispensed 10 mg tablets of oxycodone and testosterone to J.S.3, pursuant to prescriptions which J.S.3, a licensed physician, wrote to himself, in violation of Fla. Stat. § 458.331 (1)(r). ALJ-1, at 4, para. 10(a).

2. Between September 23, 2014, and January 28, 2015, the Pharmacy dispensed testosterone on at least fourteen different occasions pursuant to invalid prescriptions that indicated the ultimate user was an office, in violation of 21 C.F.R. § 1306.04(b). ALJ-1, at 4, para. 10(b).

3. Between February 12, 2014, and May 3, 2014, the Pharmacy dispensed narcotic medications to groups of customers who resided in close proximity to the Pharmacy, but who obtained their prescriptions from the same physician, who was located in Miami, Florida, more than 170 miles from their homes. ALJ-1, at 4, para. 10(c).

4. Between February 12, 2014, and May 5, 2014, the Pharmacy dispensed controlled substances, including oxycodone and hydromorphone, to customers J.S.1 and J.S.2,[3] without resolving the following red flags: (1) the prescriptions were for well-known, highly diverted /abused controlled substances; (2) the customers travelled an unusual and long distance to obtain their prescriptions; (3) the customers sought to pay cash for their prescriptions; and (4) the customers often obtained their prescriptions from the same physician on the same day. ALJ-1, at 5, para. 10(d).

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[3] Throughout this Recommended Decision the customers of the Pharmacy are identified by their initials.

5. On January 17, March 11, April 5, May 3, and October 15 of 2014, the Pharmacy dispensed large quantities of Schedule II controlled substances (including oxycodone and hydromorphone) to customer D.G. without resolving the following red flags: (1) the prescriptions were for well-known, highly diverted/abused controlled substances; (2) D.G. travelled an unusual path and distance to obtain her prescription and have it filled; and (3) D.G. sought to pay cash for the prescription. ALJ-1, at 5, para. 10(e).

6. From October 11, 2013, through March 20, 2105, the Pharmacy dispensed controlled substances (including oxycodone, Oxymorphone, morphine, fentanyl, and diazepam) to customer J.C. without resolving the following red flags: (1) the prescriptions were for well-known, highly diverted/abused controlled substances; (2) J.C. travelled an unusual path and distance to obtain the prescriptions and have them filled; (3) the prescriptions were for extraordinarily large amounts of oxycodone and J.C. at times obtained duplicate prescriptions for the same type of oxycodone and in the same dosage; (4) J.C. obtained prescriptions for highly abused prescription cocktails; and (5) IC. sought to pay for his prescriptions with cash. ALJ-1, at 5, para. 10(f).

7. From January 30, 2014, through March 24, 2015, the Pharmacy dispensed controlled substances (including oxycodone, alprazolam, and zolpidem) to customer D.B. without resolving the following red flags: (1) the prescriptions were for well-know; highly diverted /abused controlled substances; (2) D.B. travelled an unusual path and distance to obtain the prescriptions and have them filled; (3) D.B. sought to pay for many

of the prescriptions in cash; (4) many of the prescriptions were issued early; (5) D.B. obtained prescriptions for highly abused prescription cocktails. ALJ-1, at 6, para. 10(g).

8. From December 12, 2013, through May 5, 2014, the, Pharmacy filled prescriptions for large quantities of hydromorphone for customer C.C. without resolving the following red flags: (1) hydromorphone is a well-known highly diverted/abused controlled substance; (2) C.C. travelled an unusual path and distance to obtain the prescriptions and have them filled; and (3) C.C. sought to pay for the prescriptions in cash. ALJ-1, at 6, para. 10(h).

9. From January 31, 2014, through April 10, 2014, the Pharmacy filled prescriptions for large quantities of hydromorphone and oxycodone for customer P.P. without resolving the following red flags: (1) hydromorphone and oxycodone are well-known highly diverted /abused controlled substances; (2) P.P. travelled an unusual path and distance to obtain the prescriptions and have them filled; and (3) P.P. sought to pay for the prescriptions in cash. ALJ-1, at 6, para. 10(i).

10. From February 4, 2014, through April 8, 2014, the Pharmacy filled prescriptions for large quantities of hydromorphone and oxycodone for customer K.P. without resolving the following red flags: (1) hydromorphone and oxycodone are well-known highly diverted /abused controlled substances; and (2) K.P. travelled an unusual path and distance to obtain the prescriptions and have them filled. ALJ-1, at 6, para. 10(j).

11. From October 3, 2013, through March 13, 2015, the Pharmacy dispensed controlled substances (including hydromorphone, morphine, and lorazepam)

to customer M.B. without resolving the following red flags: (1) these prescriptions were for well-known highly diverted/abused controlled substances; (2) M.B. travelled an unusual path and distance to obtain the prescriptions and have them filled; (3) M.B. obtained prescriptions for two immediate release opioids and lorazepam, constituting a highly abused prescription cocktail; and (4) M.B. sought to pay for the prescriptions in cash. ALJ-1, at 6-7, para. 10(k).

12. From December 17, 2013, through February 10, 2014, the Pharmacy filled prescriptions for large quantities of hydromorphone for customer C.A. without resolving the following red flags: (1) hydromorphone is a well-known highly diverted/abused controlled substance; (2) C.A. travelled an unusual path and distance to obtain the prescriptions; and (3) C.A. sought to pay for the prescriptions in cash. ALJ-1, at 7, para. 10(l).

13. From October 18, 2013, through April 3, 2015, the Pharmacy dispensed controlled substances to customer J.D. without resolving the following red flags: (1) these prescriptions were for well-known highly diverted/abused controlled substances; (2) J.D. travelled an unusual path and distance to obtain the prescriptions and have them filled; (3) J.D. obtained prescriptions for highly abused prescription cocktails; (4) J.D. sought to pay for the prescriptions in cash; and (5) some of the prescriptions were issued early. ALJ-1, at 7, para. 10(m).

14. From December 27, 2013, through January 23, 2015, the Pharmacy filled prescriptions for large amounts of hydromorphone for customer K.B.3 without resolving the following red flags: (1) hydromorphone is a well-known highly diverted/abused controlled substance; (2) K.B.3 travelled an unusual path and distance

to obtain the prescriptions; and (3) K.B.3 sought to pay for the prescriptions in cash. ALJ-1, at 7, para. 10(n).

15. From December 16, 2013, through March 26, 2015, the Pharmacy filled prescriptions for hydromorphone, morphine, and diazepam for K.B.2 without resolving the following red flags: (1) hydromorphone, morphine, and diazepam are well-known highly diverted/abused controlled substances; (2) K.B.2 travelled an unusual path and distance to obtain the prescriptions; and (3) K.B.2 sought to pay for the prescriptions in cash. ALJ-1, at 7, para. 10(o).

16. From December 20, 2013, through January 24, 2015, the Pharmacy filled, on a monthly basis, prescriptions for hydromorphone and oxycodone for customer A.G. without resolving the following red flags: (1) the prescriptions were for well-known highly diverted/abused controlled substances; (2) the prescriptions were for two immediate-release opioids that evidenced therapeutic duplication; (3) A.G. travelled an unusual path and distance to obtain the prescriptions and have them filled; (4) A.G. sought to pay for the prescriptions in cash; and (5) the prescriptions were issued in a manner that permitted A.G. to obtain more oxycodone than was medically prescribed. ALJ-1, at 7-8, para. 10(p).

17. From April 1, 2014, through March 31, 2015, the Pharmacy dispensed oxycodone to customers K.B.1 and C.K. without resolving the following red flags: (1) both customers travelled an unusual path and distance to obtain the prescriptions and have them filled; these prescriptions were for well-known highly diverted/abused controlled substances; though K.B.1 and C.K. lived 28 miles from each other, they obtained their

similar prescriptions from the same doctor on the same date and filled their prescriptions at about the same time; (4) both customers sought to pay cash for their prescriptions. ALJ-1, at 8, para. 10(q).

18. From January 7, 2014, through March 31, 2015, the Pharmacy dispensed oxycodone to customers J.M. and M.M. without resolving the following red flags: (1) the prescriptions were for well-known highly diverted /abused controlled substances; (2) both customers travelled an unusual path and distance to obtain the prescriptions and have them filled; (3) both customers obtained their prescriptions from the same physician, usually on the same day at the same time, and filled their prescriptions at the Pharmacy usually on the same day at the same time; (4) M.M. always sought to pay cash for the prescriptions and J.M. occasionally sought to pay cash; and (5) on eight different occasions, both customers presented prescriptions for highly abused prescription drug cocktails. ALJ-1, at 8, para. 10(r).

19. From November 27, 2013, through March 31, 2015, the Pharmacy dispensed oxycodone, Adderall, alprazolam, clonazepam, Carisoprodol, and zolpidem to customer H.B. without resolving the following red flags: (1) the prescriptions were for well-known highly diverted/abused controlled substances; (2) H.B. travelled an unusual path and distance to obtain the prescriptions and have them filled; (3) H.B. frequently sought to pay for the prescriptions in cash; (4) H.B. frequently received early refills of medication; (5) in January 2015, H.B. obtained twice the amount of oxycodone as she had received the moth before; (6) H.B. presented prescriptions constituting therapeutic duplication; and (7)

H.B. presented combinations of prescriptions constituting highly abused prescription drug cocktails. ALJ-1, at 8-9, para. 10(s).

WITNESSES

I. The Government's Witnesses

The Government presented its case through the testimony of four witnesses. First, the Government presented the testimony of its expert witness, Dr. Tracey Gordon, Pharm.D. ("Dr. Gordon"). Tr. 21-311. Government Exhibit 26 is a copy of Dr. Gordon's resume. Tr. 23. Dr. Gordon holds both a bachelor's degree and a doctorate in pharmacy. Tr. 22; GE-26. Dr. Gordon is currently employed as a clinical hospice pharmacist at ProCareRX. Tr. 21. Dr. Gordon holds a regular Florida pharmacy license and a Florida consultant license. Tr. 23. Dr. Gordon has obtained pain management experience as a clinical hospice pharmacist, while working alongside doctors and nurses who manage symptoms. Tr. 24. She also has 12 years of experience as a retail pharmacist. Tr. 24. Dr. Gordon last worked as a retail pharmacist in 2013. Tr. 25. Dr. Gordon is familiar with Federal and Florida laws as they pertain to dispensing controlled substances. Tr. 26. After Respondents' counsel conducted voir dire examination of Dr. Gordon, he stated that he had no objection to Dr. Gordon's qualifications. Tr. 29. Dr. Gordon was then accepted as an expert who is familiar with the practice of pharmacy in the State of Florida. Tr. 26, 31-32.

Having closely listened to Dr. Gordon's testimony, and having closely reviewed the transcript of her testimony, I find that it was sufficiently objective, detailed, plausible, and internally consistent to be considered credible in this recommended decision.

Second, the Government presented the testimony of Diversion Investigator ("DI") James Graumlich ("Graumlich"). Tr. 312-392. Graumlich has served as a DI with the DEA for 27 years and holds a bachelor's degree from Florida State University. Tr. 312-13. Graumlich testified that his training to become a DI was a 12-week basic DI class at the FBI academy. Tr. 313. In addition, Graumlich has attended numerous advanced courses and seminars dealing with controlled substances. Tr. 313. As a DI, Graumlich monitors and regulates those who hold a COR and conducts investigations concerning those who have applied for a COR. Tr. 313-14. Graumlich also conducts periodic investigations of those who hold a COR. Tr. 315. Graumlich has conducted at least 100 investigations concerning pharmacies, and he was involved in the investigation of the Pharmacy and Suntree Medical. Tr. 315-16. The investigation was started because the Pharmacy was identified as an extremely high purchaser of oxycodone, hydromorphone, and morphine. Tr. 316-17. He also testified concerning the inspection that was conducted of the Pharmacy on September 13, 2013, with that testimony being based upon his review of a report of the inspection. Tr. 317-322, 390; GE-32.

Graumlich testified that the investigators wanted to remove prescriptions maintained by the Pharmacy because they wanted to copy and review them. Tr. 318. They did not do so, however, because Dr. Clark agreed to make copies and provide them to DEA. Tr. 318. In May 2014 Graumlich reviewed the prescriptions after they were provided by the Pharmacy. Tr. 322-23. Then in April 2015 the DEA executed an Administrative Inspection Warrant ("AIW") at the Pharmacy. Tr. 323.

Graumlich testified that prescriptions in the Government's exhibits that are dated prior to September 2013 were obtained from the Notice of Inspection, but the prescriptions after that date were obtained as a result of the AIW. Tr. 326. During the April 2015 inspection, the DEA investigators copied portions of the Pharmacy's database that it used when filling prescriptions. Tr. 326-27. Page 35 of Government Exhibit 2 is an example of the records obtained from the Pharmacy's database.[4] Tr. 325-26, 331-32. The investigators provided the Pharmacy an exact copy of what they had copied from the Pharmacy's database. Tr. 330-31. The Pharmacy also had some paper records. Tr. 332. Page 30 of Government Exhibit 5, a letter from a prescribing physician, is a sample of the paper records maintained by the Pharmacy. Tr. 332. Graumlich provided similar testimony concerning the prescription records contained in the Government Exhibits. Tr. 334-37.

Graumlich testified concerning the location of both the Pharmacy and Suntree Medical. Tr. 346-47. Graumlich also testified concerning the ownership of the Pharmacy and Suntree Medical, as well as their supervising practitioner. Tr. 337-43, 345-46, 348-52, 356; GE-27, 28.

I find Graumlich's testimony to be sufficiently objective, detailed, plausible, and internally consistent. Therefore, I merit it as credible in this Recommended Decision.

The Government's third witness was Michael Peterson ("Peterson"), who is an employee of Suntree

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[4] For ease of reference, similar pages for each identified customer will be referred to as the customer's "profile" throughout this Recommended Decision.

Medical. Tr. 394. Mr. Peterson presented testimony about: the Pharmacy's website and his association with the Pharmacy, Tr. 394-96 (GE-30); his interaction with DEA when he signed the Notice of Inspection on September 13, 2013, Tr. 396-98 (GE-32); turning over records to the DEA on September 23, 2013, Tr. 398-99 (GE-33); his current duties with Suntree Medical, Tr. 399-400; and his professional relationship with Dr. Clark. Tr. 409-10.

Peterson testified that he has been engaged in "managing, marketing and developing [the Pharmacy] for nine years." Tr. 395; GE-30, at 8. Peterson, however, considers himself to be employed by Suntree Medical because he is paid out of Suntree Medical funds. Tr. 395.

Peterson testified that he is the Manager of Suntree Medical where his duties include: business development; marketing; sales; human resources; ordering medical equipment; and the oversight of day-to-day operations. Tr. 399-400.

Peterson testified that he also works for the Pharmacy. Tr. 404. Peterson handles human resources, discipline, interviewing, and payroll for Suntree Pharmacy. Tr. 410. Other than the pharmacist-in-charge, Peterson is the senior individual in both the Pharmacy and Suntree Medical. Tr. 416. Peterson also delivered prescriptions for the Pharmacy. Tr. 573.

I find Peterson's testimony to be thorough, detailed, and internally consistent. Except as mentioned below, I merit Peterson's testimony as generally credible in this Recommended Decision. I, however, do not find Peterson's testimony that he believed that had no other choice but to sign the Notice of Inspection, or

whether Dr. Clark gave him permission to sign the Notice of Inspection, to be credible. *See* Tr. 402.

Peterson impressed me as an astute and intelligent individual. Peterson has a degree in business management. Tr. 409. By his testimony, and the Pharmacy's website, Peterson is a key member of management for the Pharmacy and Suntree Medical. When the three DEA investigators arrived at the Pharmacy in September 2013, they were wearing street clothes. Tr. 404. Peterson called Dr. Clark while the investigators were there, and he testified that she only told him to be cordial and polite. Tr. 407-08. Peterson acknowledged that most of the handwriting on the Notice of Inspection is his own. Tr. 412. The first sentence under the Statement of Rights contained on the Notice of Inspection reads, "You have a constitutional right not to have an administrative inspection made without an administrative inspection warrant." GE-32. Peterson understood what that meant. Tr. 412. But, he also testified that he did not think the he should do something that might cause an adverse reaction. Tr. 413. That is why he called Dr. Clark. Tr. 413. Given Peterson's intelligence, his position and obvious stake in the outcome of this case, and his action in calling Dr. Clark, I find it more likely that Peterson understood what he was signing, and that he did so based upon his discussion with his boss.

The Government's final witness was Dr. Diahn Clark, Pharm.D. Dr. Clark was also called a witness by the Respondents. An assessment of her credibility is contained under the discussion of the Respondents' witnesses.

II. The Respondents' Witnesses

The Respondents presented their case through the testimony of three witnesses. The first witness the Respondents called was their expert witness, Dr. Wayne H. Grant, Pham.D., ("Dr. Grant"), who has been a pharmacist since 1990. Tr. 425-527. Dr. Grant has both a bachelor's degree in pharmacy and a Doctorate in pharmacy.[5] Tr. 426. He has also been trained in neuropsych, based with pain management issues. Tr. 426. Dr. Grant is currently employed in a team approach clinical position with Hospice of the Western Reserve in Cleveland, Ohio. Tr. 426-27. The "team-based approach" includes pain management physicians. Tr. 428.

In his hospice position, Dr. Grant fills prescriptions and deals with patients who receive pain management. Tr. 427. Dr. Grant's end-of-life patients receive opiates and benzodiazepines. Tr. 427. Dr. Grant has been a member of the part-time adjunct faculty with the University of Florida for about 10 years. Tr. 428, 432. That position involves lecturing occasionally, concerning non-traditional programs, and his students are located all over the United States. Tr. 432, 437. The course that Dr. Grant teaches for the University of Florida is taught on-line.[6] Dr. Grant does not teach anything

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[5] The Respondents did not offer Dr. Grant's curriculum vitae.

[6] It is not clear just what Dr. Grant does with the University of the Florida. Initially he testified that he was a member of the adjunct faculty. Tr. 428, 432. Later Dr. Grant testified, that he does not teach, rather he lectures for an hour to an hour and a half once a year. Tr. 517. He also has presented lectures in New York Tr. 516. Dr. Grant's lectures concern, "didactics," but that was not fully explained. Tr. 432, 516.

about "red flags." Tr. 449. Other than a Florida continuing education course, which he reviewed but did not take, Dr. Grant was not aware of any other training discussing red flags. Tr. 450-51.

Previously, Dr. Grant was employed with Central Admixture Pharmacy Services, doing infusion therapies, where most of the patients were on pain management therapies. Tr. 429. There, too, patients received opiate medications. Tr. 430. Dr. Grant did consulting with NCS Healthcare, dispensing medications to long-term care patients. Tr. 430-31. Dr. Grant has about 15 years' experience working in retail pharmacies. Tr. 431.

Dr. Grant is licensed as a pharmacist in Ohio and he has taken continuing education courses to satisfy Ohio requirements. Tr. 433-34. Dr. Grant has never been disciplined. Tr. 434. Dr. Grant has never been a licensed pharmacist in Florida. Tr. 437. While Dr. Grant has reviewed continuing education courses related to the requirements for a Florida pharmacist to dispense controlled substances, he has not taken any of those courses. Tr. 433.

Dr. Grant has done peer review work for the *American Journal of Health System Pharmacy* for five or six years. Tr. 434. The focus of Dr. Grant's peer review work has been in pain management, neuropsych, and kidney disorders. Tr. 434. Most of the peer review work that Dr. Grant performed dealt with specific drugs and controlled trials. Tr. 436.

After a brief voir dire of Dr. Grant, the Government objected to accepting Dr. Grant as an expert witness. Tr. 437-442. The Government's primary objection was based upon Dr. Grant's lack of experience with pharmacy standards in the state of Florida. Tr. 438-442.

Following argument by counsel, Dr. Grant was accepted as an expert in the field of pharmacy. Tr. 437, 442.

While Dr. Grant appeared to be an honest and candid witness, I give little weight to his testimony for numerous reasons, including, but not limited, to the following six points. First, I found Dr. Grant deceptive even when answering questions about his qualifications. When specifically asked a question of whether he had taken a continuing education course concerning filling prescriptions for controlled substances in Florida, Dr. Grant explained the Florida requirements. Tr. 433. Dr. Grant, however, had not taken the course, but only reviewed it. Tr. 433. Further, while professing to be an adjunct faculty member at the University of Florida, it turns out he does not teach, but only occasionally lectures. Tr. 428, 516-17.

Second, his testimony that he did not know if he had ever been qualified as an expert in Florida was not credible. It is not credible because Dr. Grant acknowledged that he had never testified in Florida before. Tr. 438.

Third, Dr. Grant's explanation of a pharmacist's corresponding duty had no resemblance to the regulatory requirement contained in 21 C.F.R. § 1306.04(a). Dr. Grant testified that the corresponding duty "looks at a standard in which pharmacy practice is when we're reviewing prescriptions that come into our care." Tr. 444-45. Dr. Grant's "expert" explanation of the phrase "corresponding duty" is almost incomprehensible.

Fourth, Dr. Grant's testimony that he had reviewed all of the prescriptions that were addressed in the OSC, and that none of these prescriptions "on their face appeared to be a violation of that corresponding

responsibility," Tr. 445, does not hold up to scrutiny of the record or to cross-examination. Dr. Grant also testified that he did not "know the scenario that's around this case. . . . " Tr. 462. Yet, even Dr. Clark admitted that many of the prescriptions involved red flags that the Pharmacy had resolved before filling the prescriptions. Tr. 587, 597-98, 610-11, 617-18, 642, 650, 671-72, 676, 681, 688, 701, 727, 730.

On cross-examination, Dr. Grant admitted that there should have been a follow-up written prescription for the call-in prescription at GE-2, at 19, but there was none in the file. Tr. 478-79. Dr. Grant also testified he would have a discussion about repeatedly filling a prescription early, where one prescription for 30 days and another was for 28 days and the patient always came in to fill on the 28th day. Tr. 509-11. He also acknowledged that a pharmacist exercising reasonable care would have had that conversation. Tr. 511. In addition, Dr. Grant testified that with respect to the prescription filled on September 5, 2014 for M.B., he would have had a conversation with the prescriber before filling this early refill prescription. Tr. 506-09; GE-14, at 59-60.

Fifth, Dr. Grant testified that the term "drug cocktail" is not a common term used in pharmacology. Tr. 455-56. When asked what a cocktail is he replied, "Other than a drink, I'm not really sure." Tr. 456. The DEA, however, has long discussed drug cocktails. *See, e.g., Paul H. Volkman, MD.*, 73 Fed. Reg. 30630, 30637 (2008) (discussing testimony of expert in pain management that physician's practice of prescribing drug cocktails of opioids, which often included multiple opioids, a benzodiazepine and carisoprodol, "greatly increased the chance for drug abuse, diversion, [and]/or

addiction"); *see also Your Druggist Pharmacy*, 73 Fed. Reg. 75774, 75775 n.1 (2008) (discussing carisoprodol's use by drug abusers as a part of a drug cocktail which also includes an opiate and benzodiazepine).

Finally, Dr. Grant even seemed unwilling to use the term red flag. When initially asked if he was familiar with the phrase, he answered, "I'm familiar with the concept." Tr. 449. He added, "I don't teach anything about red flags." Tr. 449. He also testified that he had not heard the term red flag used in relation to opioids until two or three years ago. Tr. 518. Yet, even Dr. Clark had no trouble using the term and understanding its meaning. Tr. 587, 597-98, 610-11, 617-18, 642, 650, 671-72, 676, 681, 688, 701, 727, 730. Further, the DEA has addressed red flags in its decisions for years. *See Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62316, 62322 (2008). Accordingly, where there is conflict between the testimony of Dr. Grant and the testimony of Dr. Gordon, I find that Dr. Gordon testimony is more credible and is entitled to greater weight.

The Respondents' second witness was Dr. Diahn Clark, Pharm. D. ("Dr. Clark"), the sole owner of the Pharmacy and Suntree Medical. Tr. 529. Dr. Clark holds a Doctor of Pharmacy from Mercer University and a law degree from Stetson University. Tr. 530. Dr. Clark testified concerning her ownership of the Respondents, and her responsibilities as the pharmacist in charge. Tr. 530-32. Dr. Clark also testified about the policies and practices that the Pharmacy utilizes to resolve red flag before filling prescriptions, and how those policies were implemented. Tr. 532-37, 47. Dr. Clark testified about seeking the advice of an attorney while she developed the Pharmacy's policies, as well

as seeking guidance concerning filling prescriptions written by a doctor to himself and selling controlled substances to doctors. Tr. 536, 539, 571-73, 583, 693-97, 777-78. Dr. Clark testified about her dealings with Bert Soss, a pharmacist she hired to work in the Pharmacy, and the reasons he was eventually fired. Tr. 532, 549-560. In addition, Dr. Clark testified about the Pharmacy's filling prescriptions for the individuals identified in the OSC, and the efforts the Pharmacy took to resolve any red flag that those prescriptions may have presented. Dr. Clark testified that the Pharmacy had satisfied its corresponding duty in filling the prescriptions addressed in the OSC. Tr. 758-59.

I find Dr. Clark's testimony to be generally objective, detailed, and with some exceptions it was plausible, and internally consistent. Certain aspects of Dr. Clark's testimony, however, detracted from her overall credibility. Those aspects included unnecessary contentiousness, exaggeration, and a lack of familiarity with the Pharmacy's records.

Dr. Clark's contentiousness was demonstrated by the numerous times she answered a rather straightforward question with a question, and her unwillingness to concede an obvious point. For example, when Dr. Clark was asked whether she was satisfied with a letter of medical necessity she respond, "As to what?" Tr. 701-02. When asked whether a letter of medical necessity was ambiguous, Dr. Clark responded, "With respect to what?" Tr. 702. When asked whether she was happy with a particular letter of medical necessity, Dr. Clark answered, "As to what?" Tr. 703. When asked what the first thing she would access when trying to find out some information out about a patient, Dr. Clark replied, "What information am I looking for?"

Tr. 704. When asked what she would do to resolve a red flag, Dr. Clark queried, "What's the red flag?" Tr. 704. When asked if it was if it was a long distance between Malabar and Miami, Florida, Dr. Clark answered, "Long in relation to?" Tr. 707. Further when confronted with a letter of medical necessity that on its face was ambiguous concerning how long patient J.S. would need to be treated, she refused to acknowledge the ambiguity. Tr. 701-703; GE-6, at 16. In addition, she testified that she read the letter to indicate that J.S. would only need short term care, where there is no logical way to interpret the letter in that manner. Tr. 703; GE-6, at 16. Finally, it was necessary to pull an answer out of her to a very simple question about whether she had filled prescriptions written by Dr. Richard. Tr. 745-747.

Dr. Clark's exaggeration was demonstrated numerous times where she attempted to paint a more familiar relationship with her customers than is supported by the Pharmacy's records. For example, Dr. Clark testified that she always engaged D.B. in conversation, yet the Pharmacy records show that Dr. Clark only waited on D.B. three times. Tr. 620; GE-7, at 21-26, 57-60. Dr. Clark also testified that she recalled that D.B.'s dosage for anxiety medication was reduced "over the time that he was with me." Tr. 621. The Pharmacy records for D.B., however, do not reflect a reduction in the dosage of Xanax. GE-7. The first prescription for Xanax 2 mg was filled on May 2, 2014, and the last for the same dosage was filled on February 21, 2015. GE-7, at 15-16, 53-54. Dr. Clark testified that the Pharmacy did not fill any prescriptions for P.P. after April 30, 2014, but the Pharmacy records

show that it filled five prescriptions of controlled substances for P.P. after that date. Tr. 633; RE-H, at 256. Dr. Clark also testified that she interacted regularly with M.B., K.B.2, and K.B.3, but the Pharmacy records show that she waited on M.B. only one day, and on K.B.2 and K.B.3 only two days each. Tr. 638, 660-61; GE-14, at 53-58; GE-17, at 12-15; GE-18, at 41-44, 85-86. With respect to A.G., Dr. Clark testified that she had interacted with him, but then she also testified that she did not recall filling any prescriptions for him. Tr. 664-67. Finally, she testified that the letter of medical necessity for C.A. resolved the red flag concerning the distance that he was driving, but the letter does not mention why C.A. was treating with the doctor who wrote the letter, as opposed to a doctor located closer to where C.A. lived. Tr. 650; RE-H, at 288.

At least twice, Dr. Clark testified that the Pharmacy had received a letter of medical necessity concerning a customer, but the letter had been misplaced. Tr. 663, 672, 778-79. In both of these instances, the letters were contained in the Pharmacy records. GE-17, at 29; GE-20, at 66. In addition, Dr. Clark relied upon an aid she prepared prior to the hearing to recall her testimony, but the aid was not offered as an exhibit. Tr. 605-607.

While the above noted aspects of Dr. Clark's testimony detract from her overall credibility, I find that her testimony is generally credible. To the extent, her testimony conflicts with other testimony, or exhibits, however, I find that the exhibits and the other testimony merit greater weight.

The third witness the Respondents presented was Mr. Darren Meacham, Esq. Tr. 800-30. Meacham is an attorney licensed in the state of Florida. Tr. 800.

Meacham sporadically worked for the Pharmacy from 2004 until 2008, and has regularly worked for it since then. Tr. 801. He was retained by the Pharmacy to keep up with compliance rules and regulations, as well as policies and procedures, to include distribution of controlled substances. Tr. 801. Since 2008, Meacham has continuously assisted the Pharmacy with compliance related to controlled substances. Tr. 801-02. Since 2008, Meacham has provided advice on what is considered to be a red flag. Tr. 802. Meacham provided that advice to Ms. Clark. Tr. 805. As a result of Meacham's advice the Pharmacy developed a written policy in 2008. Tr. 806. That policy required that the Pharmacy accept no out of county customers, but if they were established customers, and "everything else checked out," the Pharmacy could fill prescriptions written by out of county doctors. Tr. 806. Meacham recommended that if the doctor was out of county a letter of medical necessity should be obtained, and the Pharmacy followed his recommendation. Tr. 807. Later, customers were required to provide driver's licenses. Tr. 826.

In 2008, the Pharmacy sought advice concerning whether a doctor could self-prescribe, but the inquiry was not specific to controlled substances. Tr. 809. Meacham advised the Pharmacy that doctors could self-prescribe, but that it "required scrutiny." Tr. 809-10. After the Board of Pharmacy visited the Pharmacy in January 2015, Meacham changed his advice and advised the Pharmacy that it should not fill prescriptions written by a doctor to himself. Tr. 810. The Pharmacy followed his advice. Tr. 810. Although Meacham testified that he provided this guidance to the Pharmacy in writing, he did not have a copy of what he provided. Tr. 811, 827-30.

I find that Meacham testimony is consistent with other testimony of record. He testified in a candid and forthright manner and he was a credible witness.

THE FACTS

I. Stipulations of Fact

The Government and the Respondent stipulated the following facts ("Stip."):

1. Respondent Suntree Pharmacy is registered with the DEA as a retail pharmacy authorized to handle controlled substances in Schedules under DEA COR number BS7384174 at 7640 N. Wickham Road, Suite 117, Melbourne, Florida 32940. DEA COR BS7384174 expires on February 28, 2019.

2. Respondent Suntree Medical Equipment LLC is registered with the DEA as a retail pharmacy authorized to handle controlled substances in Schedules II-V under DEA COR number FS2194289 at 7640 N. Wickham Road, Suite 116, Melbourne, Florida 32940. DEA COR FS2194289 expires on February 28, 2019.

3. Suntree Pharmacy is owned and operated by Suntree Pharmacy, Inc., and is registered with the Florida Department of Health as a licensed pharmacy under License No. PH18030, which expire[d] on February 28, 2017.

4. Diahn L. Clark ("Ms. Clark") is listed with the Florida Department of Health as a supervising practitioner for Suntree Pharmacy, Inc. Ms. Clark is further listed as the sole Officer/Director (President) for Suntree Pharmacy, Inc., with the Florida Department of State, Division of Corporations.

5. Suntree Medical Equipment LLC is owned and operated by Suntree Medical Equipment, LLC, and is registered with the Florida Department of Health as a licensed pharmacy under License No. PH22488, which expire[d] on February 28, 2017.

6. Diahn L. Clark ("Ms. Clark") is listed with the Florida Department of Health as a supervising practitioner for Suntree Medical Equipment, LLC. Ms. Clark is further listed as the sole Officer/Director (Manager) for Suntree Medical Equipment, LLC with the Florida Department of State, Division of Corporations.

7. Pursuant to www.mapquest.com, the approximate driving distance from 265 Atz Road, Malabar, Florida 32950 to 1647 SW 27th Ave., Miami, Florida 33145-2044 is 170 miles.

8. Pursuant to www.mapquest.com, the approximate driving distance from 2207 Monroe Street NE,[7] Palm Bay, Florida 321905 (sic) to 1647 SW 27th Ave., Miami, Florida 33145-2044 is 176 miles.

9. Pursuant to www.mapquest.com, the approximate driving distance from 2207 Monroe Street NE,[8] Palm Bay, Florida 321905 (sic) to 301 Femcreek Avenue, Orlando, Florida 32803 is 74 miles.

10. Pursuant to www.mapquest.com, the approximate driving distance from 800 Faith Street NE, Palm Bay, Florida 32905 to 1647 SW 27th Ave., Miami, Florida 33145-2044 is 174 miles.

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[7] *See* Tr. 11.

[8] *See* Tr. 11.

11. Pursuant to www.mapquest.com, the approximate driving distance from 1647 SW 27th Ave. Miami, Florida 33145-2044 to 7640 N. Wickham Road, Melbourne, Florida 32940-7911 is 187 miles.

12. Pursuant to www.mapquest.com, the approximate driving distance from 7640 N. Wickham Road, Melbourne, Florida 32940-7911 to 800 Faith Street NE, Palm Bay, Florida 32905 is 22 miles.

13. Pursuant to www.mapquest.com, the approximate driving distance from 1460 Sheafe Ave NE, Palm Bay, Florida 32905 to 1647 SW 27th Ave., Miami, Florida 33145-2044 is 175 miles.

14. Pursuant to www.mapquest.com, the approximate driving distance from 1460 Sheafe Ave NE, Palm Bay, Florida 32905 to 1550 N. Federal Highway, Boynton Beach, Florida, 33435 is 122 miles.

15. Pursuant to www.mapquest.com, the approximate driving distance from 1647 SW 27th Ave., Miami, Florida 33145-2044 to 7640 N. Wickham Road, Melbourne, Florida 32940-7911 is 187 miles.

16. Pursuant to www.mapquest.com, the approximate driving distance from 7640 N. Wickham Road, Melbourne, Florida 32940-7911 to 1460 Sheafe Ave NE, Palm Bay, Florida 32905 is 18 miles.

17. Pursuant to www.mapquest.com, the approximate driving distance from 1460 Sheafe Ave. NE, Palm Bay, Florida 32905-3739 to 511 Granada Drive, Winter Park, Florida 32789-3318 is 76 miles.

18. Pursuant to www.mapquest.com, the approximate driving distance from 511 Granada Drive, Winter Park, Florida 32789-3318 to 7640 N. Wickham Road, Melbourne, Florida 32940-7911 is 62 miles.

19. Pursuant to www.mapquest.com, the approximate driving distance from 7640 N. Wickham Road, Melbourne, Florida 32940-7911 to 1460 Sheafe Ave. NE, Palm Bay, Florida 32905-3739 is 18 miles.

20. Pursuant to www.mapquest.com, the approximate driving distance from 4955 Dixie Hwy NE, Palm Bay, Florida 32905 to 1647 SW 27th Ave, Miami, Florida 33145-2044 is 175 miles.

21. Pursuant to www.mapquest.com, the approximate driving distance from 4955 Dixie Hwy NE, Palm Bay, Florida 32905 to 4921 Colonial Drive, Orlando, Florida 32803-4309 is 74 miles.

22. Pursuant to www.mapquest.com, the approximate driving distance from 100 Ocean Terrace, Indialantic, Florida to 3267 Davie Blvd, Fort Lauderdale, Florida 33312 is 158 miles.

23. Pursuant to www.mapquest.com, the approximate driving distance from 3267 Davie Blvd, Fort Lauderdale, Florida 33312 to 7640 Wickham Road, Melbourne, Florida 32940 is 162 miles.

24. Pursuant to www.mapquest.com, the approximate driving distance from 7640 Wickham Road, Melbourne, Florida 32940 to 100 Ocean Terrace, Indialantic, Florida is 16 miles.

25. Pursuant to www.mapquest.com, the approximate driving distance from 2466 SW Washington Street, Port St. Lucie, Florida 34953 to 601 University Blvd, Jupiter, Florida 33458 is 39 miles.

26. Pursuant to www.mapquest.com, the approximate driving distance from 601 University Blvd, Jupiter, Florida 33458 to 7640 Wickham Road, Melbourne, Florida 32940 is 111 miles.

27. Pursuant to www.mapquest.com, the approximate driving distance from 7640 Wickham Road, Melbourne, Florida 32940 to 2466 SW Washington Street, Port St. Lucie, Florida 34953 is 76 miles.

28. Pursuant to www.mapquest.com, the approximate driving distance from 2827 Lipscomb Street, Melbourne, Florida 32901 to 1647 SW 27th Ave., Miami, Florida 33145-2044 is 176 miles.

29. Pursuant to www.mapquest.com, the approximate driving distance from 2827 Lipscomb Street, Melbourne, Florida 32901 to 1550 N. Federal Highway, Boynton Beach, Florida 33435 is 123 miles.

30. Pursuant to www.mapquest.com, the approximate driving distance from 551 Violet Ave. NE, Palm Bay, Florida 32907 to 1647 SW 27th Ave., Miami, Florida 33145-2044 is 173 miles.

31. Pursuant to www.mapquest.com, the approximate driving distance from 1647 SW 27th Avenue, Miami, Florida, to 7840 N. Wickham Road, Melbourne Florida, is 188 miles.

32. Pursuant to www.mapquest.com, the approximate driving distance from 11094 NW 40th Street, Ft. Lauderdale, Florida, to 7640 N. Wickham Road, Melbourne, Florida, is 164 miles.

33. Pursuant to www.mapquest.com, the approximate driving distance from 1596 Street NE, Palm Bay, Florida, to 1403 Medical Plaza Drive, Sanford, Florida, is 87 miles.

34. Pursuant to www.mapquest.com, the approximate driving distance from 1403 Medical Plaza Drive, Sanford, Florida, to 7640 Wickham Road, Melbourne, Florida, is 70 miles.

35. Pursuant to www.mapquest.com, the approximate driving distance from 1001 Buttonwood Street, Sebastian, Florida, to 5105 East Colonial Drive, Orlando, Florida, is 86 miles.

36. Pursuant to www.mapquest.com, the approximate driving distance from 3375 S. Atlantic Ave., Cocoa Beach, Florida to 1403 Medical Plaza Drive, Sanford, Florida, is 75 miles.

37. Pursuant to www.mapquest.com, the approximate driving distance from 2694 Southover Drive NE, Palm Bay, Florida, to 1403 Medical Plaza Drive, Sanford, Florida, is 88 miles.

38. Pursuant to www.mapquest.com, the approximate driving distance from 2675 Center Street, Melbourne, Florida, to 1523 S. Orange Ave., Orlando, Florida is 67 miles.

39. Pursuant to www.mapquest.com, the approximate driving distance from 1114 Banana River Drive, Indian Harbour Beach, Florida, to 7655 Orange Blossom Trail, Orlando, Florida, is 65 miles.

40. Pursuant to www.mapquest.com, the approximate driving distance from 2964 Century Oaks Circle, Malabar, Florida, to 7655 Orange Blossom Trail, Orlando, Florida, is 73 miles.

41. Pursuant to www.mapquest.com, the approximate driving distance from 1380 New Haven Avenue, Melbourne, Florida, to 7655 Orange Blossom Trail, Orlando, Florida, is 65 miles.

42. Pursuant to www.mapquest.com, the approximate driving distance from 125 Cleveland Avenue, Cocoa Beach, Florida, to 7655 Orange Blossom Trail, Orlando, Florida, is 51 miles.

43. Pursuant to www.mapquest.com, the approximate driving distance from 7655 Orange Blossom Trail, Orlando, Florida, to 7640 Wickham Road, Melbourne, Florida, is 52 miles.

44. Pursuant to www.mapquest.com, the approximate driving distance from 7640 Wickham Road, Melbourne, Florida, to 125 Cleveland Ave., Cocoa Beach, Florida is 27 miles.

45. Pursuant to www.mapquest.com, the approximate driving distance from 2964 Century Oaks Circle, Malabar, Florida, to 125 Cleveland Ave., Cocoa Beach, Florida, is 28 miles.

46. Pursuant to www.mapquest.com, the approximate driving distance from 330 Harwood Ave., Satellite Beach, Florida, to 7655 Orange Blossom Trail, Orlando, Florida, is 64 miles.

47. Pursuant to www.mapquest.com, the approximate driving distance from 1036 Mary Joye Ave., Satellite Beach, Florida, to 7655 Orange Blossom Trail, Orlando, Florida, is 66 miles.

48. Pursuant to www.mapquest.com, the approximate driving distance from 7667 N. Wickham Road, Melbourne, Florida, to 4921 E. Colonial Drive, Orlando, Florida, is 54 miles.

49. Pursuant to www.mapquest.com, the approximate driving distance from 905 Brunswick Lane,[9] Rockledge, Florida, to 4921 E. Colonial Drive, Orlando, Florida, is 50 miles.

50. Pursuant to www.mapquest.com, the approximate driving distance from 4921 E. Colonial Drive,

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[9] *See* Tr. 11.

Orlando, Florida, to 7640 N. Wickham Road, Melbourne, Florida, is 55 miles.

51. Pursuant to www.mapquest.com, the approximate driving distance from 620 S. Brevard Ave., Cocoa Beach, Florida, to 7655 Orange Blossom Trail, Orlando, Florida is 56 miles.

52. Pursuant to www.mapquest.com, the approximate driving distance from 760 Carolin Street, Melbourne, Florida, to 7209 Curry Ford Rd., Orlando, Florida, is 62 miles.

53. Ambien is a brand name for zolpidem, a Schedule IV controlled substance.

54. Percocet and Endocet are brand name products containing oxycodone, a Schedule II controlled substance.

55. Oxycontin and Roxicodone are brand names for oxycodone, a Schedule II controlled substance.

56. Depo Testosterone is a brand name for testosterone cypionate, a Schedule III controlled substance.

57. Dilaudid is a brand name for hydromorphone, a Schedule II controlled substance.

58. MS Contin is a brand name for morphine sulfate controlled release, a Schedule II controlled substance.

59. Adderall is a brand name for amphetamine/dextroamphetamine, also known as amphetamine salts, all which are Schedule II controlled substances.

60. Restoril is a brand name for temazepam, a Schedule IV controlled substance.

61. Xanax is a brand name for alprazolam, a Schedule IV controlled substance.

62. Soma is a brand name for carisoprodol, a Schedule IV controlled substance.

63. Methadone is a Schedule II controlled substance.

64. Klonopin is a brand name for clonazepam, a Schedule IV controlled substance.

65. Ativan is a brand name for lorazepam, a Schedule IV controlled substance.

66. Opana is a brand name for oxymorphone, a Schedule II controlled substance.

67. Tussionex is a brand name product containing hydrocodone, a Schedule II controlled substance.

68. Valium is a brand name for diazepam, a Schedule IV controlled substance.

II. Findings of Fact

The factual findings below are based on a preponderance of the evidence, including the detailed, credible, and competent testimony of the aforementioned witnesses, the exhibits entered into evidence, and the record before me.

A. Drugs

1. Dilaudid is a brand name for hydromorphone, a Schedule II controlled substance. Tr. 67; Stip. 57. The highest strength dosage available for hydromorphone is 8 mg. Tr. 67.

2. Roxycodone and Oxycontin are brand names for oxycodone, a Schedule H controlled substance.

Stip. 55. The highest strength dosage available for oxycodone is 30 mg. Tr. 94; GE-9, at 1.

3. Valium is a brand name for diazepam, a Schedule IV controlled substance. Stip. 68. The highest strength dosage available for diazepam is 10 mg. Tr. 158; GE-18, at 1.

4. The highest available dose of Ambien is 12.5 mg. Tr. 187; GE-22, at 23.

B. Red Flags

5. A "red flag" is an indication that a prescription may have been issued for other than a legitimate medical purpose. Tr. 33-34. Pharmacists are required by law to look for red flags. Tr. 33.

6. Distance can be a red flag. Tr. 35-36. A pharmacist should consider whether the patient lives in the local community. Tr. 35. A pharmacist should consider the path that the patient took to get the prescription and then to get to the pharmacy. Tr. 36. There can be legitimate reasons for traveling a long distance to see a doctor. Tr. 242. A way to resolve that red flag is to talk to the doctor or the patient. Tr. 242.

7. A doctor prescribing outside his or her area of practice is a red flag; for example, an OB-GYN writing prescriptions for chronic back pain. Tr. 35.

8. Controlled substances prescribed together that constitute a therapeutic duplication is a red flag. Tr. 35. A pharmacist should also look for drug interactions and therapeutic duplications. Tr. 35.

9. Pharmacists should consider whether the prescription is for a "high alert medication," such as opioids, like oxycodone and hydromorphone or benzodiazepines

—anything ending with a "pam," muscle relaxers, and anything that can suppress the central nervous system ("CM"). Tr. 36.

10. A patient presenting a prescription that does not have the patient's address on the face of the prescription is a red flag. Tr. 296. That red flag is not resolved simply because the pharmacy has the patient's address on file, the pharmacy should check to make sure the address is correct. Tr. 296-98.

11. An immediate release medication, which is used for breakthrough pain, is a red flag. Tr. 37-39. It does not make pharmacological sense to prescribe two short acting opioids such as hydromorphone and oxycodone, because they do the same thing. Tr. 37-38.

12. A group of patients seeing the same doctor, receiving the same or similar prescriptions, and who present to a pharmacy at about the same time to get their prescriptions filled would constitute a red flag. Tr. 106.

13. Pattern prescribing is a red flag. Tr. 38-39. Pattern prescribing occurs when a physician prescribes the same medication over and over again for many patients, without individualizing the treatment. Tr. 38. It would take a while for a pharmacist to determine whether a doctor was a pattern prescriber. Tr. 223. If a doctor where to issue the same prescription to two patients on the same day, one after the other, that would be sufficient to suggest a red flag. Tr. 223-24.

14. A prescription cocktail is a red flag. Tr. 39-40. A prescription cocktail is two or more prescriptions that do the same thing or enhance the effects of each other. Tr. 39, 225. Five or six years ago a common prescription cocktail would have involved a soma, a

benzodiazepine, like Ativan or Xanax, and an oxycodone or hydromorphone. Tr. 40. More recently, the prescription cocktails have involved just a benzodiazepine, such as alprazolam, Xanax, Lorazepam, or Ativan, plus hydromorphone or oxycodone, or both. Tr 40. The combination of the drugs in a prescription cocktail enhances the depressive effects of those drugs on the CNS. Tr. 39, 225. Soma is a commonly known controlled substance that suppresses the CNS. Tr. 225. Anytime hydromorphone and alprazolam are prescribed together it is a drug cocktail. Tr. 302-03.

15. Patients from the same household who are receiving the same or similar prescriptions would present a red flag. Tr. 40-41, 226.

16. Paying cash for a prescription is considered a red flag. Tr. 41, 227. Less than 5% of prescriptions filled in pharmacies are paid for by cash. Tr. 229. Paying cash is a red flag due the possibility of the patient trying to circumvent insurance companies, and it can indicate an early refill. Tr. 229, 231. Drug seekers pay cash to "keep under the radar." Tr. 231-32. Some insurance companies, however, will not cover certain medications. Tr. 279. When that happens, the patient can pay for the medications. Tr. 280. Under those circumstances, paying cash would not raise a red flag. Tr. 280; *see also* Tr. 294-95.

17. Doctor shopping is a red flag. Tr. 42. Doctor shopping is where a patient goes to multiple doctors trying to obtain cocktail medications. Tr. 42.

18. Pharmacy shopping is a red flag. Tr. 42, 235. Pharmacy shopping is where a patient goes to different pharmacies to get different opioids or benzodiazepines or cocktails filled. Tr. 42. One reason a patient might

go to different pharmacies is to avoid presenting prescriptions for medications that would constitute a drug cocktail. Tr. 291-92.

19. Taking two short-acting controlled substances can be a red flag. Tr. 221. There is no need to prescribe two different short-acting opiates, because the same one can be used. Tr. 222. There would be no need to prescribe a larger dosage; rather you would increase the quantity of tablets. Tr. 222.

20. A diagnosis of back pain can be a red flag. Tr. 220.

21. A pharmacist resolves red flags by either speaking to the patient or to the physician who issued the prescription. Tr. 43-44. Some red flags, however, cannot be resolved. Tr. 44.

22. When a red flag is resolved, it must be documented before the prescription is dispensed. Tr. 45. It is important to document the resolution of a red flag on either the prescription itself or in the pharmacy's computer system. Tr. 45.

23. Dr. Clark was aware that when a pharmacist spots a red flag with a prescription, the pharmacist was supposed to resolve the red flag, and if they could not resolve the red flag, the prescription was not to be filled. Tr. 566. Dr. Clark instructed her pharmacists to resolve red flags. Tr. 556. Dr. Clark also trained her pharmacists as to what might be considered a red flag. Tr. 567. The potential red flags that Dr. Clark identified to her pharmacists included the need for a Brevard

County driver's license, and having a doctor in adjacent counties without a letter of medical necessity.[10]

C. Standard Practices

24. Pharmacists in the state of Florida, "-should assure that the medication is safe and exercise their corresponding responsibility to make sure the medication is for a legitimate medical purpose, to look at things like drug interactions, appropriateness of dose, what doctor is writing the prescription, how far the patients traveled, is it appropriate, is it safe for themselves and for the community." Tr. 33.

25. Under normal pharmacy procedures, Schedule II controlled substances are to be kept locked at all times, with only the pharmacist having access to the key. Tr. 109-110, 268. In order to fill a prescription for a Schedule II controlled substance a pharmacist is required to get them. Tr. 110. A pharmacy technician can count the medication, but after the prescription is filled, the Scheduled II controlled substance must be locked up again. Tr. 110.

26. If the prescription is for a controlled substance, the pharmacist should look carefully at the prescription. Tr. 34. A pharmacist should also consider whether the dose is appropriate. Tr. 34. For example, did the doctor start the patient on the highest dose of an opiate or a

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[10] Dr. Clark testified that the Pharmacy allowed patients to be seen by doctors outside the local area, "because there were not available practitioners in the area, especially given closed insurance networks." Tr. 568. Just as with the testimony of Dr. Gordon on the availability of local doctors, I *give* little weight to this unsupported testimony. Further the testimony is somewhat contradicted by the file of FIB., who had been seeing a pain doctor in Orlando, but then found one in Brevard County. GE-22, at 107-08, 109-10.

benzodiazepine, both of which can suppress the CNS? Tr. 34-35.

27. For a prescription to be valid, the prescription should include: the patient's name; the date the prescription was written; the patient's address; the signature of the doctor; the doctor's DEA number; the name of the drug; strength; quantity; and the directions for taking the medication. Tr. 49.

28. Under the minimal standard of practice of pharmacy in Florida, a pharmacist should not fill a prescription written by a physician to him or herself. Tr. 46.

29. Under the minimal standard of practice of pharmacy in Florida, a pharmacist should not fill a prescription written to a business or an office, rather than an actual person. Tr. 46.

30. A pharmacist can detect doctor shopping by using E-FORCSE, a computer program set up by the State of Florida. Tr. 42-43. A pharmacy is supposed to report to E-FORCSE information about each prescription the pharmacy fills, to include: the medication; the quantity; and the doctor. Tr. 43. Pharmacists can then go into E-FORCSE and pull up a patient's name and see where the patient has gone and what doctors the patient has seen. Tr. 43, 234.

31. If a red flag cannot be resolved, under the standard practice a pharmacy in Florida, the medication should not be dispensed. Tr. 46.

32. A pharmacy does not need to document red flags in their software system, but that is normal pharmacy practice for ease of retrieval of the information by other pharmacists. Tr. 204.

33. To be a pharmacist in Florida you have to pass the Pharmacy Boards. Tr. 692. That examination tests one's knowledge of pharmacy law in the state of Florida. Tr. 692.

D. Policies and Practices of the Pharmacy

34. The Pharmacy and Suntree Medical received JCAHO accreditation 2009. Tr. 530-31.

35. The Pharmacy had policies and procedures in place related to filling prescriptions for controlled substances. Tr. 532-33. When Dr. Clark took over the Pharmacy in 2008 or 2009, she hired an attorney, Meacham, to help her develop policies. Tr. 536, 539. She would follow Meacham's advice. Tr. 539. One policy required that the customer have a Brevard County driver's license, and if they were seeing a doctor in an adjacent county, the customer needed to get a letter of medical necessity from the doctor. Tr. 536. The driver's license number is entered in the Patient Record Maintenance. Tr. 684. *See e.g.*, RE-H, at 528, just above "patient memo" box.

36. Later, the Pharmacy would check customer's criminal records and, if a customer had a criminal record, the individual was dismissed as a customer. Tr. 537.

37. The Pharmacy had an employee handbook that addressed these policies, and employees signed a certification that they would comply with the policies when they were hired. Tr. 549, 710-12. Meacham has not seen the handbook. Tr. 712.

38. When a prescription is filled at the Pharmacy, the pharmacy staff was to always look at the "Patient

Record Maintenance" screen of the patient's file. Tr. 705.

39. The Pharmacy provided to its customers a letter that contained some of the Pharmacy's policies, but generally the Pharmacy relied on "day-to-day hands-on training." Tr. 709-10; RE-H, at 423.

40. Dr. Clark provided general supervision to the pharmacists she employed, but she also allowed them their independence as licensed professionals. Tr. 532.

41. Dr. Clark held weekly meetings with her employees to discuss pharmacy policies, but since it is a small business, she could also talk individually to everyone. Tr. 547.

42. Dr. Clark advised the Pharmacy staff to inform its customers who saw Dr. Richard that they should find a local physician, and the Pharmacy provided its customers with a list of local physicians. Tr. 594. Dr. Clark considered doctors in Orlando, some 50 miles away, to be local. Tr. 594.

43. Page 2 of GE-2 is a fill sticker created by the Pharmacy. Tr. 50-51. It shows: the assigned prescription number; the patient's name, address, and date of birth; the doctor's name and address; the drug; the quantity; the directions for taking the drug; information about refills; the dates the prescription was written and filled; and the amount paid for the prescription, and method of payment. Tr. 51.

44. The Pharmacy assigned a number to each prescription it filled, assigning the numbers in chronological order. Tr. 55. The set of letters next to the pre-

scription number include the initials of the pharmacist who filled the prescription and after the "I" are the initials of the technician who assisted in filling the prescription. Tr. 55. Continuing on the top line of the fill sticker are the dates the medication was dispensed by the pharmacy and the date the prescription was written. Tr. 56. The fill sticker then recorded the name of the patient and the patient's address, followed by the doctor's name and address. Tr. 56. The next line identified the name of the drug and the quality and, below that, the cost of the prescription and the method of payment. Tr. 57.

45. It was the Pharmacy's policy to make a note in the patient memo box on the customer's profile when a letter of medical necessity was received. Tr. 735-36.

E. Prescriptions Filled by the Pharmacy

J.S.3

46. The prescriptions contained in Government Exhibit 2 are prescriptions a doctor, J.S.3, wrote to himself, which the Pharmacy filled. Tr. 48-53, 571.

47. In 2008, the Dr. Clark sought advice from Meacham concerning whether a doctor could self-prescribe, but the inquiry was not specific to controlled substances. Tr. 571, 777, 809. Meacham sent Dr. Clark an email in which he advised her that it was lawful to fill a prescription that a physician wrote for himself. Tr. 809.

48. When J.S.3 requested controlled substances for the Pharmacy, in 2012, Dr. Clark did not go back to Meacham for additional guidance before providing

the controlled substance to J.S.3. Tr. 777-78. Thus, Meacham's opinion that the Pharmacy could fill a prescription that a doctor wrote to himself was not specifically about J.S.3. *See* Tr. 693.

49. After the Board of Pharmacy visited the Pharmacy in 2015 and informed Dr. Clark that it was not lawful to fill a prescription that a doctor had written for himself, Meacham changed his advice. Tr. 573. Although Meacham still believed it was lawful, he advised against filling the prescriptions. Tr. 573.

50. Page 35 of GE-2 is J.S.3's patient profile contained in the pharmacy's computer system. Tr. 60.

51. J.S.3's profile is dated April 7, 2015. Tr. 699; GE-2, at 35. In the "patient memo" box on J.S.3's profile the only entry is "E.O.M.," which stands for "end-of-month" statement. Tr. 698; GE-2, at 35.

52. The date on J.S.3's profile in Respondent Exhibit H[11] is obscured by a "sticky note." Tr. 698; RE-H, at 1. In the "patient memo" box on that form in addition to the "E.O.M." notation, is an additional comment that reads, "cannot write personal scripts, DC." Tr. 699; RE-H, at 1.

53. The last prescription that the Pharmacy filled for J.S.3 was in January 2015. Tr. 762; GE-2, at 33-34; RE-H, at 2-3.

54. Throughout Government Exhibit 2, there is no documentation showing that any of the red flags

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11 Dr. Clark testified that the copy of the Patient Record Maintenance form presented in the Respondent's Exhibit H, page 1, was available to the Government on April 7, 2015. I do not find this credible because the "sticky note" obscures the date the document was printed. *Compare* GE-2, at 35, *with* RE-H, at 2-3.

involved in the prescriptions the Respondent filled for patient J.S.3 were resolved. Tr. 60.

Office Prescriptions

55. Dr. Clark was advised by her counsel, Meacham, that the Pharmacy could dispense to a doctor's office, so long as the Pharmacy did not dispense more than a certain percentage of its volume. Tr. 583. Meacham advised the Pharmacy that "wholesaling was permitted incidentally . . . between 3 and 5 percent." Tr. 695. The Pharmacy never exceeded that percentage. Tr. 584.

56. Dr. Clark submitted a written inquiry to Meacham concerning selling drug to doctors, but she does not have a copy of her inquiry. Tr. 696. Meacham provided a written response to Dr. Clark's inquiry about selling controlled substances directly to doctors, "wholesaling," but Dr. Clark does not have a copy of Meacham's response. Tr. 583, 696-97.

57. It is permissible for a pharmacy to dispense to a practitioner as long as the pharmacy does not exceed more than 5% of its total volume. Tr. 273-74; *see also* 21 C.F.R. 1307.11(a)(iv). A pharmacy can dispense controlled substances to a doctor's office based upon an invoice for those controlled substances. Tr. 277-79.

58. Government Exhibit 3 contains "prescriptions" that were written for office use, rather than prescriptions for controlled substances written for an individual. Tr. 63-64, 577. The exhibit contains prescription forms from Dr. Ivery and from Dr. Abraham that the Pharmacy filled. Tr. 695-96; GE-3, at 1-4.

59. The Pharmacy dispensed testosterone to Dr. Ivery's office 13 times and once to Dr. Abraham's office. Tr. 577; GE-3.

60. Government Exhibit 3, at 5, is an example of an order form that the Pharmacy created for Dr. Ivery's use when ordering testosterone. Tr. 582.

61. Meacham was never presented with copies of the documentation the Pharmacy used to sell controlled substances directly to doctors. Tr. 696. Meacham never told the Pharmacy that it was okay to use prescription blanks for doctors to order controlled substances for their office use. Tr. 694-95.

62. After the Board of Pharmacy visited the Pharmacy in 2015 and informed the Pharmacy that "wholesaling was not allowed . . .," Meacham changed his advice and the Pharmacy stopped dispensing to Dr. Ivery's office. Tr. 584.

Prescriptions Written by Dr. Richard

63. Government Exhibit 29 contains a May 22, 2014 letter from Dr. Richard to Dr. Clark, which was written by Dr. Richard "on behalf of [his] Brevard County patients." GE-29, at 1. In the letter, Dr. Richard stated that he had treated many of his Brevard County patients at the Broward Pain Center, but that he had moved his practice to Miami. *Id.* Dr. Richard also stated that many of his patients had "developed a great patient/Dr., relationship with myself and PA Nicole Russel," and had decided to continue treatment under his care. *Id.* Dr. Richard also informed Dr. Clark that he did not tolerate doctor shopping and he listed his office protocols to ensure against diversion.

Id. The letter from Dr. Richard, however, does not provide the names of any of his patients. *Id.*

64. On February 12, 2014, customers S.P., A.J., and J.S.1 presented similar prescriptions to the Pharmacy that had been written by Dr. Richard and the Pharmacy filled all of the prescriptions about the same time of the day. Tr. 106; GE-4, at 3-4; GE-5, at 3-4; GE-6, at 1-2. The prescriptions for S.P. and A.J. were both written on February 11, 2014. GE-4, at 3-4; GE-5, at 3-5.

65. On March 11, 2014, the Pharmacy filled similar prescriptions for customers D.G. and J.S.1, at about the same; the prescriptions were written by Dr. Richard on March 6, 2014. Tr. 107; GE-6, at 3-4; GE-9, at 5-6.

66. On Mach 15, 2014,[12] and April 11, 2014, the Pharmacy filled similar prescriptions for customers E.H., A.J., and S.P., all at about the same time, with each set of prescriptions written by Dr. Richard on the same days, March 11, 2014, and April 10, 2014. Tr. 106-07; GE-4, at 1-2, 5-6; GE-5, at 5-8; GE-8, at 1-4.

67. On May 3, 2014, the Pharmacy filled similar prescriptions for customers J.S.1 and D.G. at about the same; the prescriptions were written by Dr. Richard on May 1, 2014. Tr. 106-07; GE-6, at 11-12; GE-9, at 9-10.

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[12] The Order to show cause alleges 2013 rather than 2014. Given the documents provided by the Government to the Respondents, I find this to be a de minimus typographical error.

S.P.

68. Government Exhibit 4 contains prescriptions filled for customer S.P. Tr. 66-67; GE-4. The prescriptions record S.P.'s address as being in Malabar, Florida. Tr. 67; 706-07; GE-4, at 1, 3, 5. The prescriptions were written by Dr. Richard in Miami, Florida. Tr. 67; 706-07; GE-4, at 1, 3, 5. The distance from the doctor's office in Miami to S.P.'s address in Malabar is 170 miles. Stip. 7. S.P., however, lived very near to the Pharmacy. Tr. 250.

69. The prescriptions written to S.P. raise red flags. Tr. 67. The red flags for these prescriptions include: the type a medication; the fact that they are written for the highest available dosage; the patient lives three hours away from the doctor who issued the prescription; and the patient paid cash.[13] Tr. 67-68. The prescriptions are for hydromorphone, 8 mg, which is the highest dosage available for the drug. Tr. 67, 73-74; GE-4, at 1, 3, 5.

70. S.P.'s file contains a letter of medical necessity from the prescribing doctor concerning his reasoning for the prescriptions he wrote for S.P. Tr. 69; GE-4, at 8. The letter provides a diagnosis of chronic back pain and thoracic/lumbosacral impingement, conditions that are sometimes associated with diversion. Tr. 70; GE-4, at 8.

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[13] Dr. Gordon testified that the price the Pharmacy charged for the prescriptions was a fair price. Tr. 68, 250. Thus, if cash were the only red flag, I would not find it significant in this case. *See Jones Total Health Care Pharmacy, L.L.C.*, 81 Fed. Reg. 79188, 79199-200 (2016).

A.J.

71. Government Exhibit 5 contains prescriptions filled for customer A.J. Tr. 75-76; GE-5. Some of the prescriptions were written by Dr. Richard in Miami, Florida. Tr. 75; GE-5, at 1-8. The prescriptions record A.J.'s address as being in Palm Bay, Florida. GE-5, at 3, 5, 7. The distance from the doctor's office in Miami to A.J.'s address in Palm Bay is 176 miles. Stip. 8. Additional prescriptions were written by Dr. Daviglus in Orlando, Florida. GE-5, at 9-28. The distance from the doctor's office in Orlando to the A.J.'s address in Palm Bay is 74 miles. Stip. 9.

72. The prescriptions written to A.J. by Dr. Richard raise red flags. Tr. 77. The red flags for these prescriptions include: the type of medication; the fact that they are written for the highest available dosage; the distance the patient travelled to see the doctor; and the patient paid cash. Tr. 77-78. The prescriptions are for hydromorphone, 8 mg. Tr. 77.

73. The prescriptions written by Dr. Daviglus also raise red flags. Tr.79-86. These red flags include that the doctor's office was located in Orlando, about 70 miles from the patient's home, and the ICD codes all reflect back pain conditions. Tr. 80. The prescription for hydromorphone addressed by pages 15-16 of GE-5, was issued on the same date as the MS Contin prescription at page 13, of GE 5. The prescriptions raise a red flag because they treat the same condition. Tr. 80. Various other prescriptions in GE-5 also raise similar red flags that would require a discussion with the physician or the patient. Tr. 83.

74. The "patient memo" box of A.J.'s profile contains an entry that "Dr. Daviglus called personally

about patient & will send letter over next week 12/3/14." Tr. 734; GE-5, at 29; RE-H, at 55. Dr. Clark does not recall if a letter from Dr. Daviglus was ever received and there is no letter from Dr. Daviglus concerning A.J. in his file. Tr. 734-36; GE-5; RE-H, at 55-69. Further, it was the Pharmacy's policy to make a note in the patient memo box when letters were received, but there is no such notation in A.J.'s file. Tr. 735-36. The Pharmacy filled eight more prescriptions for A.J. after December 3, 2014. Tr. 736; GE-5, at 13-28. In addition, there was no notation in A.J.'s "patient memo" box that the Pharmacy had received a letter of medical necessity from Dr. Richard. GE-5, at 29.

75. Dr. Richard, however, provided a letter of medical necessity concerning A.J. on January 23, 2014. GE-5, at 30; RE-H, at 59. A.J.'s letter of medical necessity states that he has a "midline posterior disk" with an "associated radial tear at L-5-S1." GE-5, at 30; RE-H, at 59. The letter also states that A.J.'s last MRI was performed in January 2014. GE-5, at 30; RE-H, at 59. The letter, however does not explain why A.J. makes a 352-mile round trip to see Dr. Richard. GE-5, at 30; RE-H, at 59.

D.G.

76. Government Exhibit 9 contains prescriptions filled for customer D.G. Tr. 93-94; GE-9. Most of the prescriptions were written by Dr. Richard in Miami, Florida. GE-9, at 1-10. The prescriptions record D.G.'s address as being in Palm Bay, Florida. GE-9, at 1-10. The distance from the doctor's office in Miami to D.G.'s address in Palm Bay is 175 miles. Stip. 13. A later prescription was written by Dr. Brutus in Winter Garden, Florida. GE-9, at 11-12. The distance from

the doctor's office in Winter Garden to D.G.'s address in Palm Bay is 76 miles. Stip. 17. D.G. lived 18 miles from the Pharmacy. Stip. 19.

77. The prescriptions written to D.G. raise red flags. Tr. 94-98. The red flags for these prescriptions include: the type a medication-opioids; the fact that they are written for the highest available dosage; the distance the patient travelled to see the doctor; and the patient paid cash. Tr. 93-96. The prescription at page 11 of GE-9 raises the same red flags as the other prescriptions written for D.G., except that the distance is shorter. Tr. 97. The prescriptions are for oxycodone 30 mg or hydromorphone 8 mg. Tr. 94.

78. The "patient memo" box of D.G.'s profile contains a March 17, 2015, note that reads, "Must have *new* letter of med necessity for any further fills. DC." GE-9, at 13; RE-H, at 99. D.G.'s profile does not mention receipt of a letter of medical necessity from Dr. Richard, though one was received. GE-9, at 13-14; RE-H, at 99.

79. D.G.'s file contains an undated letter of medical necessity from the prescribing doctor concerning his reasoning for the prescriptions he wrote for D.G. GE-9, at 14. The letter provides a diagnosis of "dextro-convexity of lumbar spine with kyphotic curvature" and "chronic nonmalignant low back pain." GE-9, at 14. The letter also states that D.G. had been seen on February 11, 2014, and that his last MRI was performed on April 18, 2013. GE-9, at 14. The letter does not explain why D.G. made a 350-mile round trip to see Dr. Richard. GE-9, at 14.

E.H.

80. Government Exhibit 8 contains prescriptions filled for customer E.H. Tr. 100; GE-8. Some of the prescriptions for E.H. were written by Dr. Richard in Miami, Florida. GE-8, at 1-6. The prescriptions record E.H.'s address as being in Palm Bay, Florida. GE-8, at 1-24. The distance from the doctor's office in Miami to E.H.'s address in Palm Bay is 175 miles. Stip. 20. Later prescriptions were written by different doctors with A Stop Pain Management, LLC in Orlando, Florida. GE-8, at 7-24. The distance from the doctors' office in Orlando to E.H.'s address in Palm Bay is 74 miles.[14] Stip. 21.

81. The prescriptions written to Eli. raise red flags. The red flags for these prescriptions include: the type a medication (opioids); the fact that they are written for the highest available dosage; the distance the patient travelled to see the doctor; and the patient paid cash. Tr. 100. The prescriptions written for E.H. by the doctors in Orlando raise the same red flags as those written by Dr. Richard, except that the distance is shorter. Tr. 102. The prescriptions are for oxycodone 30 mg or hydromorphone 8 mg. Tr. 101; GE-8.

82. E.H.'s profile contains a note that a letter of medical necessity was received from Dr. Richard on March 14, 2014. GE-8, at 25; RE-H, at 223. The letter provides diagnosis codes of 722.73, 724.02, and 724.3 and indicates that E.H.'s last MRI was performed on

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[14] The fill sticker for a prescription filled on September 18, 2014, lists the doctor's address as being in Rockledge, Florida. Tr. 103; GE-8, at 11. The prescription, however, shows his address to be in Orlando. GE-8, at 10. Rockledge is located in the same vicinity where E.H. lives. Tr. 104-05.

December 21, 2012. GE-8, at 26; RE-H, at 227. The letter does not explain why E.H. made a 350-mile round trip to see Dr. Richard. GE-8, at 26; RE-H, at 227.

J.S.1 and J.S.2

83. Government Exhibit 6 contains prescriptions filled for customers J.S.1 and J.S.2. Tr. 87, 112; GE-6. The prescriptions for J.S.1 and J.S.2 were written by Dr. Richard in Miami, Florida. GE-6, at 1-14. The prescriptions record the address for both J.S.1 and J.S.2 as being at the same address in Palm Bay, Florida. Tr. 585; *compare* GE-6, at 1-2 *with* GE-6, at 5-6. The distance from the doctor's office in Miami to the address of J.S.I and J.S.2 in Palm Bay is 174 miles. Stip. 10. They lived 22 miles from the Pharmacy. Stip. 12.

84. The prescriptions written to J.S.1 and J.S.2 raise red flags. Tr. 87, 112-14. The red flags for these prescriptions include: the type of medication; the fact that they are written for the highest dosage; the distance the patients travelled to see the doctor; and the patient paid cash. Tr. 87, 112-13. The prescriptions for J.S.1 were for 30 mg of oxycodone, and the prescriptions for J.S.2 included both oxycodone 30 mg and 8 mg of hydromorphone. Tr. 88, 113; GE-6, at 1-14.

85. The fact that J.S.1 and J.S.2 have the same address raises another red flag—that being that the patients are a group. Tr. 114. These two patients live at the same address, they are getting the same or the same type of controlled substances from the same doctor, whose office is in Miami, 174 miles from where they live, and they have similar diagnosis of back pain.

Tr. 114. In addition, they paid cash to fill each prescription. GE-6.

86. Government Exhibit 6 contains a letter of medical necessity concerning J.S.2, but not for J.S.1. GE-6, at 16. The "patient memo" block of J.S.1's profile contains an entry dated May 13, 2014, that reads, "no out of county scripts per DC." GE-6, at 17; RE-H, at 74. The Pharmacy filled its last prescription for J.S.1 on May 3, 2014. GE-6, at 11-12.

87. Dr. Richard provided a letter of medical necessity for J.S.2 on March 10, 2014. GE-6, at 16; RE-H, at 93. The letter provides the following diagnoses: "724.3 chronic nonmalignant lower back pain with bilateral radiculitis" and "724.5 chronic pain syndrome." GE-6, at 16; RE-H, at 93. The letter also reports March 4, 2014, as the date of J.S.2's last MRI. GE-6, at 16; RE-H, at 93. The letter does not explain why J.S.2 made a 348-mile round trip to see Dr. Richard. GE-6, at 26; RE-H, at 227.

C.C.

88. Government Exhibit II contains prescriptions filled for C.C. Tr. 124; GE-11. The first six prescriptions for C.C. were written by Dr. Richard in Miami, Florida. GE-11, at 1-12. The remaining prescriptions were written for C.C. by Dr. Willis in Rockledge, Florida. The prescriptions and the fill stickers show that C.C. lived in Melbourne, Florida. Tr. 123; GE-11. The distance from the doctor's office in Miami to C.C.'s address in Melbourne is 176 miles. Stip. 28.

89. The prescriptions written to C.C. raise red flags. Tr. 124. The first six prescriptions were written by Dr. Richard for 140 tablets of hydromorphone 8 mg.

Tr. 123-25. The red flags those prescriptions raise include: the type of medication-opioids; the fact that they are written for the highest available dosage; the distance the patient travelled to see the doctor; and the patient paid cash. Tr. 123. Even though the doctor who wrote the remaining prescriptions for C.C. was a local doctor for her, those prescriptions still present red flags. Tr. 125. Those red flags include: the type a medication-opioids; the fact that they are written for the highest dosage; a diagnosis of chronic back pain; and the patient paid cash. Tr. 125.

90. The Pharmacy entered notes in the "patient memo" box on C.C.'s profile indicating that they had received a letter of medical necessity from Dr. Richard and also that the Pharmacy would no longer accept out of county prescriptions, as of May 13, 2014. Tr. 624; GE-11, at 45; RE-H, at 242. The Pharmacy obtained the letter from Dr. Richard on April 7, 2014, to verify a legitimate medical necessity for the prescription. Tr. 625-26; GE-11, at 46; RE-H, at 245. By April 7, 2014, however, the Pharmacy had already filled five prescriptions for C.C. that had been written by Dr. Richard.[15] Further, Dr. Richard's letter does not explain why C.C. was making a 352-mile round trip to treat with him. GE-11, at 46; RE-H, at 245.

P.P

91. Government Exhibit 12 contains prescriptions filled for P.P. Tr. 127; GE-12. The prescriptions for

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[15] Dr. Clark testified that she only filled one prescription for C.C., the one on December 28, 2013. Tr. 631. The prescription, however, has Soss' initial and license number on the face of the prescription. GE-11, at 1; RE-H, at 250-51.

P.P. were written by Dr. Richard in Miami, Florida. GE-12. Both the prescriptions and the fill stickers show that P.P. lived in Palm Bay, Florida. GE-12. The distance from the doctor's office in Miami to P.P.'s address in Palm Bay is 173 miles. Stip. 30.

92. Each of the prescriptions written by Dr. Richard for P.P. was for 130 tablets of hydromorphone 8 mg or oxycodone 30 mg. These prescriptions raise numerous red flags. Tr. 128. Those red flags include: the type of medication (opioids); the fact that they are written for the highest available dosage; the distance the patient travelled to see the doctor; and the patient paid cash for one of the prescriptions.[16] Tr. 128. The prescriptions both before and after the one paid for by cash were both paid for by Blue Cross/Blue Shield. GE-12, at 2, 4, 6.

93. There is no entry in the "patient memo" box on P.P.'s profile. Tr. 748; GE-12, at 7; RE-H, at 252. The file does, however, contain a letter form Dr. Richard, dated January 23, 2014. Tr. 633-34, 748; GE-12, at 8; RE-H, at 255. The letter of medical necessity was kept in a paper file. Tr. 748-49)[17] Dr. Richard's

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[16] P.P. used his insurance to pay for his prescriptions on January 31, 2014, and April 10, 2014. Tr. 634; GE-12, at 1-2, 5-6. P.P. paid cash for his prescription on February 28, 2014. GE-12, at 3-4. Dr. Clark testified that it would be a red flag if a customer had insurance and was not using it to pay for a prescription. Thus, P.P.'s cash purchase on February 18, 2014, should have been considered a red flag by the Pharmacy. GE-12, at 3-4.

[17] Dr. Clark testified that when filling P.P.'s prescriptions the pharmacists could have accessed the letter of medical necessity from the paper file. Tr. 749. That testimony begs the question, why would a pharmacist look in the paper file when there was no

letter concerning PP indicates that she had a condition of "chronic nonmalignant" and was being treated for "low back pain with bilateral radiculitis." GE-12, at 8; RE-H, at 255. Dr. Richard also reported that P.P.'s last MRI was performed on January 13, 2014. GE-12, at 8; RE-H, at 255. Dr. Richard's letter, however, did not explain why P.P. was travelling 346 miles, round trip, to obtain her prescriptions from him. GE-12, at 8; RE-H, at 255.

94. The Pharmacy filled three prescriptions for P.P., and Soss filled all of them. Tr. 632-33. The "patient memo" box on P.P.'s profile does not indicate that the Pharmacy would no longer take out of county prescriptions. GE-12, at 7; RE-H, at 252 Dr. Clark testified that the Pharmacy did not fill any prescriptions for P.P. after April 30, 2014, but the Respondents' own exhibit shows that the Pharmacy filled five prescriptions for P.P. since that date, written by a doctor located in Melbourne, Florida. Tr. 633; RE-H, at 256.

K.P.

95. Government Exhibit 13 contains prescriptions written for patient K.P. Tr. 132. The first five prescriptions and the fill stickers show that K.P. lived in Ft. Lauderdale, Florida. Tr. 132; GE-11. The distance between K.P.'s address and the pharmacy is 164 miles. Stip. 32. These five prescriptions were written by doctors, who were also located in Ft. Lauderdale or Miami, for 140-45 tablets of Dilaudid 8 mg, and 130-50 tablets of oxycodone 30 mg. Tr. 132-33; GE-13, at 1-10. The remaining three prescriptions were written

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entry in the "patient memo" box on P.P.'s profile indicating that a letter had been received?

by Dr. Richard, in Miami, for either 145 tablets of oxycodone 30 mg or Dilaudid 8 mg. Tr. 634; GE-13, at 11-16. The prescriptions that Dr. Richard issued indicate K.P.'s address was in Sunrise, Florida,[18] but the fill stickers still reflect a Ft. Lauderdale address. Tr. 134-35; GE-13, at 11-16. The distance from Dr. Richard's office to the Pharmacy is 188 miles. Stip. 31

96. The prescriptions written for K.P. in GE-13 raise numerous red flags. Tr. 132. Those red flags include: the types of medication (opioids); the fact that they are written for the highest dosage; the distance the patient travelled; and the patient paid cash for one of the prescriptions. Tr. 132. In fact, the first five prescriptions suggest that K.P. lived in Ft. Lauderdale, but was traveling all the way to the Respondent's location in Melbourne, Florida, to get his prescriptions filled. Tr. 132; GE-13, at 1-10. The prescriptions that record that K.P. lives in Sunrise, but where the fill sticker records a Ft. Lauderdale address, raises another red flag. Tr. 134-35.

97. The "patient memo" box in K.P.'s profile indicates that the Pharmacy would no longer take out of county prescriptions, but the entry is not dated. Tr. 635; GE-13, at 17; RE-H, at 260. Dr. Clark did not fill any of the prescriptions for K.P. Tr. 636, 749. The Pharmacy received a letter of medical necessity concerning K.P. Tr. 636; GE-13, at 18; RE-H, at 264. The letter was received on January 31, 2014, four days before the Pharmacy filled the first prescription for K.P. from Dr. Richard.[19] Tr. 637; GE-13, at 11-12.

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[18] Sunrise, Florida, is just slightly west of Ft Lauderdale.

[19] It is noted that the Pharmacy had filled five prescriptions for K.P. between April 2013 and August 2013 written by doctors

Each of the three prescriptions from Dr. Richard indicates that K.P. had severe pain. GE-13, at 11, 13, 15; *see also* Tr. 637.

98. Dr. Clark could provide no explanation as to why K.P. who lived in Ft. Lauderdale, Florida, and whose doctors were in Ft. Lauderdale, travelled to the Pharmacy in Melbourne, Florida, to get his prescriptions filled. Tr. 749.

Other Prescriptions

J.C.

99. Government Exhibit 10 contains prescriptions filled for customer J.C. Tr. 114; GE-10. The prescriptions for J.C. were written by Dr. Gershenbaum in Ft. Lauderdale, Florida. GE-10. Most of the prescriptions record only a street address without a city. GE-10. A few of the prescriptions list J.C.'s address in Palm Bay, Florida. GE-10, at 71-82. All of the fill stickers, however, indicate that J.C. lives in Indialantic, Florida.[20] GE-10. The distance from the doctor's office in Ft. Lauderdale to J.C.'s address in Indialantic is 158 miles. Stip. 22. The distance between J.C.'s Indialantic address and the Pharmacy is 16 miles. Stip. 24.

100. The prescriptions written to J.C. raise red flags. For example, the first five prescriptions for J.C.

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located in Fort Lauderdale, Florida. GE-13, at 1-10. There is no letter of medical necessity in K.P.'s file from any of those doctors.

[20] Nothing contained in GE-10 explains the address discrepancy between the prescriptions and the fill stickers.

were written and filled on January 3, 2014.[21] Tr. 115-17; GE-10, at 1-10. These five prescriptions raise multiple red flags. Tr. 115. First, all five prescriptions are for the same controlled substance, Roxicodone, which is a brand name of oxycodone, at different strengths, 5 mg, 10 mg, and 20 mg. Tr. 115. There are also two separate prescriptions for 10 mg and two for 20 mg. Tr. 115. All of these prescriptions are short acting medications. Tr. 116-17. Furthermore, the instructions for taking these five prescriptions for the same controlled substance suggested that J.C. could have been taking all of these medications at the same time. Tr. 834-35. In addition, the prescribing doctor was located in Ft. Lauderdale, FL, several hours away from where J.C. lived. Tr. 116.

101. Another red flag of J.C.'s prescriptions were drug cocktails. Tr. 117. In addition to filling five oxycodone prescriptions for J.C. on January 3, 2014, the Pharmacy also filled prescription for J.C. for the highest available dosage of diazepam, 10 mg. Tr. 117; GE-10, at 175-76. The Pharmacy filled this same drug cocktail of oxycodone and diazepam for J.C. on: January 28, 2014 (Tr. 118-19; GE-10, at 11-20, 177-78); March 8, 2014 (GE-10, at 33-42, 181-82); July 19, 2014 (GE-10, at 95-96, 189-90); September 3, 2014 (GE-10, at 111-14, 191-92); September 23, 2014 (GE-10, at 119-26, 193-94); December 22, 2014 (GE-10, at 141-44, 197-98); and January 16, 2015 (GE-10, at 145-46, 199-200).

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[21] These same prescriptions were re-issued on January 28, 2014, GE-10, at 11-20, and numerous other times until March 20, 2015, GE-10, at 159-164.

102. J.C. also presented prescriptions, which the Pharmacy filled, resulting in early refills of oxycodone. For example, the Pharmacy filled multiple oxycodone prescriptions for J.C. on January 28, 2014, Tr. 121, GE-10, at 11-18, and another on the next day. GE-10, at 19-20. Then just two weeks later on February 11, 2014, Tr. 121-22, GE-10, at 21-26, the Pharmacy filled three more prescriptions for oxycodone, and two more on February 26, 2014. GE-10, at 27-30. Nothing is written on any of these prescriptions to resolve this early refill red flag. Tr. 122.

103. The fill stickers for J.C.'s prescriptions show whether J.C. paid cash for the prescription or whether it was covered by insurance. Tr. 614-15. If J.C. paid cash, the fill sticker states "cash." Tr. 615. If J.C. used insurance the fill sticker states "Advance," for "Advanced Prescribers." Tr. 615. J.C. paid cash for his prescriptions 10 times. Tr. 613.

M.B.

104. Government Exhibit 14 contains prescriptions filled for M.B. Tr. 139; GE-14. The prescriptions for M.B. were written by Dr. Comfort in Sanford, Florida. Tr. 138; GE-14. Both the prescriptions and the fill stickers document that M.B. lived in Palm Bay, Florida. Tr. 138; GE-14. Although the parties did not stipulate to the distance between the doctor's office in Sanford and M.B.'s address in Palm Bay, the distance is about 85 miles. *See* Stip. 33, 37.

105. The prescriptions written to M.B. raise red flags. Tr. 138. Those red flags include: the types of medication (Ativan, hydromorphone, morphine sulfate, MS Contin); the fact that the hydromorphone was written for the highest dosage; the distance the patient

travelled; the patient paid cash some of the prescriptions, and drug cocktails. Tr. 137-38; GE-14.[22]

106. The Pharmacy filled a "drug cocktail" of hydromorphone 8 mg and lorazepam 1 mg for M.B. on December 30, 2013. Tr. 137; GE-14, at 9-12. Then between January 30, 2014, and March 13, 2015, the Pharmacy filled 12 more prescriptions that constituted drug cocktails for M.B. Tr. 138; GE-14, at 13-14, 17-22, 27-30, 33-36, 47-48, 51-54, 57-62, 65-88. Beginning in December 2014, the Pharmacy was filling two prescriptions for hydromorphone for M.B. at the same time it filled a prescription for lorazepam for him. GE-14, at 65-88. While most of these prescriptions were filled by a pharmacist who no longer works for the Respondent, the cocktail prescriptions on August 15, 2014, were filled by Dr. Clark. GE-14, at 53-58.

107. The patient memo box in M.B.'s profile indicates that the Pharmacy received a letter of medical necessity concerning M.B. from Dr. Comfort on May 6, 3013. Tr. 641; GE-14, at 89. The letter from Dr. Comfort provides a medication list, a diagnosis code, the initial date of treatment with an unknown length of treatment. GE 14, at 90-92. The letter from Dr. Comfort provides no information about why M.B. was making a 170-mile round trip to see Dr. Comfort.

108. M.B. paid for his prescriptions with both cash and insurance coverage. Tr. 642, GE-14.

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[22] The Pharmacy also provided M.B. with early refills of his prescriptions for hydromorphone, and lorazepam on September 5, 2014. *See* GE-14, at 53-54, 57-62. The Government did not allege early refills concerning M.B. therefore, the early refill to M.B. carries no weight in this decision.

C.A.

109. Government Exhibit 15 contains prescriptions filled for C.A. Tr. 140-41; GE-15. The prescriptions for C.A. were written by Dr. Kuhn in Orlando, Florida. Tr. 140-41; GE-15. The prescriptions record C.A.'s address as being in Barefoot Bay, Florida, but the fill stickers list his address as Sebastian, Florida, though both the prescriptions and the fill stickers report the same street address. Tr. 141; GE-15, at 1-6. The distance between the doctor's office in Orlando and C.A.'s address in Sebastian is about 86 miles. Stip. 35.

110. The prescriptions written to C.A. raise red flags. Tr. 140-41. Those red flags include: the types of medication (opioids); the fact that the two of the prescriptions are written for the highest available dosage of hydromorphone; the distance the patient travelled; and the patient paid cash. Tr. 140-41. Two of the three prescriptions that contain these red flags were filled by Dr. Clark. Tr. 142; GE-15, at 1-2, 5-6.

D.B.

111. Government Exhibit 7 contains prescriptions for patient D.B. Tr. 144; GE-7. The prescriptions record D.B.'s address as being in Jupiter, Florida, but the fill stickers list his address as Port St. Lucie, Florida. Tr. 144; GE-7. The prescriptions were written by Dr. Duran in Jupiter, Florida. Tr. 145, GE-7. The distance from the doctor's office to the Pharmacy is 111 miles. Stip. 26. Some prescriptions were filled by the Pharmacy on the same day they were written. GE-7, at 3-6. The distance between D.B.'s address recorded on the fill stickers to the Pharmacy is 76 miles. Stip. 27.

112. The prescriptions written to D.B. raise red flags. Tr. 144-49. Those red flags include: the types of medication; the fact that the two of the prescriptions are written for the highest available dosage, oxycodone, and Xanax; the distance the patient travelled; the patient paid cash; drug cocktails; filling the exact same prescription twice on the same day; and early refills. Tr. 144-47; ALJ-1, at 6.

113. The prescriptions at pages 1-3, of GE-7 represent a drug cocktail of oxycodone and Xanax that were filled in December 2013. Tr. 145-46. Significantly D.B. presented the prescription for Xanax six days after he had the prescription for oxycodone filled. Tr. 146. Dr. Clark apparently filled the prescription for Xanax. GE-7, at 3. In addition, on July 1, 2014, Dr. Clark filled a drug cocktail combination of oxycodone, Percocet, and Xanax, which included two immediate release opioids. Tr. 148; GE-7, at 21-26. Dr. Clark filled two additional prescriptions for D.B. in March 2015. GE-7, at 57-60. Another example of a prescription cocktail that the Respondent filled for D.B. is Percocet, Xanax and Ambien all filled on February 21, 2015. Tr. 146-47; GE-7, at 51-56. The Pharmacy also filled two identical prescriptions for the highest dosage of oxycodone on October 24, 2014. Tr. 147; GE-7, at 35-38. Dr. Clark filled 13 prescriptions for D.B. Tr. 623.

114. On June 19, 2014, the Pharmacy filled a prescription for D.B. for a 30 day supply of Percocet. Tr. 726; GE-7, at 19. On June 19, 2014, the Pharmacy filled a prescription for D.B. for a 30 day supply of oxycodone 30 mg. Tr. 726; GE-7, at 20. On July 1, 2014, the Pharmacy filled a prescription for D.B. for a 30 day supply of Percocet, as well as a 30 day supply of oxycodone 30 mg. Tr. 726-27; GE-7, at 21-24. Both of the

prescriptions that the Pharmacy filled for D.B. on July 1, 2014, were filled in less than 30 days from the June 19th prescriptions the Pharmacy filled for D.B. Tr. 727. This early refill is a red flag. Tr. 727. Dr. Clark filled the July 1, 2014, prescriptions for D.B. Tr. 727. There is nothing on the July 1, 2014 prescriptions, or in the patient profile, that resolves this early refill red flag. Tr. 727-28; GE-7, at 21-24, 61.

115. The "patient memo" box on D.B.'s patient profile indicates that an entry was made on March 30, 2015, which reads, "address on RX must match driver's license." Tr. 733; GE-7, at 61. The Pharmacy had been filling D.B.'s prescriptions since December of 2013, yet all of the prescription addresses indicated that D.B. lived in Jupiter, Florida, while the fill stickers indicated he lived in Port St. Lucie, as indicated on his patient profile. Tr. 733; GE-7.

J.D.

116. Government Exhibit 16 contains prescriptions for patient J.D. Tr. 151; GE-16. The prescriptions record J.D.'s address as being in Cocoa Beach, Florida, though a few of the fill stickers list his address as Titusville, Florida. GE-16, at 1-6. The prescriptions were written by Dr. Comfort in Sanford, Florida. Tr. 152, GE-16. The distance from the doctor's office to J.D.'s address in Cocoa Beach is 75 miles. Stip. 36.

117. The prescriptions written to J.D. raise red flags. Tr. 152. Those red flags include: the types of medication; the fact that the two of the prescriptions are written for the highest available dosage of hydromorphone and Xanax; the distance the patient travelled; the patient paid cash; and drug cocktails of hydromorphone and Xanax being filled on the same day.

Tr. 152-154. In fact, GE-16 reveals 16 different dates when the Respondent filled prescriptions for J.D. for both hydromorphone and Xanax. GE-16, at 7-70. When the hydromorphone was filled for J.D., the Pharmacy typically provided him with 180 8 mg tablets. GE-16, at 7-8, 11-12, 15-16, 19-20, 23-24, 27-28, 31-32, 35-36, 39-40, 43-44, 47-48, 51-52, 55-56, 59-60, 63-64, 67-68, 71-72. In addition, the Pharmacy provided J.D. with early refills on March 21, 2014, May 16, 2014, October 3, 2014, November 21, 2014, and January 9, 2015. GE-16, at 11-26, 39-62.

118. The patient memo box in J.D.'s profile indicates that the Pharmacy received a letter of medical necessity concerning J.D. from Dr. Comfort on May 14, 3013. GE-16, at 73. The letter from Dr. Comfort provides a medication list, a diagnosis code, the initial date of treatment with an unknown length of treatment. GE-16, at 74-75. The letter from Dr. Comfort does not comment on why J.D. is treating with him rather than a doctor closer to J.D.'s home. GE-16, at 74.

K.B.3

119. Government Exhibit 17 contains prescriptions for patient K.B.3. Tr. 155; GE-17. The prescriptions record K.B.3's address as being in Palm Bay, Florida, and the fill stickers list his address as Palm Bay. GE-17, at 1-6. The prescriptions were written by Dr. Sokoloff in Sanford, Florida. Tr. 155; GE-17. The distance from the doctor's office to K.B.3's address in Palm Bay is 88 miles. Stip. 37.

120. The prescriptions written to K.B.3 raise red flags. Tr. 155. Those red flags include: the type of medi-

cation (hydromorphone); the fact that the prescriptions are written for the highest available dosage of hydromorphone, the distance the patient travelled; and the patient paid cash. Tr. 155-157.

121. Dr. Clark filled prescriptions for K.B.3 for the maximum available dosage of hydromorphone on June 25, 2014, and July 22, 2014. GE-17, at 12-15. Dr. Clark saw no red flags related to K.B.3. Tr. 660.

122. Government Exhibit 17 contains letters from K.B.3's prescribing doctors and some of K.B.3's medical records. Tr. 156-57; GE-17, at 29-34. Those documents, however, do not explain why the patient is paying cash or why he is treating with those doctors rather than seeing a doctor located closer to where K.B.3 lives. Tr. 156-57; GE-17, at 29-34.

K.B.2

123. Government Exhibit 18 contains prescriptions for patient K.B.2. Tr. 158; GE-18. The prescriptions record K.B.2's address as being in Melbourne, Florida. Tr. 158; GE-18. The prescriptions were written by Dr. Prieto in Orlando, Florida. Tr. 158, GE-18. The distance from the doctor's office to K.B.2's address in Melbourne is 67 miles. Stip. 38.

124. The prescriptions written for K.B.3 raise red flags. Tr. 158-64. Those red flags include: the type of medications (diazepam, hydromorphone, and morphine sulfate); the fact that the prescriptions are written for the highest available dosage of diazepam and hydromorphone, the distance the patient travelled; the patient paid cash, and that the Pharmacy was filling drug

cocktails for K.B.2 consisting of diazepam, hydromorphone, and morphine sulfate.[23] Tr. 158-63. In fact, the Pharmacy filled this drug cocktail 13 times between January 13, 2014, and March 26, 2014. GE-18, at 11-98. Although K.B.2 would normally receive his prescriptions for these three controlled substances on the same day, he would frequently present the prescriptions to the Pharmacy within a two or three day time frame. *See, e.g.*, GE-18, at 11-16, 17-22, 27-32, 33-38, 39-44, 45-50, 77-82, 77-82, 93-98. Dr. Clark filled a prescription cocktail of morphine sulfate and diazepam on June 10, 2014. GE-18, at 4144.

125. K.B.2's prescribing physician was Dr. Prieto, whose office was in Orlando, which is in an adjacent county to the Pharmacy. Tr. 659. Under the Pharmacy policy, K.B.2 needed a letter of medical necessity because his prescribing physician was outside the county. Tr. 659.

126. Government Exhibit 18 contains a letter from K.B.2's prescribing doctor dated April 15, 2013, and some of K.B.2's medical records, to include an MRI. Tr. 165; GE-18, at 100-02. The MRI was performed on July 30, 2012, and it indicated that K.B.2 had a herniated disc. Tr. 659; GE-18, at 101-02; RE-H, at 389-90. Those documents, however, do not explain why K.B.2 was paying cash or why he was making a 130-mile round trip to obtain a prescriptions for an opioid and Valium. Tr. 165; GE-18, at 100-02.

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[23] While the OSC did not allege that the prescriptions for K.B.2 included "cocktails," the Respondents were put on notice of this allegation in the Government's Prehearing Statement. ALJ-8, at 16.

A.G.

127. Government Exhibit 19 contains prescriptions for customer A.G. Tr. 167; GE-19. The prescriptions do not contain A.G.'s address, but the fill stickers list his address as being in Indian Harbor, Florida. Tr. 167; GE-19. The prescriptions were written by Dr. Karumanchi in Orlando, Florida. Tr. 167; GE-19. The distance from the doctor's office to A.G.'s address in Indian Harbor is 65 miles. Stip. 39.

128. The prescriptions written for A.G. raise red flags. Tr. 167. Those red flags include: two immediate release opioids, oxycodone and hydromorphone, that the Respondent repeatedly filled; the fact that the oxycodone prescription was written for the highest available dosage; the distance the patient travelled; the patient always paid cash; the prescribing physician did her residency in OB-GYN,[24] and the treatment plan was old. Tr. 167-71. In fact, the Pharmacy filled prescriptions for these two immediate release opioids for A.G. 17 times between December 20, 2013 and March 20, 2014. GE-19, at 1-68. Dr. Clark filled prescriptions for oxycodone 30 mg and hydromorphone 4 mg on February 21, 2014. GE-19, at 9-12.

129. The Pharmacy consistently filled two prescriptions for A.G., one for hydromorphone and one for oxycodone. GE-19, at 13-60. A.G. would pick up one filled prescription for 84 tablets of hydromorphone 4 mg, to be taken 3 times a day. GE-19, at 16. Thus, each time the Pharmacy filled the hydromorphone prescrip

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[24] A letter from Dr. Karumanchi identifies A.G. as a male. Dr. Gordon testified that under the acceptable standards of practice for a pharmacy, a pharmacist should look up a particular doctor's credentials. Tr. 168.

tion, A.G. was provided with a 28 day supply. The other prescription that A.G. would pick up was for 150 tablets of oxycodone 30 mg, to be taken 5 times a day. GE-19, at 14. Thus, each time the Pharmacy filled the oxycodone prescription, A.G. was provided with a 30 day supply. A.G. filled these two prescriptions every 28 days between March 21, 2014, and January 23, 2015. GE-19, at 13-60. Thus each time A.G. filled the prescriptions he received ten tablets of oxycodone over what had been prescribed. By January 23, 2015, A.G. had refilled the oxycodone prescription early 11 times, and had received an extra 110 tablets of oxycodone 30 mg than had been prescribed to him. GE-19, at 19-20, 23-24, 27-28, 31-32, 36-36, 39-40, 43-44, 47-50, 55-58; *see also* ALJ-1, at 8.

130. Government Exhibit 19 contains a letter from A.G.'s prescribing doctor dated March 21, 2014. GE-19, at 70; RE-H, at 407. In addition, the Pharmacy received a half-year treatment plan for February through August 2013, and a 2011 MRI report concerning A.G. Tr. 170-71, 668-69; GE-19, at 71-72; RE-H, at 408-09. The letter of medical necessity states that A.G. had a "Herniated Lumbar IVD," that he treated with Dr. Karumanchi once a month, and that his last MRI was dated April 13, 2013. GE-19, at 70; RE-H, at 407. In addition, the letter of medical necessity stated that it was necessary for A.G. to "use this medication," but it does not indicate what medication A.G. must use. GE-19, at 70; RE-H, at 407. The documents provided by Dr. Karumanchi also do not explain why A.G. was paying cash or why he was making a 130-mile round trip to obtain prescriptions for two immediate release opioids. GE-19, at 70-72.

K.B.1 and C.K.

131. Government Exhibit 20 contains prescriptions for customers K.B.1 and C.K. Tr. 171-72; GE-19. The prescriptions do not contain K.B.1's address, yet all but one of the fill stickers list his address as being in Malabar, Florida. GE-20, at 4-30, 65. The prescriptions do not contain C.K.'s address, but the fill stickers list her address as being in Cocoa Beach, Florida. GE-20, at 31-64. The prescriptions were written by Dr. Karumanchi in Orlando, Florida. Tr. 172; GE-20. The distance from the doctor's office to K.B.1's address in Malabar is 73 miles. Stip. 40. The distance from the doctor's office to C.K.'s address in Cocoa Beach is 51 miles. Stip. 42.

132. The prescriptions written to K.B.1 and C.K. raise red flags. Tr. 172. Those red flags include: commonly sought after opioid (oxycodone), the fact that the oxycodone prescriptions were written for the highest available dosage[25]; the distance the patients travelled; the patients always paid cash, the prescribing physician did her residency in OB-GYN,[26] and K.B.1 and C.K. presented as a "group" going to the same doctor on the same day and obtaining similar prescriptions, with the prescriptions being filled frequently at about the same time. Tr. 172-74. In fact, the Pharmacy filled oxycodone prescriptions for these two individuals on the same day 14 times between April 1, 2014, and March 31, 2015, and by September 2014,

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[25] Initially the prescription for K.B.1 was for oxycodone 15 mg, but it was increased to 30 mg on September 16, 2014. GE-20, at 3-4, 15-16.

[26] A letter from Dr. Karumanchi identifies K.B.1 as a male. GE-20, at 66.

they were both receiving the maximum available dosage. Tr. 173; GE-20, at 3-30, 37-64; RE-H, at 426. Many times the prescription numbers on the fill stickers were sequentially only one number apart, and other times they were separated by only a few numbers, and they were frequently filled within minutes of each other. Tr. 173-74; GE-20, at 3-30, 37-64: RE-H, at 426.[27] Dr. Clark filled sequential prescriptions for oxycodone for these two patients, and one minute apart, on May 28, 2014 and November 11, 2014. GE-20, at 7-8, 41-42, 19-20, 53-54; RE-H, at 426.

133. Because K.B.1 and C.K. saw a prescribing physician who was outside the county, the Pharmacy required a letter of medical necessity for each of them. Tr. 673.

134. The letter of medical necessity for K.B.1 is dated April 1, 2014.[28] Tr. 672; GE-20, at 66. The letter of medical necessity provides a diagnosis of "Chronic Lymphocytic Leukemia and extreme bone pain," that K.B.1 had been a monthly patient since March 2014, that K.B.1's last MRI was in October 2013, and that it was "medically necessary for the patient to use this medication." GE-20, at 66. The letter of medical necessity, however, does not state what medication it was necessary that K.B.1 use. GE-20, at 66. The letter from

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[27] I admitted RE-H after receiving testimony that "all of the records in this exhibit [were) used in the usual course of business." Tr. 545-46. Page 426 of RE-H obviously was not used in the usual course of business and was obviously prepared in preparation for the hearing.

[28] Although Dr. Clark testified that K.B.1's letter of medical necessity was misplaced, it was in K.B.1's file. Tr. 672, 778-79; GE-20, at 66.

Dr. Karumanchi concerning K.B.1 does not provide any explanation why K.B.1 was making a 146-mile round trip to see Dr. Karumanchi rather than a doctor located closer to K.B.1's home. GE-20, at 66.

135. The Pharmacy received a letter of medical necessity for C.K. on April 15, 2013. Tr. 673; GE-20, at 68; RE-H, at 422. The letter of medical necessity for C.K. indicates that the doctor had prescribed Roxicodone 30 mg because of C.K.'s diagnosis of lumbar IVD displacement without myelopathy. The prescribing physician also returned a copy of the Pharmacy's letter to its customers, and an MRI. Tr. 674-76. The MRI, however, was not in C.K.'s file. GE-20; RE-H, at 419-435. The letter from Dr. Karumanchi concerning C.K. does not provide any explanation why C.K. was making a 102-mile round trip to see Dr. Karumanchi rather than a doctor located closer to C.K.'s home. GE-20, at 68.

J.M. and M.M.

136. Government Exhibit 21 contains prescriptions for patients J.M. and M.M. Tr. 176; GE-21. The prescriptions do not contain addresses for the patients, but the fill stickers list their addresses as being in Satellite Beach, Florida Tr. 177; GE-21, at 1-4. The prescriptions were written by Dr. Karumanchi in Orlando, Florida. Tr. 177; GE-21. The distance from the doctor's office to the addresses of J.M. and M.M. in Satellite Beach is about 65 miles. Stip. 46-47.

137. The prescriptions written to J.M. and M.M. raise red flags. Tr. 176-81. Those red flags include: a commonly sought after opioid (oxycodone); the fact that the oxycodone prescriptions for M.M. were written for the highest available dosage; the distance the patients

travelled; the patients sometimes paid cash; the prescribing physician did her residency in OB-GYN[29]; drug cocktails; and J.M. and M.M. presented as a "group" going to the same doctor on the same day and obtaining similar prescriptions, to include drug cocktails, with the prescriptions being filled at about the same time. Tr. 176-81.

138. The Pharmacy filled prescriptions for these two individuals on the same day 15 times between January 7, 2014, and March 31, 2015. GE-21. Many times the prescription numbers on the fill stickers were sequentially only one number apart, and other times they were separated by only a few numbers, and the prescriptions were frequently picked up within minutes of each other. GE-21, at 1-12, 15-30, 33-36, 39-42, 57-60, 63-66, 69-76, 79-82, 85-88, 95-102, 105-16, 119-22, 129-32, 135-38; RE-H, at 484, 527.

139. Dr. Clark filled prescriptions for oxycodone for J.M. and M.M. on January 7, 2014, May 27, 2014, July 22, 2014, December 9, 2014, January 6, 2015, March 3, 2015, and March 31, 2015. GE-21, at 1-4, 23-26, 33-36, 63-66, 69-72, 79-82, 85-88, 109-12, 135-38. These prescriptions were dropped off and picked up within minutes of each other, and in all but one instance the prescription numbers were in sequence, one after the other. RE-H, at 484, 527.[30]

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[29] Both J.M. and M.M. are identified as males. Tr. 177-78; GE-20, at 143, 146.

[30] Pages 484 and 527 of RE-H are additional examples of records in RE-H that were not used in the usual course of business of the Pharmacy.

140. The Pharmacy filled drug cocktails of oxycodone and Soma and oxycodone and Xanax for both J.M. and M.M., frequently on the same day. Tr. 179-81; GE-21, at 3-4, 89-90; GE-21, at 7-8, 91-92; GE-21, at 11-12, 93-94; GE-21, at 15-16, 95-96; GE-21, at 17-18, 97-98; GE-21, at 19-20, 101-02; GE-21, at 21-22, 99-100; GE-21, at 25-26, 103-04; GE-21, at 27-28, 107-08; GE-21, at 29-30, 105-06; GE-21, at 39-40, 115-16; GE-21, at 41-42, 113-14; GE-21, at 45-46, 117-18; GE-21, at 57-58, 121-22; GE-21, at 59-60, 119-20; GE-21, at 63-64, 127-28; GE-21, at 65-66, 125-26; GE-21, at 69-70, 133-34; GE-21, at 73-74, 131-32; GE-21, at 75-76; 129-30; GE-21, at 79-80, 137-38; GE-21, at 81-82, 135-36; GE-21, at 87-88, 139-40. Additionally, Dr. Clark filled these cocktail prescriptions on January 7, 2014, May 27, 2014, July 22, 2014, December 9, 2014, January 6, 2015, March 3, 2015, and March 31, 2015. GE-21, at 3-4, 89-90; GE-21, at 25-26, 103-04; GE-21, at 33-34, 111-12; GE-21, at 35-36, 109-10; GE-21, at 63-64, 127-28; GE-21, at 65-66, 125-26; GE-21, at 69-70, 133-34; GE-21, at 79-80, 137-38; GE-21, at 81-82, 135-36; GE-21, at 87-88, 139-40.

141. Because J.M. and M.M. saw a prescribing physician who was outside the county, the Pharmacy required a letter of medical necessity for each of them. Tr. 678-79, 681.

142. The letter of medical necessity for J.M. is dated March 29, 2013. Tr. 678; GE-21, at 145. The letter of medical necessity provides: a diagnosis of "Lumbar IVD Degeneration with herniated lumbar IVD at multiple sites & Osteoarthritis;" that J.M. had been a patient since September 2009; that J.M.'s MRI was attached; and that the doctor felt it was "medically necessary to prescribe Roxicodone 15 mg. . . . " GE-21,

at 145. The letter from Dr. Karumanchi concerning J.M. does not provide any explanation why J.M. was making a 130-mile round trip to see Dr. Karumanchi, rather than a doctor located closer to J.M.'s home. GE-21, at 145.

143. The letter of medical necessity for M.M. is dated March 14, 2013. Tr. 681; GE-21, at 147. The letter of medical necessity provides: a diagnosis of "Degenerative Joint Disease" and "anxiety;" that M.M. had been a patient since August 2011; that two MRIs concerning M.M. were attached; and that the doctor felt it was "medically necessary to prescribe Roxicodone 30 mg . . .," and "Xanax 1 mg." GE-21, at 147. The letter from Dr. Karumanchi concerning M.M. does not provide any explanation why M.M. was making a 130-mile round trip to see Dr. Karumanchi, rather than a doctor located closer to M.M.'s home. GE-21, at 147.

H.B.

144. Government Exhibit 22 contains prescriptions for H.B. from several different doctors, including a psychiatrist. Tr. 185; GE-22. It is unclear where H.B. actually lived because GE-22 reports several different addresses, though the most consistent seems to be on North Wickham Rd., Melbourne, Florida. GE-22, at 4-6. Until January 13, 2015,[31] H.B.'s pain doctors were located in Orlando. Tr. 186; GE-22, at 45-46, 107-08. The distance from the doctors' office in Orlando to H.B.'s North Wickham address in Melbourne is about 54 miles. Stip. 48.

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31 After January 13, 2015, H.B. was treating with Brevard Fain Care in Merritt Island, Florida. GE-22, at 107-22.

145. The prescriptions written to H.B. raise red flags. Tr. 185-90. Those red flags include: prescriptions for both uppers and downers, Adderall, Xanax and Ambien; the prescription instructions for the Xanax had H.B. taking it at bedtime; taking both Xanax and Ambien at the same time, because both are CNS suppressants; two different prescriptions for oxycodone, both 15 mg and 30 mg, constituting therapeutic duplication; receiving the highest available dosages of oxycodone and Ambien; drug cocktails of oxycodone, Xanax, and Ambien, as well as oxycodone and Soma; early refills; and the distance that the patient drove to obtain the prescriptions for opioids. Tr. 185-90; GE-22, at 15-20, 23-30, 109-12, 123-25. Dr. Clark filled prescriptions constituting therapeutic duplication on July 1, 2014, and one of two prescriptions constituting therapeutic duplication on September 23, 2014.[32] GE-22, at 49-52, 71-72.

146. H.B. was receiving prescriptions for an amphetamine, which speeds-up a patient, while at the same time she was receiving a prescription for Xanax, which can bring a patient back down. Tr. 187; GE-22, at 19-22. These controlled substances are contraindicated. Tr. 187. The same prescriptions were filled by the Pharmacy on January 7, 2015, and March 18, 2015. GE-22, at 100-04, 115-18.

147. H.B. also received early refills from the Pharmacy. On February 12, 2014, H.B. received an early

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[32] On September 23, 2014, Clark filled prescription number 2377210 for 120 tablets of oxycodone 15 mg. GE-22, at 72. Based on the pharmacist's markings on the face of the next prescription filled in order, it appears that pharmacist Sloss filled prescription number 2377211 for 56 tablets of oxycodone 30 mg. GE-22, at 73-74.

refill of Adderall, after having received a 30-day supply on January 31, 2014. GE-22, at 13-14, 19-20. Then on February 20, 2014, H.B. received an early refill of alprazolam, after having received a 30-day supply on February 12, 2014. GE-22, at 21-22, 25-26. In addition, H.B. received an early refill of oxycodone on February 3, 2015, after having received a 30-day supply on January 13, 2015. GE-22, at 107-10.

148. Between February 12 and February 20, 2014, the Pharmacy filled a controlled substance cocktail of oxycodone, Xanax, and Ambien for H.B. Tr. 187; GE-22, at 15-18, 21-26. H.B. also received a drug cocktail of two prescriptions of oxycodone and one of Adderall on March 12, 2014. Tr. 188-89; GE-22, at 27-32. Another drug cocktail of oxycodone and Soma was dispensed on February 3, 2015. Tr. 189-90; GE-22, at 109-12.

149. Because H.B.'s prescribing physician for oxycodone was located in Orlando, she needed a letter of medical necessity. Tr. 682. The Pharmacy received letters of medical necessity for H.B. on October 10, 2013, and November 25, 2013. Tr. 682-84; GE-22, at 124-25; RE-H, at 543-44. The October 10, 2013 letter concerning H.B. states that she had been seen at Mid Florida Health for pain management since July 2013. GE-22, at 124; RE-H, at 543. The Mid Florida Health letter states that it was medically necessary for H.B. to have her medications, but it did not identify the medications, nor was it signed by a doctor. GE-22, at 124; RE-H, at 543. The November 25th unsigned letter from Dr. Skolnik indicates that H.B. has a lumbar tear, and lumbago. Tr. 686; GE-22, at 125; RE-H, at 544. A note in H.B.'s file indicates that H.B. had been advised that her address on her license and the

address on her prescriptions needed to match. Tr. 683; GE-22, at 123; RE-H, at 528.

Relationship Between the Pharmacy and Suntree Medical

150. Dr. Clark is the owner of the Pharmacy and Suntree Medical, as well as their supervising practitioner. Tr. 337-43, 345-46, 348-52, 356; GE-27, 28.

151. The Pharmacy and Suntree Medical have separate doors, but the Pharmacy and Suntree Medical are collocated. Tr. 346; GE-30, at 2. The two businesses share a lobby entrance. Tr. 347. Entering either door allows access to either business. Tr. 347. The two businesses are separated by a partition that only comes about 3/4 of the way towards the lobby. Tr. 347. The offices of the two businesses can be reached from either suite. Tr. 347.

152. Dr. Clark is normally in the building when it was open. Tr. 533.

153. Suntree Medical does not handle controlled substances. Tr. 356

154. Peterson is the Manager of Suntree Medical where his duties include: business development; marketing; sales; human resources; ordering medical equipment; and the oversight of day-to-day operations. Tr. 399-400. Peterson works directly for Dr. Clark, who is his boss. Tr. 409-10.

155. Peterson also works for the Pharmacy. Tr. 404. Peterson handles human resources, discipline, interviewing, and payroll for the Pharmacy. Tr. 410. Other than the pharmacist-in-charge, Peterson is the senior individual in both the Pharmacy and Suntree Medical

Tr. 416. Peterson also delivered prescriptions for the Pharmacy. Tr. 573, 794-95.

156. Peterson wrote "Manager" in the "Title" box on September 18, 2013 Notice of Inspection. Tr. 397; GE-32.

157. Mike Peterson signed the Notice of Inspection on September 18, 2013. Tr. 388; GE-32. The Pharmacy did not provide DEA with the requested records until September 23, 2013, and also on October 24, 2013. Tr. 388. Peterson turned over the records. Tr. 388; GE-33.

158. Peterson has been engaged in "managing, marketing, and developing the Pharmacy for over nine years." Tr. 395; GE-30, at 8. Peterson, however, considers himself to be employed by Suntree Medical because he has paid out of Suntree Medical funds. Tr. 395.

159. Over the last two quarters of 2016, Mike Peterson was the only employee of Suntree Medical. Tr. 354-55.

160. Meacham only has two pharmacy clients right now, the Pharmacy and Suntree Medical, but he considers it as only one client. Tr. 821-22.

Additional facts required to resolve the issues in this case are included in the Analysis section of this Recommended Decision.

ANALYSIS

To revoke a respondent's registration, the Government must prove, by a preponderance of the evidence, that the regulatory requirements for revocation are satisfied. *Steadman v. SEC*, 450 U.S. 91, 100-02 (1981);

21 C.F.R. § 1301.44(e). Under 21 U.S.C. § 824(a)(4), the DEA may revoke a registrant's COR if the registrant acted in a way that renders continued registration "inconsistent with the public interest." The DEA considers the following five factors to determine whether continued registration is in the public interest:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.
>
> (3) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.[33]

21 U.S.C. § 823(f).

These public interest factors are considered separately. *See Robert A. Leslie*, *MD.*, 68 Fed. Reg. 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Moral' v. DEA*, 412 F.3d 165, 173-74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, MD.*, 58 Fed. Reg. 37507, 37508 (1993). Thus, there is no need to enter findings on each of the factors. *Hoxie v. DEA*, 419 F.3d 477, 482

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[33] The Government has not made any Factor Five allegations against the Respondents.

(6th Cir. 2005). Further, there is no requirement to consider a factor in any given level of detail. *Trawick v. DEA*, 861 F.2d 72, 76-77 (4th Cir. 1988). When deciding whether registration is in the public interest, the totality of the circumstances must be considered. *See generally Joseph Gaudio*, *M.D.*, 74 Fed. Reg. 10083, 10094-95 (2009).

The Government bears the initial burden of proof, and must justify revocation by a preponderance of the evidence. *Steadman*, 450 U.S. at 100-03. If the Government makes a *prima facie* case for revocation, the burden of proof shifts to the registrant to show that revocation would be inappropriate. *Med. Shoppe—Jonesborough*, 73 Fed. Reg. 364, 387 (2008). A registrant may prevail by successfully attacking the veracity of the Government's allegations or evidence. Alternatively, a registrant may rebut the Government's *prima facie* case for revocation by accepting responsibility for wrongful behavior and by taking remedial measures to "prevent the re-occurrence of similar acts." *Jeri Hassman, M.D.*, 75 Fed. Reg. 8194, 8236 (2010) (citations omitted). In addition, when assessing the appropriateness and extent of sanctioning, the DEA considers the egregiousness of the offenses and the DEA's interest in specific and general deterrence. *David A. Ruben, MD.*, 78 Fed. Reg. 38363, 38385 (2013).

Here, all of the Government's allegations focus on the manner in which the Pharmacy, through its agents, dispensed controlled substances.

I. The Government's Position

The Government argues[34] that the Pharmacy's "pharmacists repeatedly violated state and Federal law by: (1) filling prescriptions written by a practitioner to himself; (2) filling prescriptions for 'office use;' and (3) failing to exercise their corresponding responsibility to ensure that prescriptions for controlled substances were issued for a legitimate medical purpose." ALJ-35, at 38 The Pharmacy's "pharmacists also dispensed controlled substances outside the usual course of professional practice by . . . failing to resolve red flags inherent in those prescriptions and/or failing to document the resolution of any red flags in the prescriptions that they ultimately decided to fill." ALJ-35, at 38-39.

Specifically, the Government argues that the Pharmacy violated state law by filling prescriptions that a doctor, J.S.3, wrote to himself for oxycodone and testosterone, both of which are scheduled drugs under Florida law. ALJ-35, at 39. The Government also asserts that the Pharmacy violated Florida law by dispensing controlled substances when it knew, or had reason to know, that the prescriptions were not based on a valid practitioner-patient relationship. ALJ-35, at 42. Finally, the Government asserts that the pharmacy violated Florida law by dispensing controlled substances in excessive or inappropriate quantities. ALJ-35, at 42.

In addition, the Government argues that the Pharmacy violated Federal law by filling prescriptions

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[34] The Government made these arguments in its "Proposed Findings of Fact, Conclusions of Law and Argument" ("Government's Brief"). The Government's Brief has been marked as ALJ-35.

that were issued to a physician's "office" rather than to an individual. In support of this argument, the Government cites 21 C.F.R. § 1306.04 (b) which states that a "prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients." ALJ-35, at 39.

The Government also argues that the Pharmacy violated its corresponding responsibility under 21 C.F.R. § 1305 to only dispense lawful prescriptions. ALJ-35, at 39-40. The Government asserts that the Pharmacy failed in its corresponding responsibility by repeatedly filling prescriptions that contained one or more unresolved red flags. ALJ-35, at 41.

The Government also argues that the Pharmacy violated 21 C.F.R. § 1306.06 when it filled prescriptions outside the "usual course of . . . professional practice." ALJ-35, at 41 Specifically, the Government alleges that the Pharmacy's practices were outside the usual course of professional practice because the pharmacy failed to document "comments relevant to the individual's drug therapy," "any related information indicated by a licensed health care practitioner" or information to explain "over-utilization or under-utilization . . . therapeutic duplication . . . or clinical abuse/misuse." ALJ-35, at 44-45 (citing Fla. Admin. Code r. 64B16-27.800). Therefore, the Government asserts that the Pharmacy violated Florida law when it failed to document resolution of the numerous red flags concerning the prescriptions it filled. ALJ-35, at 45.

The Government acknowledges that no specific allegations of misconduct were alleged against Suntree Medical. ALJ-35, at 48. The Government argues, however, that misconduct attributable to "owners, officers,

or key employees of a pharmacy," can be the basis of the denial of an application for, or the revocation of a COR of a different pharmacy that has the same owners, officers or key employees. ALJ-35, at 48-49 (citing *Superior Pharmacy I and Superior Pharmacy 11*, 81 Fed. Reg. 31310, 31341 n.71 (2016)).

In conclusion, the Government argues that the Pharmacy has consistently demonstrated an inability or unwillingness to comply with state and Federal laws related to controlled substances. The Government also notes that the Pharmacy has failed to take responsibility for his actions, and that Dr. Clark owns and controlled Suntree Medical as well as the Pharmacy. Therefore, the Government argues that the Respondents' CORs should be revoked. ALJ-35, at 50.

II. The Respondents' Position

The Respondents argue[35] that the Government's case is predicated on two inaccurate conclusions: that a pharmacist is required to document all of efforts to resolve a red flag, and that a pharmacist violates the "standard of care" and the "corresponding responsibility" by filling a prescription without resolving a red flag. ALJ-36, at 51. In support of its position the Respondents note that no Florida statute or rule requires a pharmacist to "document the resolution of every red flag." ALJ-36, at 51. The Respondents further argue that the Government is required to prove more than the existence of red flags, suggesting that the Government must prove actual knowledge to establish a violation

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35 The Respondents' "Closing Argument, Proposed Findings of Fact, and Conclusions of Law" ("Respondents' Brief") have been marked as ALJ-36.

of 21 C.F.R. § 1306.04(a). ALJ-36, at 51. The Respondents also assert that there is no agreement on whether there is an obligation to document the resolution of red flags, citing the consistent testimonies of Dr. Clark and Dr. Grant, and the changing testimony of Dr. Gordon. ALJ-36, at 52.

Arguing that the Government seeks to impose a higher standard upon the Pharmacy than is required, the Respondents argue that the Pharmacy was compliant. ALJ-36, at 52. In support, the Respondents cite to the many actions that Dr. Clark took to ensure the Pharmacy personnel were well trained and knowledgeable of the law when it came to dispensing controlled substance. ALJ-36, at 52.

The Respondents also argue that the testimony of Dr. Gordon, the Government's expert, should be given no weight. ALJ-36, at 53-59. In support, the Respondents challenge Dr. Gordon's recent experience and credentials. ALJ-36, at 53. The Respondents also dissect Dr. Gordon's testimony to challenge most of her opinions concerning what she considered to be a red flag and how they could be resolved. ALJ-36, at 53-59.

With respect to all of the alleged violations against the Pharmacy that rely upon Florida law, the Respondents argue that Florida's laws and regulations "must be construed strictly, in favor of the one against whom the penalty would be imposed." ALJ-36, at 59 (citations omitted). Thus, the Respondents assert that Florida Statute 458.331(1)(r), and Florida Administrative Rules 64B16-27.800(1) and 64B16-27.831 should be strictly construed in favor of the Respondents. ALJ-36, at 60. These provisions address a physician writing prescriptions to himself, the records a pharmacy is required to maintain, and actions that a pharmacist

is required to take when filling a prescription. ALJ-36, at 60-63, 65-67.

The Respondents argue that Florida law does not prohibit a pharmacy from filling a prescription for a doctor who wrote the prescription for himself. ALJ-36, at 60-63. While the OSC alleges that the Pharmacy filled these prescriptions in violation of Florida Statute 458.331(1)(r), the Respondents argue that that statute "does not directly prohibit a pharmacist from doing anything." ALJ-36, at 61. The Respondents also assert that the statute provides an exception when the drug is "prescribed, dispensed, or administered to the physician by another practitioner authorized to prescribe, dispense, or administer medicinal drugs." ALJ-36, at 61 (citing Fla. Stat. § 458.331(1)(r)). The Respondents then interpret this exception to apply because the Pharmacy was a "practitioner authorized to prescribe, dispense, or administer medicinal drugs." ALJ-36, at 62. The Respondents also argue that Florida Statute 458.303 provides that Florida Statute 458.331(1)(r), only applies to doctors, and thus has no application to the Pharmacy.

The Respondents acknowledge that 21 C.F.R. § 1306.04(b) makes it unlawful to fill a prescription to an individual practitioner if that practitioner is going to dispense the drugs to patients. ALJ-36, at 63. The Respondents, however, assert that the alleged "prescriptions" mentioned in paragraph 10(b) of the OSC were not prescriptions, "but rather were permissible wholesale transactions." ALJ-36, at 63. In addition, the Respondents allege that the controlled substances were not dispensed to individual patients, but rather that they were used for "in-office administration." ALJ-36, at 63. The Respondents note that the Government did

not present any evidence that the prescriptions the Pharmacy filled for "in-office administration" were intended "for general dispensing to patients." ALJ-36, at 63-64.

With respect to the prescriptions that the Pharmacy filled for individual patients, the Respondents argue that Florida law does not require the documentation of red flags. The Respondent sets out the requirements contained in Florida Administrative Rule 64B16-27.800(1). ALJ-36, at 65-66. The Respondents argue that this Rule was adopted in 1998, "well before the phrase 'red flag' was ever used in a pharmaceutical context." ALJ-36, at 66. Rather, the Respondents argue that Florida Administrative Rule 64B16-27.831 is the appropriate rule to examine to determine whether the Pharmacy properly exercised its sound professional judgment in filling prescriptions. ALJ-36, at 67. The Respondents note that this rule does not "require a pharmacist to document its validation of a prescription on the body of the prescription or the patient's record." ALJ-36, at 67.

The Respondents also note that Florida Administrative Rule 64B16-27.831 provides for a pharmacist's independent judgment when determining whether to fill a prescription. ALJ-36, at 68. Further, it argues that, 21 C.F.R. § 1306.4 only applies to the person filling the prescription and not to the pharmacy itself. ALJ-36, at 68. There the Respondent agues the Government is improperly attempting to hold the Pharmacy liable for not usurping the independent judgment of the pharmacist (Soss) who filled most of the prescriptions in this case. ALJ-36, at 69. In light of the Florida Administrative Rule and the C.F.R. provision, the only way the Pharmacy could be held liable is "if

it knew that its pharmacists were filling prescriptions outside the course of professional practice or for other than a legitimate medical purpose — and did nothing to prevent this practice." ALJ-36, at 69. The Respondents note, however, that when Dr. Clark became aware of Soss filling prescriptions that had been written by Dr. Richard, she took action to resolve the problem. ALJ-36, at 69.

Citing *Hills Pharmacy LLC*, 81 Fed. Reg. 49816, 49836 n.33 (2016), the Respondents argue that the Pharmacy could not violate its "corresponding responsibility if a prescription was nonetheless issued for a legitimate medical purpose." ALJ-36, at 71. While acknowledging that it is possible to prove lack of medical purpose through circumstantial evidence, the Respondents argue that the Government has failed to prove that the individual prescriptions were not issued for a legitimate medical purpose. ALJ-36, at 70-71. The Respondents also assert that the red flags alone cannot be used to prove that the prescription lacked a legitimate medical purpose or the pharmacist's knowledge that the prescription lacked a legitimate medical purpose. ALJ-36, at 72. Thus, lacking proof, "the Government's case must fail." ALJ-36, at 70.

The Respondents also assert that the Government's case must fail because it failed to prove the scienter requirement contained in 21 C.F.R. § 1604.04(a) that the pharmacist either knew that the prescription lacked a legitimate medical purpose or that the pharmacist was willfully blind to that fact. ALJ-36, at 75. While the Government might attempt to prove willful blindness by showing that the Pharmacy failed to investigate red flags, the Respondent's argue that the "willful blindness doctrine cannot be read so broadly as

to require an affirmative duty." ALJ-36, at 76 (citations omitted). Further, the Respondents argue that the Pharmacy's "diligent compliance efforts strongly rebut any indication that they remained willfully blind." ALJ-36, at 76.

With respect to Suntree Medical, the Respondents argue that the OSC did not list a single violation against Suntree Medical. Further, the Respondent argues that "the Government failed to present any evidence, statute, or rule suggesting that revocation of Suntree Medical Equipment's registration is appropriate simply because both companies share common ownership." ALJ-36, at 77. Thus, the Respondents argue, the allegations against Suntree Medical should be dismissed. ALJ-36, at 77.

Finally, the Respondents allege that many of the records listed in the Government's Exhibits were obtained as a result of an unlawful search. ALJ-36, at 77. The Respondents base this argument upon its claim that the DEA conducted an inspection of the Pharmacy without obtaining authorization for the "owner, operator, or agent in charge" of the Pharmacy. ALJ-36, at 77.[36]

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[36] I reject this argument for two reasons. First, for the reasons discussed in my assessment of the witnesses, I do not find the testimonies of Dr. Clark and Mr. Peterson to be credible that Dr. Clark did not give Peterson authority to sign the Notice of Inspection on September 18, 2013. GE-32. Second, the DEA did not obtain any records on September 18, 2013. Rather the DEA obtained the records when the Pharmacy delivered the records to the DEA on September 23, 2013. In that Dr. Clark was present at the Pharmacy while the DEA agents were there on September 18, 2013, it strains credulity to suggest that she did not willingly consent to delivering the documents to the DEA five days later.

Factor One & Three: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority, and Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances

In this case, it is undisputed that the Respondents held valid state pharmacy licenses in Florida. The record contains no evidence of a recommendation regarding the Respondents' privileges to operate as a pharmacy by a relevant state licensing board or professional disciplinary authority. However, possession of a state license does not entitle a holder of that license to a DEA registration. *Mark De La Lama, P.A.*, 76 Fed. Reg. 20011, 20018 (2011). It is well established that a "state license is a necessary, but not a sufficient condition for registration." *Robert A. Leslie, MD.*, 68 Fed. Reg. 15227, 15230 (2003). The ultimate responsibility to determine whether a DEA registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. *Edmund Chein, MD.*, 72 Fed. Reg. 6580, 6590 (2007), *aff'd Chien v. DEA*, 533 F.3d 828 (D.C. Cir. 2008).

Agency precedent establishes that where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation. *See Roni Dreszer, MD.*, 76 Fed. Reg. 19434, 19444 (2011) ("The fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public

interest.") Accordingly, Factor One does not weigh for or against revocation in this matter.

As to Factor Three, there is no evidence that Respondents, or any of their agents, have been convicted of an offense under either federal or Florida law "relating to the manufacture, distribution, or dispensing of controlled substances." 21 U.S.C. § 823(f)(3). However, there are a number of reasons why even a person who has engaged in criminal misconduct may never have been convicted of an offense or even prosecuted for one. *Dewey C. MacKay, MD.*, 75 Fed. Reg 49956, 49973 (2010), *pet. for rev. denied, MacKay v. DEA*, 664 F.3d 808, 822 (10th Cir. 2011). The DEA has, therefore, held that "the absence of such a conviction is of considerably less consequence in the public interest inquiry" and is therefore not dispositive. *Id.* Accordingly, Factor Three neither weighs for or against revocation in this case.

Factors Two and Four: The Respondent's Experience in Dispensing Controlled Substances and Compliance with Applicable State, Federal, or Local Laws Relating to Controlled Substances

Factors Two and Four are often analyzed together. *See, e.g., Fred Samimi, MD.*, 79 Fed. Reg. 18698, 18709 (2014); *John V. Scalera, MD.*, 78 Fed. Reg. 12092, 12098 (2013). Under Factor Two, the DEA analyzes a registrant's "experience in dispensing . . .controlled substances." 21 U.S.C. § 823(f)(2). Factor Two analysis focuses on an applicant's acts that are inconsistent with the public interest, rather than on an applicant's neutral or positive acts and experience. *Randall L.*

Wolff, MD., 77 Fed. Reg. 5106, 5121 n.25 (2012) (explaining that "every registrant can undoubtedly point to an extensive body of legitimate [dispensing] over the course of [the registrant's] professional career") (quoting *Jayam Krishna-Iyer, MD.*, 74 Fed. Reg. 459, 463 (2009)). Similarly, under Factor Four, the DEA analyzes an applicant's compliance with federal and state laws concerning controlled substances. 21 U.S.C. § 823(0(4). Factor Four analysis also focuses on violations of state and federal regulations. *Volkman v. DEA*, 567 F.3d 215, 223-24 (6th Cir. 2009) (citing *Gonzales v. Oregon*, 546 U.S. 243, 272, 274 (2006)); *see Joseph Gaudio, MD.*, 74 Fed. Reg. 10083, 10090-91 (2009).

Under DEA regulations, in order for a prescription to be lawful, it "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). The regulations further provide that "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.* An individual who knowingly fills a prescription not issued in the usual course of professional treatment "shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Id.*

The DEA has consistently interpreted a pharmacist's corresponding responsibility "as prohibiting a pharmacist from filling a prescription for a controlled substance when he either `knows or has reason to know that the prescription was not written for a legitimate medical purpose.'" *Medicine Shoppe—Jonesborough*,

73 Fed. Reg. 364, 381 (2008) (quoting *Medic-Aid Pharmacy*, 55 Fed. Reg. 30043, 30044 (1990)). In short, a pharmacist has a "corresponding responsibility under Federal law" to dispense only lawful prescriptions. *Liddy's Pharmacy, L.L.C.*, 76 Fed. Reg. 48887, 48895 (2011) (citation omitted). The regulation does not require the pharmacist to practice medicine, but instead, imposes a responsibility upon the pharmacist "not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute because he knows [or has reason to know] that the issuing practitioner issued it outside the scope of medical practice." *East Main St. Pharmacy*, 75 Fed. Reg. 66149, 66157 (2010) (quoting *United States v. Hayes*, 595 F.2d 258, 261 (5th Cir. 1979)).

Providing further guidance concerning a pharmacist's corresponding responsibility the DEA has held:

> [W]hen the circumstances surrounding the presentation of a prescription would give rise to suspicion in a "reasonable professional," there is a duty to "question the prescription[]." *Ralph J. Bertolino, d/b/a/Ralph J. Bertolino Pharmacy*, 55 Fed. Reg. 4729, 4730 (1990). Though initially framed as a "reasonable professional" standard, the Agency has considered the duty to discharge the corresponding responsibility by evaluating the circumstances in light of what would be considered suspicious by a "reasonable pharmacist." *East Main Street Pharmacy*, 75 Fed. Reg. 66149, 66165; *see also Winn's Pharmacy*, 56 Fed. Reg. 52559, 52561 (1991). Accordingly, a pharmacist or pharmacy may not dispense a pre-

> scription in the face of a red flag (*i.e.*, a circumstance that does or should raise a reasonable suspicion as to the validity of a prescription) unless he or it takes steps to resolve the red flag and ensure that the prescription is valid. *Id.* Because Agency precedent limits the corresponding responsibility to circumstances which are known or should have been known, *Sun & Lake Pharmacy, Inc.*, 76 Fed. Reg. 24523, 24530 (2011), it follows that, to show a violation of a corresponding responsibility, the Government must establish that: (1) the Respondent dispensed a controlled substance; (2) a red flag was or should have been recognized at or before the time the controlled substance was dispensed; and (3) the question created by the red flag was not resolved conclusively prior to the dispensing of the controlled substance. *See Sun & Lake Pharmacy*, 76 Fed. Reg. at 24532 (Finding that pharmacy violated corresponding responsibility where it took no steps to resolve red flags prior to dispensing controlled substances.). The steps necessary to resolve the red flag conclusively will perforce be influenced by the nature of the circumstances giving rise to the red flag.

Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 & 5195, 77 Fed. Reg. 62316, 62341 (2012)

Further, to establish a violation of a pharmacist's corresponding responsibility, the Government must establish the requisite degree of scienter. *Hills Pharmacy, LLC.*, 81 Fed. Reg. 49816, 49835 (2106) (citing *JM Pharmacy Group, Inc., d/b/a Farmacia Nueva*

and Best Pharma Corp., 80 Fed. Reg. 28667, 28669 (2015)). To establish scienter, the Government can show that a pharmacist violated his or "corresponding responsibility" by filling a prescription while knowing that it lacked a legitimate medical purpose. *Hills Pharmacy*, 81 Fed. Reg. at 49835. In the case before me, however, the Government presented no evidence that one of the Pharmacy's pharmacists filled a prescription with actual knowledge that the prescription was not legitimate. Absent actual knowledge, the Government can establish scienter by showing that a pharmacist was "willfully blind (or deliberately ignorant) to the fact that the prescription lacked a legitimate medical purpose." *Id.* To establish willful blindness it is necessary to show that a pharmacist subjectively believed that there was a high probability that the prescription lacked a legitimate medical purpose and that the pharmacist deliberately avoided learning the truth. *Id.* Here the Government argues that the Pharmacy's failure to document the resolution of numerous red flags when it filled many prescriptions establishes that the Pharmacy was willfully blind as to the medical legitimacy of those prescriptions. ALJ-35, at 39-41 (citing *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy*, 55 Fed. Reg. 4729, 4730 (1990); *East Main Street Pharmacy*, 75 Fed. Reg. 66149, 66165 (2010); *Holiday CVS, L.L.C. d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62316, 62341 (2012); and *Sun & Lake Pharmacy, Inc., d/b/a The Medicine Shoppe*, 76 Fed. Reg. 24523, 24530 (2011)).

Since the Pharmacy is located in Florida, it is important to review the requirements of Florida law, as it relates to pharmacists. First under Florida law:

A pharmacist may not dispense a controlled

> substance listed in Schedule II, Schedule III, or Schedule IV to any patient or patient's agent without first determining, in the exercise of her or his professional judgment, that the prescription is valid. The pharmacist may dispense the controlled substance, in the exercise of her or his professional judgment, when the pharmacist or pharmacist's agent has obtained satisfactory patient information from the patient or the patient's agent.

Fla. Stat. § 893.04(2)(a). Further, under Florida law a person my not "dispense a controlled substance in violation of this chapter." Fla. Stat. § 893.13(7)(a)(1).

The Florida Board of Pharmacy has also promulgated regulations concerning records that must be maintained by a pharmacy. Those regulations provide that:

> (1) A patient record system shall be maintained by all pharmacies for patients to whom new or refill prescriptions are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing. The pharmacist shall ensure that a reasonable effort is made to obtain, record and maintain the following information:
>
> (a) Full name of the patient for whom the drug is intended;
>
> (b) Address and telephone number of the patient;
>
> (c) Patient's age or date of birth;

(d) Patient's gender;

(e) A list of all new and refill prescriptions obtained by the patient at the pharmacy maintaining the patient record during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and

(f) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) The pharmacist shall ensure that a reasonable effort is made to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review. The pharmacist shall record any related information indicated by a licensed health care practitioner.

Fla. Admin. Code r. 64B16-27.800(1)-(2).

Florida regulations also require that a pharmacist conduct a prospective drug review before filling a prescription. Specifically those regulations require that:

(1) A pharmacist shall review the patient record and each new and refill prescription presented for dispensing in order to promote

therapeutic appropriateness by identifying:

(a) Over-utilization or under-utilization;

(b) Therapeutic duplication;

(c) Drug-disease contraindications;

(d) Drug-drug interactions;

(e) Incorrect drug dosage or duration of drug treatment;

(f) Drug-allergy interactions;

(g) Clinical abuse/misuse.

(2) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber.

Fla. Admin. Code r. 64B16-27.810. In addition, a pharmacist is subject to disciplinary action by the Florida Board of Pharmacy should the pharmacist dispense a controlled substance "based upon . . . [what] purports to be a prescription . . . when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship." Fla. Stat. § 465.016(1)(s).

Thus, a pharmacist in Florida may not fill a prescription without first determining that the prescription is valid. Further, a Florida pharmacist is required to obtain satisfactory patient information prior to filling a prescription. The Florida pharmacist is also required to maintain a patient record, allowing for immediate retrieval of information relative to previously dispensed drugs and those records are to

include comments peculiar to the patient, and information provided by a licensed health care provider. Also before filling a prescription, a Florida pharmacist is required to review a prospective medication for therapeutic appropriateness. Should a Florida pharmacist fail to carry out these obligations, the pharmacist can be disciplined by the Florida Board of Pharmacy.

Finally, "[t]he corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself." *Holiday CVS*, 77 Fed. Reg. at 62341 (citing *Med. ShoppeJonesborough*, 73 Fed. Reg. at 384; *United Prescription Servs., Inc.*, 72 Fed. Reg. 50397, 5040708 (2007); *EZRX, LLC*, 69 Fed. Reg. 63178, 63181 (2004); *Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies*, 75 Fed. Reg. 61613, 61617 (2010); *Issuance of Multiple Prescriptions for Schedule II Controlled Substances*, 72 Fed. Reg. 64921, 64924 (2007) (other citations omitted)). The DEA has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist or other key employee. *EZRX, LLC*, 69 Fed. Reg. 63178, 63181 (1988); *Plaza Pharmacy*, 53 Fed. Reg. 36910 (1988). Similarly, "[k]nowledge obtained by the pharmacists and other employees acting within the scope of their employment may be imputed to the pharmacy itself." *Holiday CVS*, 77 Fed. Reg. at 62341.

In support of its allegations that the Pharmacy violated its corresponding responsibility, the Government convincingly argues that the Pharmacy filled prescriptions to customers without documenting the resolution of numerous red flags. Regarding documentation of red flags in Florida, the DEA has held

that "while there is no requirement that a pharmacist document the resolution of a red flag on a prescription," Florida statutes and regulations require a pharmacist to document information in a patient profile. *See Hills Pharmacy*, 81 Fed. Reg. at 49836.

A. J.S.3's Prescriptions

The Government alleges that from March 2014 through December 2014, the Pharmacy dispensed 10 mg tablets of oxycodone and testosterone to J.S.3, pursuant to prescriptions which J.S.3, a licensed physician, wrote to himself. ALJ-1, at 4. The Government argues that this prescription presented with a red flag because it is unlawful in Florida for a physician to write prescriptions to himself. ALJ-35, at 7, 39. The Government further argues that the Pharmacy violated its corresponding responsibility by dispensing controlled substances to J.S.3 without resolving this red flag. ALJ-35, at 7-8. The Government only provided the prescriptions and the Pharmacy's profile of J.S.3. *See* GE-2.

Under Florida law, it is a ground for denial of a medical license or for disciplinary action for a physician to prescribe, administer, or dispense [a controlled substance] to himself, "except one prescribed, dispensed, or administered to the physician by another practitioner authorized to prescribe, dispense, or administer medicinal drugs." Fla. Stat. § 458.331(1)(r). Furthermore, filling such a prescription would not be in the usual course of the professional practice of a pharmacy. Tr. 50, 62.

In *Hills Pharmacy, LLC*, the Government alleged that Hills Pharmacy's "pharmacists repeatedly failed to exercise their corresponding responsibility to ensure

that controlled substances they dispensed were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting within the usual course of their professional practice." *Hills Pharmacy, LLC*, 81 Fed. Reg. 49816, 49816 (2016). The Respondent Pharmacy argued that in order to establish that the pharmacy violated its corresponding responsibility, the Government must first establish "that the prescription lacked a legitimate medical purpose and that the issuing physician acted outside of the usual course of professional practice." *Id.* at 49836 n.33. The Acting Administrator held "that a pharmacist cannot violate his corresponding responsibility if a prescription was nonetheless issued for a legitimate medical purpose." *Id.* However, the Acting Administrator establishes that "the invalidity of a prescription can be proved by circumstantial evidence." *Id.*

Similarly, where a registrant has been charged with failing to properly annotate the receipt or return of controlled substances on DEA 222 order forms, the Acting Administrator has rejected those allegations where the Government failed to produce evidence that the controlled substances were actually received or shipped. *Edge Pharmacy*, 81 Fed. Reg. 72092, 72094, 7211 n.55 (2016)

Under the exception in Fla. Stat. § 458.331(1)(r), the prescriptions written by J.S.3 would be proper if "prescribed, dispensed, or administered to [J.S.3] by another practitioner authorized to prescribe, dispense, or administer medicinal drugs." Fla. Stat. § 458.331 (1)(r). Under the rationale of both *Hills Pharmacy* and *Edge Pharmacy* it would be incumbent upon the Government to prove that the exception under Fla. Stat. § 458.331(1)(r) did not apply in this case. Here, the

Government did not provide any evidence, other than the prescription itself, to establish that J.S.3 had not been receiving the prescriptions from another practitioner. While the Government failed in its proof, the Respondent came to the rescue.

In presenting its case, the Respondents offered records concerning J.S.3. RE-H, at 1-41. First, the Respondents presented J.S.3's PMP from January 1, 2013 through December 10, 2015. RE-H, at 2-5. This exhibit documents that J.S.3 prescribed testosterone to himself as early as April 5, 2013, and oxycodone/acetaminophen (Percocet) as early as October 7, 2013. RE-H, at 4-5. The PMP also shows that J.S.3 is the only doctor who had been prescribing testosterone and Percocet to J.S.3. RE-H, at 2-5. Further, the Respondent presented treatment notes that J.S.3 prepared as he treated himself between March 13, 2014 and December 29, 2014. RE-H, at 15-22. A review of those easily readable treatment notes does not reveal any indication that J.S.3 had been treated by any other doctor for his conditions for which he prescribed testosterone and Percocet to himself. RE-H, at 15-22. Finally, the Respondents presented a two-page letter from J.S.3 in which he indicated that he had been self-prescribing with testosterone since 2002 and that, in "mind set [of] 'Physician heal thyself;'" he began prescribing Percocet to himself in 2014. RE-H, at 40-41. This evidence, provided by the Respondent, clearly establishes that the exception to Fla. Stat. § 458.331 (1)(r), relied upon by the Respondent, does not apply in this case.

Accordingly, the Government's allegation that the Pharmacy violated its corresponding responsibility by filling prescriptions that J.S.3 wrote to himself is

SUSTAINED and weighs in favor of revocation of the Pharmacy's DEA registration.

B. Office Prescriptions

Next, the Government alleges that between September 23, 2014, through January 28, 2015, the Pharmacy dispensed testosterone on at least fourteen different occasions pursuant to invalid prescriptions that indicated the ultimate user was an office, in violation of 21 C.F.R. § 1306.04(b). ALJ-1, at 4, para. 10(b). Pursuant to DEA regulations, "[a] prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients." 21 C.F.R. § 1306.04(b).

The DEA has held that "prescriptions," however, which listed the prescribing physician as the patient, are not prescriptions as defined by DEA regulations. *See Wedgewood Village Pharmacy*, 71 Fed. Reg. 16593, 16594 (2006). The Administrator outlined that prescriptions for controlled substances are required to "bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner." *Id.* (quoting 21 C.F.R. § 1306.05(a)). The Administrator concluded that "[u]nless the physicians are the patients, these documents are not prescriptions for purposes of the Controlled Substances Act." *Id.*

Here, the Government alleges that the Pharmacy dispensed testosterone thirteen times to Dr. Ivery and once to Dr. Abraham pursuant to "invalid prescriptions," violating 21 C.F.R. § 1306.04(b). ALJ-1, at 4. However, as these "prescriptions" were issued to physicians,

they do not fall under the DEA's interpretation of a prescription. *See Wedgewood Village Pharmacy*, 71 Fed. Reg. at 16594. The Respondents argue that the transactions, between the Pharmacy and Drs. Ivery and Abraham, were "permissible wholesale transactions" conducted pursuant to 21 C.F.R. § 1307.11. ALJ-36, at 63. As the Respondents argued in their Post-Hearing Brief, "[t]he Government did not present any notice or evidence that Dr. Ivery [or Dr. Abraham] is not registered under the CSA to dispense, that the distribution was improperly recorded, or that the total number of distributions exceeded five percent (5%) of Suntree's volume." ALJ-36, at 64. While I agree with the Respondents that the Government has not presented any evidence to establish that there was a violation of 21 C.F.R. § 1307.11, the Respondent was never charged with a violation of that section.

Even assuming that the "prescriptions" the Pharmacy filled for Drs. Ivery and Abraham were actual prescriptions and not wholesale transactions, 21 C.F.R. § 1306.04(b) is not an outright proscription of filling prescriptions to a doctor's office. Rather what is proscribed is filling a prescription "for the purpose of general dispensing to patients." *Id.* Under the same rationale discussed above concerning *Hills Pharmacy* and *Edge Pharmacy*, in order to prove a violation of 21 C.F.R. § 1306.04(b) it was incumbent upon the Government to prove that Drs. Ivery and Abraham were going to be dispensing the controlled substances to patients.

While the Government did present evidence that the Pharmacy filled the prescriptions contained Government Exhibit 3, it presented absolutely no evidence that the purpose of the dispensing was to enable

Drs. Ivery and Abraham to then dispense the controlled substances to their patients. In fact, the "prescriptions" the Government presented indicate that controlled substances were to be "for office use," "for office-use only," or "for office administration." GE-3, at 2-11, 13. That evidence is consistent with Dr. Clark's credible testimony that Dr. Ivery administered the testosterone to her patients while they were in her office. Tr. 579. Finally, while 21 U.S.C. § 885(a)(1) provides that the Government is not required prove that an exception does not apply, 21 U.S.C. § 885(a)(1) does not apply in this instance because the exception is contained in a the Federal Regulations and not in Subchapter 1 of Chapter 13 of Title 21 of the United Sates Code. *See Peter F. Kelly, D.P.M.*, 82 Fed. Reg. 28676, 28688 (2017).

Accordingly, the Government's allegation that the Pharmacy dispensed testosterone on at least fourteen different occasions pursuant to invalid prescriptions that indicated the ultimate user was an office, in violation of 21 C.F.R. § 1306.04(b), is NOT SUSTAINED, and does not weigh in favor of revocation of the Pharmacy's DEA registration.

C. Prescriptions Written By Dr. Richard

1. Group Prescriptions (S.P., A.J., J.S.1,[37] D.G., and E.H.)

The Government alleges that between February 12, 2014, and May 3, 2014, the Pharmacy dispensed narcotic medications to groups of customers who

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37 Additional prescriptions dispensed to J.S.1 are discussed in the next subsection.

resided in close proximity to the Pharmacy, but who obtained their prescriptions from the same physician, Dr. Richard, who was located in Miami, Florida, more than 170 miles from their homes. ALJ-1, at 4, para. 10(c).

At the hearing Government Counsel recorded some of the information contained in GE 4, at 5, 6, 8, 9, for patients S.P., A.J., J.S.1, D.G., and E.H., onto a chart. Although the chart was not in introduced into evidence, it was informative and it is reproduced here:

Customer/ Patient	Dispense Date	RX Number (last 3 digits)	Type of CS	Exhibit
J.S.1	2/12/14	-162	Oxycodone	GE-6, at 1-2
A.J.	2/12/14	-189	Hydromorphone	GE-5, at 3-4
S.P.	2/12/14	-195	Hydromorphone	GE-4, at 3-4
D.G.	3/11/14	-927	Oxycodone	GE-9, at 5-6
J.S.1	3/11/14	-928	Oxycodone	GE-6, at 3-4
E.H.	3/15/14	-027	Hydromorphone	GE-8, at 1-2
S.P.	3/15/14	-028	Hydromorphone	GE-4, at 5-6

A.J.	3/15/14	-029	Hydromorphone	GE-5, at 5-6
S.P.	4/11/14	-795	Hydromorphone	GE-4, at 1-2
A.J.	4/11/14	-796	Hydromorphone	GE-5, at 7-8
E.H.	4/11/14	-797	Hydromorphone	GE-8, at 3-4
J.S.1	5/3/14	-439	Oxycodone	GE-6, at 11-12
D.G.	5/3/14	-440	Hydromorphone	GE-9, at 9-10

As this chart illustrates, on February 12, 2014, the Pharmacy dispensed oxycodone or hydromorphone to a group of three of Dr. Richard's patients who each travelled more than 170 miles to obtain their prescriptions. Stip. 7, 8, 10. Similarly, on March 11, 2017, the Pharmacy dispensed oxycodone to a group of two of Dr. Richard's patients who each travelled more than 170 miles to obtain their prescriptions. Stip. 10, 13. On March 15, 2014, the Pharmacy dispensed hydromorphone to a group of three of Dr. Richard's patients who travelled more than 170 miles to obtain their prescriptions. Stip. 7, 8, 20. Then on April 11, 2014, the Pharmacy dispensed hydromorphone to the same group of three of Dr. Richard's patients who travelled more than 170 miles to obtain their prescriptions. Stip. 7, 8, 20. Finally, on May 3, 2014, the Pharmacy dispensed oxycodone and hydromorphone to a group of two of Dr.

Richard's patients. Based upon her observation of the chart, Dr. Gordon aptly concluded that the chart demonstrated that the prescriptions written for patients S.P., A.J., J.S.1, D.G., and E.H. raise a red flag of "a group of patients going to see the same doctor, getting the same type of medication, same class of medication, and going to the [same] pharmacy on the same day to get their prescriptions filled." Tr. 106; *see also* Tr. 107. The chart also demonstrates that many of the prescriptions were filled at approximately the same time, one after the other. *See* Rx numbers.

Additionally, under normal procedures in a pharmacy, Schedule II controlled substances are to be kept locked at all times, with only the pharmacist having access to the key. Tr. 109-10; Finding of Fact ("FF") 25. Thus, a pharmacist would have been personally involved with filling all of these prescriptions for Schedule II controlled substances. Tr. 110-11. In Dr. Gordon's opinion, the red flags demonstrated by the chart are not resolvable, and she would not have filled the prescriptions detailed on the chart. Tr. 111.

Dr. Gordon reviewed GE-29, at 1, a letter from Dr. Richard to the Respondent. Tr. 193, 270. In Dr. Gordon's opinion the letter does not resolve any of the red flags that Dr. Gordon identified involving patients S.P.,[38] A.J., J.S.1, D.G., and E.H. Tr. 193, 270. In Dr. Gordon's opinion, Dr. Richard's letter raises an additional red flag because it indicates that Dr. Richard is relocating even farther from the patients. Tr. 194. The biggest red flag is the distance to Dr. Richard's office

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38 Although the transcript says S.A., the is no patient S.A. Tr. 193.

and possibly driving that distance while taking the prescribed controlled substances. Tr. 194. In Dr. Gordon's opinion, that red flag cannot be resolved. Tr. 194. Dr. Clark asked Dr. Richard to write a letter explaining why some patients were visiting his practice and then going to the Pharmacy. Tr. 269. Dr. Gordon does not know if Dr. Clark, or anyone else at the Pharmacy, had a conversation with Dr. Richard because no such conversation is documented in the file. Tr. 270. Nothing in the Pharmacy's records confirmed that Dr. Richard was checking E-FORCSE every month, communicating with DEA and law enforcement about drug diversion, conducting DNA testing, doing monthly drug screens, or conducting pill counts, as he claimed in his letter that he was doing. Tr. 286-87; GE-29, at 1. In addition, the Pharmacy records did not contain any letters from patients explaining why they were travelling long distances to see Dr. Richard.

Specifically, the letter of medical necessity concerning S.P. did not resolve the red flag of why S.P. was making a 340-mile round trip to see Dr. Richard. Rather, the diagnoses contained in the letter of chronic back pain and thoracic/lumbosacral impingement, caused Dr. Gordon to wonder how a person with such back pain could either sit in a car for three hours, or drive for three hours while taking the prescribed medication,[39] in order to obtain the prescriptions. Tr. 70, 251. As a pharmacist, working under the minimal

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[39] I give no weight to the suggestion that patients drove long distances because there is no evidence to support a finding that they drove to see their doctor or drove to the Pharmacy. The record does support a conclusion that the patients were at a minimum passengers who traversed long distances to either see their doctor or present their prescriptions to the Respondent, or both.

standards of practice of pharmacy in Florida, Dr. Gordon would not have filled the prescriptions contained in GE-4. Tr. 75. In her view, there is nothing in GE-4 that resolves the red flag of why the patient was travelling for three hours to obtain these prescriptions. Tr. 69, 75.[40] Accordingly, the Pharmacy did not fulfill its corresponding duty to ensure the prescriptions for S.P., contained in GE-4, were issued for a legitimate medical purpose, and the Pharmacy did not dispense them within the normal course of professional practice. Tr. 70: FF 68-70.

Regarding patient A.J., in addition to the prescriptions issued by Dr. Richard, A.J. was issued prescriptions by Dr. Daviglus, which also raise numerous red flags. FF 71. Dr. Daviglus's office was located about 70 miles from A.J.'s home, which raises a red flag. FF 73. Additionally, it is a red flag that there was a note in A.J.'s patient profile that indicates that Dr. Daviglus called the Pharmacy and said that he would send over a letter of medical necessity, however, the Pharmacy has no record of receiving such a letter. FF 74. There is nothing in GE-5 that resolves the red flags identified upon review of the prescriptions the Pharmacy filled for A.J. Tr. 78, 85; GE-5. Therefore, the Pharmacy did not fulfill its corresponding duty to ensure that the prescriptions for A.J., contained in GE-5, were issued for a legitimate medical purpose,

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[40] I give no weight to Dr. Gordon's testimony that there were 16 pain specialists in the area near where patient S.P. lived. *See* Tr. 69. As developed on cross examination, Dr. Gordon based that testimony on a Google search she conducted, but she did not contact any of those doctors to determine if they were accepting new patients or to determine what type insurance they accepted. Tr. 241-42.

and the Pharmacy did not dispense them within the normal course of professional practice. Tr. 86; FF 71-75.

Similarly, nothing in the record resolves the red flags raised by prescriptions dispensed to patient D.G. Dr. Clark testified that patient D.G., changed physicians from Dr. Richard to a doctor in Orlando. Tr. 593-94. Dr. Clark encouraged customers to switch doctors "to avoid that heightened scrutiny for south Florida."[41] Tr. 593-94. D.G.'s files shows that in October 2014 he had a prescription filled at the Pharmacy that was written by a doctor located in Winter Park, Florida. GE-9, at 11-12. In November 2014, however, D.G. was back to seeing Dr. Richard, but rather than going to the Pharmacy to have the prescription filled, D.G. went to a Wal-Mart in West Melbourne, Florida. RE-H, at 100.

The prescriptions written to D.G. raise red flags, including: the type of medication-opioids; the fact that they are written for the highest available dosage; the distance the patient travelled to see the doctor; and the patient paid cash. Tr. 93-96; FF 77. Further the prescription written by Dr. Brutus at page 11 of GE-9 raises the same red flags as the other prescriptions written for D.G., except that the distance is shorter. Tr. 97; GE-9, at 11; FF 77. All of the prescriptions were for oxycodone 30 mg or hydromorphone 8 mg.

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41 The fact that Dr. Clark was concerned about the "heightened scrutiny for south Florida" is an indication that she was aware that the distances these patients were travelling raised a red flag. Nothing in the Pharmacy's records, however, documents how the red flag was resolved.

Tr. 94; FF 77. In addition, D.G.'s profile does not mention receipt of a letter of medical necessity from Dr. Richard, though an undated letter was received. GE-9, at 13-14; RE-H, at 99; FF 78. Thus, a pharmacist filling a prescription for D.G. would not have been alerted to check the paper file to see what Dr. Richard had written.

Nothing in GE-9 resolves the red flags raised by the prescriptions contained in GE-9. Tr. 98. Accordingly, the Pharmacy did not fulfill its corresponding duty to that ensure the prescriptions it filled for D.G., contained in GE-9, were issued for a legitimate medical purpose, and the Pharmacy did not dispense them within the normal course of professional practice. Tr. 98; FF 76-79.

Furthermore, nothing in GE-8 resolves the red flags raised by the prescriptions issued to E.H. contained in GE-8 issued by Dr. Richard. Tr. 105. Those red flags include: the type of medication (opioids); the fact that they are written for the highest available dosage; the distance the patient travelled to see the doctor; and the patient paid cash. Tr. 100, 102; FF 81. All of E.H.'s prescriptions were for oxycodone 30 mg or hydromorphone 8 mg. Tr. 101; GE-8; FF 81. While the file for E.H. contains a letter of medical necessity from Dr. Richard, it does not explain why E.H. was making a 350-mile round trip to obtain his prescriptions. FF 80, 82. In addition, Dr. Clark did not provide any specific testimony concerning the prescriptions the Pharmacy filled for E.H. Considering all these factors, the Pharmacy did not fulfill its corresponding duty to ensure that the prescriptions contained in GE-8 were

issued for a legitimate medical purpose, and the Pharmacy did not dispense them within the normal course of professional practice. Tr. 105; FF 80-82.

The Acting Administrator has held that travelling long distances to obtain prescriptions for controlled substances is a red flag, and would have widely been known in 2010 to be an indicator of diversion or abuse of controlled substances.[42] *See Jones Total Health Care Pharmacy, L.L.C. and SND Healthcare, L.L.C.*, 81 Fed. Reg. 79188, 79194 (2016) (citing *East Main Street Pharmacy*, 75 Fed. Reg. 66149, 66164 (2016)). It is a red flag for patients to travel long distances because "it is obvious that patients travelling great distances to obtain large quantities of potent narcotics such as oxycodone 30 are likely seeking the drugs to either abuse them or divert them to others." *Id.* at 79195. Here, not only were S.P., A.J., J.S.1, D.G., and E.H. all patients of Dr. Richards but they also travelled long distances to obtain prescriptions for highly abused controlled substances, and they frequently presented in groups at the Pharmacy to have those prescriptions filled. Furthermore, nothing in the patient records for these individuals indicate that the Pharmacy resolved any of these red flags posed by the prescriptions that these patients presented to the Pharmacy.

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[42] While the Acting Administrator, in *Hills Pharmacy, LLC*, refused to adopt a categorical rule regarding distance, he concluded that "[d]istance is just one of the factors that a pharmacist must evaluate, and while a patient's willingness to travel a long distance to obtain a prescription is highly suspicious, a patient who seeks drugs for other than legitimate medical purposes may live in the same city as the prescriber and/or pharmacy." 81 Fed. Reg. 49816, 49841 n.45 (2016).

Accordingly, the Government's allegations that the Pharmacy violated its corresponding responsibility by dispensing narcotic medications to groups of customers who resided in close proximity to the Pharmacy, but who obtained their prescriptions from the same physician, who was located in Miami, Florida, more than 170 miles from their homes, without resolving red flags raised by these prescriptions is SUSTAINED and weighs in favor of revocation of the Pharmacy's DEA registration.

2. J.S.1 & J.S.2

Next, the Government alleges that the Pharmacy violated its corresponding responsibility when it dispensed controlled substances, including oxycodone and hydromorphone, between February 12, 2014, and May 3, 2014, to customers J.S.1 and J.S.2, without resolving the following red flags: (1) the prescriptions were for well-known, highly diverted/abused controlled substances; (2) the customers travelled an unusual and long distance to obtain their prescriptions; (3) the customers sought to pay cash for their prescriptions; and (4) the customers often obtained their prescriptions from the same physician on the same day. ALJ-1, at 5, para. 10(d). The Government asserts that the Pharmacy's actions were in violation of 21 C.F.R. § 1306.04(a), Fla. Stat. § 89104, and Fla. Admin. Code r. 64B16-27.800 and r. 64B16-27.810.

The prescriptions that the Pharmacy filled for J.S.1 and J.S.2 raised the following red flags: the type of medication (oxycodone 30 mg and 8 mg of hydromorphone); the fact that they were written for the highest dosage; the distance the patients travelled to see the doctor; and the cash payments. Tr. 87, 112-13;

FF 84. Both J.S.1 and J.S.2 travelled approximately 174 miles to obtain their prescriptions from Dr. Richard. Stip. 10; FF 83. Soss filled the prescriptions for J.S.1, and Dr. Clark filled several of the prescriptions for J.S.2. Tr. 586. Dr. Clark recalls talking to J.S.2 about why he was traveling such a long distance but she does not recall the details of the conversation, and she did not she document the conversation. Tr. 716. Dr. Clark recognized that the distance that J.S.2 travelled to see Dr. Richard raised a red flag, but she does not know how she resolved it, only that she had a conversation with J.S.2. Tr. 774. Dr. Clark confirmed that J.S.1 and J.S.2 lived at the same address. Tr. 585. However, when filling the prescriptions, Dr. Clark did not know that J.S.1 and J.S.2 lived at the same address.[43] Tr. 586. The Pharmacy software did not provide any sort of alert about customers with the same address. Tr. 586.

Dr. Clark considered the distance that J.S.2 travelled to see Dr. Richard to be a red flag, but she testified that she considered the red flag resolved based upon the letters she had received from Dr. Richard regarding his practice[44] and concerning J.S.2.

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[43] I find this testimony credible. A review of the fill stickers for the prescriptions for J.S.1 and J.S.2 reveals that, although J.S.1 and J.S.2 obtained their prescriptions for Dr. Richard on the same day, they never presented their prescriptions to the Pharmacy on the same day. GE-6, at 1-14.

[44] This letter, dated May 22, 2014, was written after Dr. Clark had filled the prescription for J.S.2 on April 7, 2014. Tr. 590; GE-6, at 7-8; RE-H, at 81, 95-96. Thus, she could not have considered this letter in resolving the "distance" red flag before she filled the prescription for J.S.2 on April 7, 2014. This is another of Dr. Clark's exaggerations.

Tr. 587, 701. The letter concerning J.S.2 reads that that he was being treated, "for short term care, less than six months, or long-term care, greater than 99 months . . . ." Tr. 702; GE-6, at 16; RE-H, at 93. Dr. Clark, however, saw no ambiguity in this language and somehow read the letter to mean that J.S.2 was a short term patient. Tr. 702-03. Further, Dr. Clark saw no obligation to inquire about the diagnosis for J.S.2 provided by Dr. Richard in his letter concerning J.S.2. Tr. 589-90, 702-03; GE-6, at 16; RE-H, at 93. Dr. Clark also spoke to J.S.2, and recalls that he said his treatment with Dr. Richard was short term, but there is no documentation of the conversation. Tr. 588. Dr. Clark filled a prescription for J.S.2 for hydromorphone 8 mg on April 7, 2014. Tr. 715-16. Although Dr. Clark testified that she decided not to fill additional prescriptions for J.S.2 in May 2014, that decision was not recorded in J.S.2's profile. Tr. 588; GE-6, at 15; RE-H, at 90.

Dr. Clark filled two prescriptions written by Dr. Richard after she had established the Pharmacy policy that prescriptions would not be filled from out of county prescribers. Tr. 746-47, 761, 773. She had established that policy by as early as March 29, 2013. Tr. 775-76; RE-H, at 423. One of those prescriptions was when she filled a prescription for J.S.2 on April 7, 2014. Tr. 773; GE-6, at 7-8.

Both J.S.1 and J.S.2 paid cash for their prescriptions. GE-6, at 2, 4, 6, 8, 10, 12, 14; Tr. 112-13. Dr. Clark did not consider paying cash to be a red flag, because she would have asked J.S.2 if he had insurance, but that is not noted anywhere in the file. Tr. 718-19. If J.S.2 had said he had insurance, but he did not want to use it, Dr. Clark would have considered

a decision not to use insurance to be a red flag. Tr. 720-21. However, the DEA has held that customers seeking to pay cash for prescriptions can be a red flag of diversion or abuse. *Jones Total Health Care Pharmacy, L.L.C. and SND Health Care, L.L.C.*, 81 Fed. Reg. 79188, 79194 (2016) ("Any reasonable pharmacist knows that a patient that wants to pay cash for a large quantity of controlled substances is immediately suspect." (quoting *East Main Street Pharmacy*, 75 Fed. Reg. 66149, 66158 (2010))). While the prices paid by J.S.1 and J.S.2 were not outlandish to render these prescriptions suspect, combined with other factors, such as distance and the type of controlled substance prescribed, the fact that J.S.1 and J.S.2 sought to pay cash would be considered another red flag. *See Hills Pharmacy, LLC*, 81 Fed. Reg. 49816, 49839 & n.39 (2016).

There is no letter of medical necessity for J.S.1. FF 86. Furthermore, nothing in the file for J.S.2 documents resolution of the distance red flag that Dr. Clark had recognized. GE-6; RE-H, 90-97. Accordingly, nothing in GE-6 resolves the red flags raised by the prescriptions written for J.S.1 and J.S.2, contained in GE-6. Tr. 113; GE-6. The Pharmacy did not fulfill its corresponding duty to ensure that the prescriptions for J.S.1 and J.S.2, contained in GE-6, were issued for a legitimate medical purpose, and the Pharmacy did not dispense them within the normal course of professional practice. Tr. 113-14; FF 83-87. Accordingly, the Government's allegation that the Pharmacy violated its corresponding responsibility by filling the prescriptions in GE-6 to J.S.1 and J.S.2 is SUSTAINED and weighs in favor of revocation of the Pharmacy's DEA registration.

3. C.C.

Next, the Government alleges that the Pharmacy violated its corresponding responsibility under 21 C.F.R. § 1306.04(a), Fla. Stat. § 893.04, and Fla. Admin. Code r. 64B16-27.800 and r. 64B16-27.810 by issuing large quantities of hydromorphone to customer C.C. The Government argues that the Pharmacy filled prescriptions to C.C. from December 12, 2013, through May 5, 2014, without resolving the following red flags: (1) hydromorphone is a well-known highly diverted /abused controlled substance; (2) C.C. travelled an unusual path and distance to obtain the prescriptions and have them filled; and (3) C.C. sought to purchase the prescriptions with cash. ALJ-1, at 6, para. 10(h).

Patient C.C. was written prescriptions by Dr. Richard in Miami, Florida, and Dr. Michael Willis in Rockledge, Florida. FF 88. Although Dr. Willis is. local, C.C. lives more than 170 miles from Dr. Richard's office. FF 88; Stip. 28. Besides the distance, Dr. Gordon indicated that additional red flags raised by C.C.'s prescriptions include: the type of medication prescribed; the fact that the prescriptions were written for the highest available dosage; and that C.C. sought to pay cash for the prescriptions. FF 89.

Nothing in GE-11 resolves the numerous red flags raised by the prescriptions written by Dr. Richard for C.C., contained in GE-11. Tr. 126. The Pharmacy had already filled five prescriptions from Dr. Richard before receiving a letter of medical necessity from Dr. Richard for C.C. on April 7, 2014. FF 90. Furthermore, Dr. Richard's letter does not address why C.C. travelled so far to obtain treatment. FF 90.

Accordingly, the Pharmacy did not fulfill its corresponding duty to ensure that the prescriptions contained in GE-11, written by Dr. Richard for C.C., were issued for a legitimate medical purpose, and the Pharmacy did not dispense them within the normal course of professional practice. Tr. 126-27; FF 88-90. Therefore, the Government's allegation that the Pharmacy violated its corresponding responsibility by filling the prescriptions in GE-11 to C.C. is SUSTAINED and weighs in favor of revocation of the Pharmacy's DEA registration.

4. P.P.

The Government next alleges that the Pharmacy violated its corresponding responsibility under 21 C.F.R. § 1306.04(a), Fla. Stat. § 893.04, and Fla. Admin. Code r. 64B16-27.800 and r. 64B16-27.810 by issuing large quantities of hydromorphone and oxycodone to customer P.P. The Government argues that the record establishes that the Pharmacy filled prescriptions to P.P. from January 31, 2014, through April 10, 2014, without resolving the following red flags: (1) hydromorphone and oxycodone are well-known highly diverted /abused controlled substances; (2) P.P. travelled an unusual path and distance to obtain the prescriptions and have them filled; and (3) P.P. sought to pay for the prescriptions in cash. ALJ-1, at 6, para. 10(i); FF 92.

As previous discussed, travelling long distances to obtain prescriptions for controlled substances, and seeking to pay cash for controlled substances are red flags. Additionally, Dr. Gordon indicated that the fact that the prescriptions were written for the highest available dosage of the controlled substance raises further red flags. FF 92. Further, P.P.'s profile does

not mention receipt of a letter of medical necessity from Dr. Richard, though a letter dated January 23, 2014, was received. Tr. 633-34, 748; GE-12, at 8; RE-H, at 255; FF 93. Thus, a pharmacist filling a prescription for P.P. would not have been alerted to check the paper file to see what Dr. Richard had written.

Nothing in GE-12 resolves the numerous red flags raised by the prescriptions contained in GE-12 concerning P.P. Tr. 129. Further, the Pharmacy did not fulfill its corresponding duty to ensure that the prescriptions written for P.P., contained in GE-12, were issued for a legitimate medical purpose, and the Pharmacy did not dispense them within the normal course of professional practice. Tr. 129-30; FF 91-94. Accordingly, the Government's allegation that the Pharmacy violated its corresponding responsibility by filling the prescriptions contained in GE-12 to P.P. is SUSTAINED and weighs in favor of revocation of the Pharmacy's DEA registration.

5. K.P.

The last of Dr. Richard's patients is K.P., who also presented prescriptions to the Pharmacy from other doctors in Ft. Lauderdale, Florida. The Government alleges that the Pharmacy violated its corresponding responsibility under 21 C.F.R. § 1306.04(a), Fla. Stat. § 893.04, and Fla. Admin. Code r. 64B16-27.800 and r. 64B16-27.810 by dispensing large quantities of hydromorphone and oxycodone to customer K.P. The Government argues that the Pharmacy filled prescriptions to K.P. from February 4, 2014, through April 8, 2014, without resolving the following red flags: (1) hydromorphone and oxycodone are well-known highly diverted/abused controlled substances; and (2) K.P.

travelled an unusual path and distance to obtain the prescriptions and have them filled. ALJ-1, at 6, para. 10(j).

Dr. Gordon indicated that there were again numerous red flags raised by the prescriptions that the Pharmacy filled for K.P. Again, the distance travelled by K.P. is a red flag. The address on five of the prescriptions in GE-13 indicate that K.P. lives in Ft. Lauderdale, so travelling all the way to the Pharmacy in Melbourne, Florida would be a red flag. FF 96. Additionally, the inconsistent addresses between the prescriptions and the Pharmacy's fill stickers raise further red flags. Other red flags include: the types of medication (opioids); the fact that they are written for the highest dosage; and paying cash for the prescriptions. Tr. 132; FF 96. Although there was a letter of medical necessity in K.P.'s file from Dr. Richard, there were no letters of medical necessity in the file from any of K.P.'s Ft. Lauderdale doctors. FF 97.

Nothing in GE-13 resolves the numerous red flags raised by the prescriptions contained in GE-13 concerning K.P. Tr. 135-36. The Pharmacy did not fulfill its corresponding duty to ensure that the prescriptions written for K.P., contained in GE-13, were issued for a legitimate medical purpose, and the Pharmacy did not dispense them within the normal course of professional practice. Tr. 136; FF 95-98. Accordingly, the Government's allegation that the Pharmacy violated its corresponding responsibility by filling the prescriptions contained in GE-13 to K.P. is SUSTAINED and weighs in favor of revocation of the Pharmacy's DEA registration.

D. Other Prescriptions

1. J.C.

The Government alleges that the Pharmacy violated its corresponding responsibility under 21 C.F.R. § 1306.04(a), Fla. Stat. § 893.04, and Fla. Admin. Code r. 64B16-27.800 and r. 64B16-27.810 by dispensing large quantities of controlled substances (including oxycodone, oxymorphone, morphine, fentanyl, and diazepam) to customer J.C. from October 11, 2013, through March 20, 2015. The Government argues that the Pharmacy filled prescriptions to J.C. without resolving the following red flags: (1) the prescriptions were for well-known, highly diverted/abused controlled substances; (2) J.C. travelled an unusual path and distance to obtain the prescriptions and have them filled; (3) the prescriptions were for extraordinarily large amounts of oxycodone and J.C. at times obtained duplicate prescriptions for the same type of oxycodone and in the same dosage; (4) J.C. obtained prescriptions for highly abused prescription cocktails; and (5) J.C. sought to pay for his prescriptions with cash. ALJ-1, at 5, para. 10(f).

Although there are some inconsistencies regarding J.C.'s address on his prescriptions, all of the Pharmacy's fill stickers indicate that J.C. lived in Indialantic, Florida, which is about 16 miles from the Pharmacy. FF 99. The distance from Indialantic to Dr. Gershenbaum's office in Ft. Lauderdale, FL was 158 miles. This distance, in conjunction with the concerns listed below, should have raised a red flag. Additionally, as discussed previously, J.C. paying cash for his prescriptions 10 times raises additional red flags. FF 103.

The fact that J.C. was receiving five prescriptions for the same short-acting opioid and the doctor's instructions for taking the medication seemingly allowed for the J.C. to be taking all that was prescribed were red flags that needed to be resolved. Tr. 837; FF 100. In Dr. Gordon's opinion, these five different prescriptions for oxycodone, all written and filled at the same time, made no sense, because all the prescriptions did the same thing, control pain. Tr. 115, 833; FF. 100. Dr. Gordon would have called the prescribing doctor to seek clarification. Tr. 835. Dr. Gordon would not have filled these five different prescriptions for oxycodone. Tr. 848.

Furthermore, with respect to the drug cocktail that the Pharmacy filled for J.C. seven times, Dr. Gordon testified that while diazepam can be used to treat anxiety it is not used for anxiety due to its long half-life and because it can suppress the CNS. Tr. 267; FF 101. Further, J.C. received the highest available dosage of diazepam. FF 101.

J.C. also presented prescriptions, which the Pharmacy filled, resulting in early refills of oxycodone. For example, the Pharmacy filled multiple oxycodone prescriptions for J.C. on January 28, 2014, Tr. 121, GE-10, at 11-18, and another on the next day. GE-10, at 19-20. Then just two weeks later on February 11, 2014, Tr. 121-22, GE-10, at 21-26, the Pharmacy filled three more prescriptions for oxycodone, and two more on February 26, 2014. GE-10, at 27-30. Nothing is written on any of these prescriptions to resolve this early refill red flag. Tr. 122; FF 102.

Dr. Clark testified that she knows J.C., who was a Pharmacy customer for 10 years. Tr. 596, 740. According to Dr. Clark, J.C. was a veteran who was

injured in a helicopter crash and who had post-traumatic stress disorder. Tr. 596-97. Dr. Clark testified that she spoke with the prescribing doctor about J.C. and his various prescriptions, but none of the discussions are documented in the patient profile. Tr. 597; GE-10; RE-H, at 117-55. Dr. Clark also testified that she spoke with J.C. about why he was traveling to Ft. Lauderdale to see a doctor, but those discussions are also not documented in the patient profile. Tr. 597-98, 741; GE-10; RE-H, at 117-55. Dr. Clark did document that she spoke with J.C.'s doctor on October 2, 2012 to verify the medical necessity of J.C.'s prescriptions. Tr. 610-11; GE-10, at 201; RE-H, at 117.

Nothing in GE-10 resolves the numerous red flags raised by the prescriptions contained in GE-10 concerning J.C. Tr. 120. Dr. Clark does not know if more information was contained in the "patient memo" box in J.C.'s profile. Tr. 792. In fact, Dr. Clark could not identify any "patient memo" boxes in the Government Exhibits that contained more information than was presented in the exhibits. Tr. 793.

Therefore, and in light of Findings of Fact 99-103, the Pharmacy did not fulfill its corresponding duty to ensure that the prescriptions contained in GE-10 were issued for a legitimate medical purpose, and the Pharmacy did not dispense them within the normal course of professional practice. Tr. 120. Accordingly, the Government's allegation that the Pharmacy violated its corresponding responsibility by filling the prescriptions contained in GE-10 to IC. is SUSTAINED and weighs in favor of revocation of the Pharmacy's DEA registration.

2. M.B.

The Government alleges that the Pharmacy violated its corresponding responsibility under 21 C.F.R. § 1306.04(a), Fla. Stat. § 893.04, and Fla. Admin. Code r. 64B16-27.800 and r. 4B16-27.810 by dispensing large quantities of controlled substances (including hydromorphone, morphine, and lorazepam) to customer M.B. The Government argues that the Pharmacy filled prescriptions to M.B. from October 3, 2013, through March 13, 2015, without resolving the following red flags: (1) these prescriptions were for well-known highly diverted /abused controlled substances; (2) M.B. travelled an unusual path and distance to obtain the prescriptions and have them filled; (3) M.B. obtained prescriptions for two immediate release opioids and lorazepam, constituting a highly abused prescription cocktail; and (4) M.B. sought to pay for the prescriptions in cash. ALJ-1, at 6-7, para. 10(k).

Dr. Gordon testified that there were numerous red flags raised by the prescriptions written to M.B. As previously discussed, the distance that M.B. travelled to obtain his prescriptions from his doctor's office in Sanford, Florida to his address in Palm Bay, Florida (85 miles) raises a red flag. FF 104, 105. Additionally, M.B. sought to pay cash for some of his prescriptions. Furthermore, Dr. Gordon indicated that M.B. was written a prescription for the highest dosage of hydromorphone. FF 105. Most significantly, M.B. was written numerous prescriptions, which the Pharmacy filled, for what Dr. Gordon considered to be "drug cocktails." FF 106.

Dr. Clark testified that she knew patient M.B. because she had regular discussions with him when he

came into the Pharmacy. Tr. 638. A review of the prescriptions between October 2013 and March of 2015, however, reveals that Dr. Clark only filled M.B.'s prescriptions on one occasion, August 14, 2014. GE-14, at 53-58. Dr. Clark testified that although she never discussed M.B. with his treating physician, Dr. Comfort, she had spoken to him shortly after she received the first prescription from him. Tr. 640. Dr. Clark testified that she spoke to M.B. about paying cash for his prescriptions and found the red flag resolved because his insurance would not cover a particular medication. Tr. 642. That discussion is not documented in M.B.'s file. GE-14; RE-H, at 267-83. Later, Dr. Clark testified that she did not discuss with M.B. why he was paying cash, the prescriptions just were not covered by insurance. Tr. 791.

Even Dr. Grant testified that with respect to the prescription filled on September 5, 2014, for M.B., he would have had a conversation with the prescriber before filling this early refill prescription. Tr. 506-09; GE-14, at 59-60. No such discussion, however, is documented in M.B.'s records.

Nothing in GE-14 resolves the numerous red flags raised by the prescriptions contained in GE-14 concerning M.B. Tr. 139. The Pharmacy did not fulfill its corresponding duty to ensure that the prescriptions contained in GE-14 were issued for a legitimate medical purpose, and the Pharmacy did not dispense them within the normal course of professional practice. Tr. 139-40; FF 104-108. Accordingly, the Government's allegation that the Pharmacy violated its corresponding responsibility by filling the prescriptions contained in GE-14 to M.B. is SUSTAINED and weighs in favor of revocation of the Pharmacy's DEA registration.

3. Prescriptions for C.A., D.B., J.D., K.B.3, K.B.2, and A.G.

Next, the Government alleges that the Pharmacy violated its corresponding responsibility, under 21 C.F.R. § 1306.04(a), Fla. Stat. § 893.04, and Fla. Admin. Code r. 64B16-27.800 and r. 64B16-27.810, by dispensing large quantities of controlled substances to customers C.A., D.B., J.D., K.B.3, K.B.2, and A.G.

First, the Government alleges that from December 17, 2013, through February 10, 2014, the Pharmacy filled prescriptions for large quantities of hydromorphone for customer C.A. without resolving the following red flags: (1) hydromorphone is a well-known highly diverted/abused controlled substance; (2) C.A. travelled an unusual path and distance to obtain the prescriptions; and (3) C.A. sought to pay for the prescriptions in cash. ALJ-1, at 7, para. 10(1).

Dr. Gordon testified that the prescriptions the Pharmacy filled for C.A. raised many red flags. First, the distance that C.A. travelled to obtain prescriptions from the doctor in Orlando, Florida to C.A.'s address in Sebastian, Florida is about 86 miles. FF 109. As previously discussed, the fact that C.A. sought to pay cash for the prescriptions raises additional concerns. FF 110. Additionally, Dr. Gordon indicated that the fact that C.A. was written prescriptions for opioids, some at the highest dosages available raises concern. FF 110.

Dr. Clark testified that she did not know CA. particularly well, though she filled two prescriptions for him. Tr. 646, 649; GE-15, at 1-2, 5-6; RE-H, at 289. The "patient memo" box in C.A.'s profile indicates that

the Pharmacy would require a letter of medical necessity before filling a prescription for C.A. from Dr. Kuhn in March 2014. Tr. 649; GE-15, at 7; RE-H, at 284. The file for C.A. does contain an undated letter of medical necessity. Tr. 649-50; GE-15, at 8; RE-H, at 288. Exaggerating the significance of the letter of medical necessity concerning C.A., Dr. Clark testified that it resolved the red flag of the distance that C.A. was travelling to get his prescriptions filled. Tr. 650. The letter of medical necessity, however, is not from Dr. Kuhn, or his practice, and it does not indicate why C.A. was traveling outside his local area to receive medical care. GE-15, at 8.

Furthermore, nothing in GE-15 resolves the numerous red flags raised by the prescriptions contained in GE-15 concerning C.A. Tr. 142-43. Accordingly, the Pharmacy did not fulfill its corresponding duty to ensure that the prescriptions for C.A., contained in GE-15, were issued for a legitimate medical purpose, and the Pharmacy did not dispense them within the normal course of professional practice. Tr. 142-43; FF 109-10; *see also* Tr. 130-40.[45]

Similarly, the Government alleges that the Pharmacy filled prescriptions for controlled substances (including oxycodone, alprazolam, and zolpidem) to D.B. without resolving the following red flags: (1) the prescriptions were for well-known, highly diverted

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[45] Dr. Gordon was not asked specifically if the pharmacist or pharmacists who dispensed the prescriptions to C.A. fulfilled their corresponding responsibility to ensure that a controlled substance was issued for a legitimate medical purpose. However, the red flags she discussed with C.A. prescriptions contained in GE-15 were similar to those discussed with regard to other customers. *See* Tr. 139-40, 149.

/abused controlled substances; (2) D.B. travelled an unusual path and distance to obtain the prescriptions and have them filled; (3) D.B. sought to pay for many of the prescriptions in cash; (4) many of the prescriptions were issued early; (5) D.B. obtained prescriptions for highly abused prescription cocktails. ALJ-1, at 6, para. 10(g).

The prescriptions written to D.B. raise numerous red flags. First, the distance from D.B.'s doctor to the Pharmacy is 111 miles, and the distance from D.B.'s address listed on the prescription fill stickers to the Pharmacy is 76 miles. FF 111. Additionally, Dr. Gordon testified that the types of medication that were prescribed to D.B. raise additional red flag, along with the fact that D.B. was written prescriptions for the highest available dosages of oxycodone and Xanax. FF 112. Significantly, D.B. was written numerous prescriptions that Dr. Gordon would consider to be constitute drug cocktails. FF 113. Additionally, the Pharmacy filled prescriptions for D.B. that Dr. Gordon indicated were early refills of oxycodone. FF 114.

Dr. Clark testified that she knows D.B., who was a long term Pharmacy customer. Tr. 617. Dr. Clark talked with D.B. about his medical condition, his employment, where he lived, where he worked, and the reasons he received early refills. Tr. 617-18, 730. None of this is documented in D.B.'s patient profile, or on any of the prescriptions, prior to service of the AIW.[46]

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46 There is a hand written note on a largely unreadable prescription, which appears to be for oxycodone HCL 30 mg, written on March 24, 2015. RE-H, at 164. Dr. Clark testified it is her handwriting on the prescription, indicating that D.B. would be moving back to Satellite Beach in July. Tr. 619. That prescription is not contained in GE-7, and there is no fill sticker for

Tr. 727-732; GE-7, at 21-24, 61. Dr. Clark never discussed D.B. with the prescribing doctor. Tr. 620, 730.

Dr. Clark testified that she always engaged D.B. in conversation. Tr. 620. Dr. Clark, however, only filled prescriptions for D.B. on three different dates during the relevant time period. GE-7, at 21-26, 57-60. Further exaggerating her familiarity with D.B., Dr. Clark also testified, "I recall the dose of his anxiety medication decreasing over the time that he was with me." Tr. 621. No such decrease is reflected in the records. The Pharmacy consistently provided D.B. 60 tablets of Xanax (alprazolam) 2 mg. GE-7, at 15-16, 25-26, 28, 41-42, 53-54; RE-H, at 167-170.

Dr. Clark acknowledged that D.B.'s prescriptions presented a red flag because his driver's license indicated that he lived in Port St. Lucie, an hour and a half from the Pharmacy. Tr. 618. She testified that she resolved this red flag when she made a notation on a prescription she filled for D.B. that he was moving back to Satellite Beach in July. Tr. 619-20; RE-H, at 164. The prescription, however, is barely legible, is not contained in the Government's exhibits concerning D.B., and was not filled until May 4, 2015. Tr. 730-31. Thus, while Dr. Clark recognized the distance red

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that prescription in evidence. That prescription was apparently filled by Dr. Clark on May 4, 2015, since she wrote that date on the prescription. Tr. 729-32; RE-H, at 164. Dr. Clark testified that the purpose of the note was to resolve the red flag of seeing a doctor in Port St. Lucie. Tr. 620, 729-30. Dr. Clark's note on this prescription, however, were made after the Administrative Inspection Warrant was served on the Pharmacy. Tr. 732. Thus, the note could not have resolved the distance red flag prior to the prescription being filled.

flag, she did not resolve it until after the Pharmacy was served with the AIW. Tr. 619-20, 732.

Furthermore, nothing in GE-7 resolves the numerous red flags raised by the prescriptions filled for D.B., contained in GE-7. Tr. 147-49. The Pharmacy did not fulfill its corresponding duty to ensure that the prescriptions contained in GE-7 were issued for a legitimate medical purpose, and the Pharmacy did not dispense them within the normal course of professional practice. Tr. 149; FF 111-15.

The Government next alleges that from October 18, 2013, through April 3, 2015, the Pharmacy dispensed controlled substances to customer J.D. without resolving the following red flags: (1) these prescriptions were for well-known highly diverted/abused controlled substances; (2) J.D. travelled an unusual path and distance to obtain the prescriptions and have them filled; (3) J.D. obtained prescriptions for highly abused prescription cocktails; (4) J.D. sought to pay for the prescriptions in cash; and (5) some of the prescriptions were issued early. ALJ-1, at 7, para. 10(m).

The prescriptions written to J.D. raise many red flags. The distance that J.D. travelled from his address in Cocoa Beach, Florida, to Dr. Comfort's office in Sanford, Florida, is 75 miles. FF 116. This distance travelled raises a red flag. FF 117. Additionally, the type of medication prescribed, and the fact that prescriptions for hydromorphone and Xanax were written for the highest dosage available raises concern. FF 117. As previously discussed, the fact that J.D. sought to pay cash for his prescriptions raises concern. FF 117. Significantly, on multiple occasions, the Pharmacy filled prescriptions that Dr. Gordon would consider to constitute early refills. FF 117.

Dr. Clark testified that J.D. was a regular customer who had been using the Pharmacy for a number of years, though Dr. Clark did not fill any of his prescriptions. Tr. 651-52. Dr. Clark had no interaction with J.D. concerning his medical conditions. Tr. 652. Dr. Clark provided no explanation of how the red flags concerning the prescriptions written for J.D. had been resolved prior to the Pharmacy filling his prescriptions.

Nothing in GE-16 resolves the numerous red flags raised by the prescriptions written for J.D., contained in GE-16. Tr. 154. Accordingly, the Pharmacy did not fulfill its corresponding duty to ensure that the prescriptions contained in GE-16 were issued for a legitimate medical purpose, and the Pharmacy did not dispense them within the normal course of professional practice. *See* Tr. 149; FF 116-18.[47]

Regarding patient K.B.3, the Government argued that from December 27, 2013, through January 23, 2015, the Pharmacy filled prescriptions for large amounts of hydromorphone for customer K.B.3 without resolving the following red flags: (1) hydromorphone is a well-known highly diverted/abused controlled substance; (2) K.B.3 travelled an unusual path and distance to obtain the prescriptions; and (3) K.B.3

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[47] Dr. Gordon was not asked specifically if the pharmacist or pharmacists who dispensed the prescriptions to J.D. fulfilled their corresponding responsibility to ensure that a controlled substance was issued for a legitimate medical purpose. However, the red flags she discussed with La's prescriptions contained in GE-16 were similar to those discussed with regard to other customers. Tr. 139-40, 149.

sought to pay for the prescriptions in cash. ALJ-1, at 7, para. 10(n).

The prescriptions written to K.S.3 raise many red flags. First, although K.B.3 lived in Palm Bay, Florida, which is located in the same county as the Pharmacy, the doctor who wrote prescriptions to K.S.3 was located in Sanford, Florida, which is 88 miles from the Pharmacy. Tr. 658; FF 119. Additionally, the fact the K.S.3 paid cash is a red flag. FF 120. Furthermore, the fact that K.S.3 was written prescriptions for the highest available dosage of hydromorphone should have been a red flag to the Pharmacy. FF 120-121.

While Dr. Clark testified that she interacted with K.B.3 "regularly," she only filled his prescriptions twice, on June 25, 2014, and July 22, 2014, both times for the maximum dosage of hydromorphone. Tr. 660; GE-17, at 12-15. Dr. Clark also testified that she saw no red flags with the prescriptions that K.B.3 presented to the Pharmacy. Tr. 660. Thus, she resolved none.

Nothing in GE-17 resolves the numerous red flags raised by the prescriptions written for K.B.3, contained in GE-17. Tr. 156-57. Accordingly, the Pharmacy did not fulfill its corresponding duty to ensure that the prescriptions written for K.B.3, contained in GE-17, were issued for a legitimate medical purpose, and the Pharmacy did not dispense them within the normal course of professional practice. Tr. 157-58; FF 119-122.

Next, the Government alleges that from December 16, 2013, through March 26, 2015, the Pharmacy filled prescriptions for hydromorphone, morphine, and diazepam for K.B.2 without resolving the following red flags: (1) hydromorphone, morphine, and diazepam

are well-known highly diverted/abused controlled substances; (2) K.B.2 travelled an unusual path and distance to obtain the prescriptions; and (3) K.B.2 sought to pay for the prescriptions in cash. ALJ-1, at 7, para. 10(o).

The prescriptions written to K.B.2 raise numerous red flags. First, K.B.2 travelled about 67 miles from his address in Melbourne, Florida, to Dr. Prieto's office in Orlando, Florida, to obtain his prescriptions. FF 123. Additionally, Dr. Gordon indicated that the type of Medication prescribed, diazepam, hydromorphone, and morphine sulfate, and the fact that the prescriptions were written for the highest available dosage of diazepam and hydromorphone, are red flags. FF 124. Additionally, K.B.2 sought to pay in cash. FF 124. Significantly, between January 13 and March 26, 2014, the Pharmacy filled a drug cocktail for K.B.2 consisting of diazepam, hydromorphone, and morphine sulfate thirteen times. FF 124.

Dr. Clark filled some prescriptions for K.B.2. Tr. 660. While she testified that she had personal interactions with K.B.2, she only filled his prescriptions for morphine sulfate and Valium on June 10, 2014, and a prescription for Valium on January 29, 2015. Tr. 660; GE-18, at 41-44, 85-86.

Nothing in GE-1 8 resolves the numerous red flags raised by the prescriptions written for K.B.2, contained in GE-18. Tr. 164-66. Accordingly, the Pharmacy did not fulfill its corresponding duty to ensure that the prescriptions written for K.B.2, contained in GE-18, were issued for a legitimate medical purpose, and the Pharmacy did not dispense them within the

normal course of professional practice. Tr. 157-58; FF 123-26.[48]

Finally, the Government alleges that from December 20, 2013, through January 24, 2015, the Pharmacy filled, on a monthly basis, prescriptions for hydromorphone and oxycodone for customer A.G. without resolving the following red flags: (1) the prescriptions were for well-known highly diverted/abused controlled substances; (2) the prescriptions were for two immediate-release opioids that evidenced therapeutic duplication; (3) A.G. travelled an unusual path and distance to obtain the prescriptions and have them filled; (4) A.G. sought to pay for the prescriptions in cash; and (5) the prescriptions were issued in a manner that permitted A.G. to obtain more oxycodone than was medically prescribed. ALJ-1, at 7-8, para. 10(p).

The prescriptions the Pharmacy filled for A.G. raise numerous red flags. First, the distance from the prescribing physician's office in Orlando, Florida, to A.G.'s residence in Indian Harbor, Florida, is 65 miles. FF 127. Additionally, A.G. paid cash for his prescriptions. FF 128. Furthermore, Dr. Gordon indicated that the Pharmacy consistently filled prescriptions for two immediate release opioids, oxycodone and hydromorphone, which raises concern. FF 128. The Pharmacy filled early refills for A.G. for oxycodone in such a way that enabled A.G. to receive ten tablets of oxycodone over what had been prescribed each time the prescription was filled. FF 129. This should have raised significant concern by of the Pharmacy because by January 23, 2015, A.G. had refilled the oxycodone prescription early 11 times, and had received an extra 110

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48 *See supra* notes 45 and 47.

tablets of oxycodone 30 mg than had been prescribed to him. FF 129.

Additionally, the prescribing physician did her residency in OB-GYN, and A.G. is a male. FF 128. Dr. Gordon indicated that under the acceptable standards of practice for a pharmacy, a pharmacist should look up a physician's credentials. Tr. 168. Accordingly, the fact that the prescribing physician did her residency in OB-GYN was a red flag that the Pharmacy should have resolved. *See Jones Total Health Care Pharmacy, L.L.C., and SND Health Care, L.L.C.*, 81 Fed. Reg. 79188, 79192 (2016) ("[E]ven assuming that in Florida, a physician is not prohibited from prescribing a particular drug regardless of the area in which he/she specializes, certainly when physicians issue prescriptions for large quantities of highly abused controlled substances which as oxycodone 30 . . . and these drugs are not usually prescribed by physicians with a particular specialty, there is a compelling reason to question the legitimacy of the prescription.").

Dr. Clark testified that she recalled interacting with A.G., but she only filled two prescriptions for A.G., both on February 21, 2014 Tr. 665; GE-19, at 9-12. She also testified, however, that she could not recall if she had filled any prescriptions for A.G. at all. Tr. 666-67. Because A.G.'s prescribing physician was out of county, the Pharmacy required a letter of medical necessity. Tr. 666. The letter of medical necessity for A.G. is dated March 21, 2014. Tr. 667; GE-19, at 70; RE-H, at 407. The letter of medical necessity provides a diagnosis of "herniated lumbar IVD," that A.G. has been a monthly patient since May 2009, that A.G.'s last MRI was in 2011, and that it was "medically necessary for the patient to use this medication." GE-19, at

70; RE-H, at 407. The letter of medical necessity, however, does not state what medication it was necessary that A.G. use. GE-19, at 70; RE-H, at 407.

Even Dr. Grant testified he would have had a discussion about repeatedly filling a prescription early, where one prescription for 30 days and another was for 28 days and the patient always came in to fill on the 28th day. Tr. 509-11. He also acknowledged that a pharmacist exercising reasonable care would have that conversation. Tr. 511. There are no such discussions documented in the patient file for A.G.

Nothing in GE-19 resolves the numerous red flags raised by the prescriptions written for A.G., contained in GE-19. Tr. 168-69. Accordingly, the Pharmacy did not fulfill its corresponding duty to ensure that the prescriptions written for A.G., contained in GE-19, were issued for a legitimate medical purpose, and the Pharmacy did not dispense them within the normal course of professional practice. Tr. 169; FF 127-130.

Accordingly, the Government's allegations that the Pharmacy violated its corresponding responsibility by filling the prescriptions contained in GE-7 and GE-15-19 to C.A., D.B., J.D., K.B.3, K.B.2, and A.G. are SUSTAINED and weigh in favor of revocation of the Pharmacy's DEA registration.

4. K.B.1 & C.K.

The Government alleges that the Pharmacy violated its corresponding responsibility under 21 C.F.R. § 1306.04(a), Fla. Stat. § 893.04, and Fla. Admin. Code r. 64B16-27.800 and r. 64B16-27.810 by dispensing oxycodone to customers K.B.1 and C.K. The Government

argues that the Pharmacy filled prescriptions to K.B.1 and C.K. without resolving the following red flags: (1) both customers travelled an unusual path and distance to obtain the prescriptions and have them filled; (2) these prescriptions were for well-known highly diverted /abused controlled substances; (3) though K.B.1 and C.K. lived 28 miles from each other, they obtained their similar prescriptions from the same doctor on the same date and filled their prescriptions at about the same time; (4) both customers sought to pay cash for their prescriptions. ALJ-1, at 8, para. 10(q).

The prescriptions the Pharmacy filled for K.B.1 and C.K. raise numerous red flags. First, while their prescriptions did not contain home addresses, the fill stickers indicate that K.B.1's address is in Malabar, Florida, and C.K.'s address is in Cocoa Beach, Florida. The prescribing physician's office is located in Orlando, Florida, which is 73 miles from Malabar, and 51 miles to Cocoa Beach. FF 131. Additionally, all of the prescriptions were purchased with cash. FF 132. Additionally, as previously discussed, the prescribing physician did her residency in OB-GYN. FF 132. Significantly, most of the prescriptions written to these patients were for the highest available dosage of oxycodone. FF 132. Additionally, in Dr. Gordon's opinion, these patients presented as a "group" because they went to the same physician on the same day, obtained similar prescriptions, which the Pharmacy frequently filled at the same time. FF 132. Between April 1, 2014 and March 31, 2015, the Pharmacy had filled oxycodone prescriptions for these two individuals on the same day 14 times. FF 132.

Dr. Clark testified that she has seen these two customers together in the Pharmacy, but she does not

know their relationship. Tr. 671. C.K. and K.B.1 are long-time Pharmacy customers. Tr. 672. Dr. Clark filled prescriptions for C.K. and K.B.1, with prescription numbers only one digit and one minute apart each time, on May 28, 2014 and on November 11, 2014. GE-20, at 7-8, 19-20, 41-42, 53-54: RE-H, at 426. Dr. Clark testified that she resolved the red flag of these to customers coming in together by handling them individually, having proper documentation for each, and having a conversation with each. Tr. 671-72. At the hearing, however, Dr. Clark could give no reason why these two customers were presenting together. Tr. 671. In Dr. Clark's opinion, the letter of medical necessity for C.K., and the "corresponding documentation" resolved any red flags prior to filling the prescriptions for C.K. Tr. 676.

While the Respondent erroneously argued that the Government had not presented any evidence that K.B.1 and C.K. were visiting the Pharmacy as a group, the Respondent did. ALJ-36, at 34; RE-H, at 426. Without question, the pharmacist who filled the prescriptions for K.B.1 and C.K. had to have known that they saw the same doctor in Orlando on the same day, that they were receiving the same controlled substance and essentially the same dosage, that they had different addresses, and that they were presenting to the Pharmacy at about the same time to get their prescriptions of oxycodone filled.

Although GE-20 contains letters from K.B.1 and C.K.'s prescribing doctor, those documents do not resolve any of the red flags. Tr. 174-75; GE-20, at 66, 68. These documents do not explain why the patients were paying cash or why they were traveling together a long distance to obtain similar prescriptions for an

opioid. Tr. 174; GE-20, at 66, 68. Nothing in GE-20 resolves the numerous red flags raised by the prescriptions contained in GE-20 concerning K.B.1 or C.K. Tr. 174-75. Therefore, the Pharmacy did not fulfill its corresponding duty to ensure that the prescriptions contained in GE-20 were issued for a legitimate medical purpose, and the Pharmacy did not dispense them within the normal course of professional practice. Tr. 175-76; FF 131-35.

Accordingly, the Government's allegations that the Pharmacy violated its corresponding responsibility by filling the prescriptions contained in GE-20 to K.B.1 and C.K. are SUSTAINED and weigh in favor of revocation of the Pharmacy's DEA registration.

5. J.M. & M.M.

The Government alleges that the Pharmacy violated its corresponding responsibility under 21 C.F.R. § 1306.04(a), Fla. Stat. § 893.04, and Fla. Admin. Code r. 64B16-27.800 and r. 64B16-27.810 by dispensing oxycodone to customers J.M. and M.M. The Government argues that the Pharmacy filled prescriptions to J.M. and M.M. without resolving the following red flags: (1) the prescriptions were for well-known highly diverted/abused controlled substances; (2) both customers travelled an unusual path and distance to obtain the prescriptions and have them filled; (3) both customers obtained their prescriptions from the same physician, usually on the same day at the same time, and filled their prescriptions at the Pharmacy usually on the same day at the same time; (4) M.M. always sought to pay cash for the prescriptions and J.M. occasionally sought to pay cash; and (5) on eight different occasions, both customers presented prescriptions for

highly abused prescription drug cocktails. ALJ-1, at 8, para. 10(r).

The prescriptions the Pharmacy filled for J.M. and M.M., contained in GE-21, raise numerous red flags. First, while the prescriptions for these patients do not contain an address, the fill stickers list their addresses as being in Satellite Beach, Florida, which is approximately 65 miles from their prescribing physician. FF 136. Additionally, the patients sometimes sought to pay for their prescriptions in cash. FF 137. The prescribing physician is the same OB-GYN that prescribed to K.B.1, C.K., and A.G, and both J.M. and M.M. are male. FF 137.

Significantly, in Dr. Gordon's opinion, these patients presented as a "group" because they went to the same physician, on the same day, obtained similar prescriptions, sometimes for drug cocktails, which the Pharmacy frequently filled at the same time. FF 137, 140. In fact, the Pharmacy filled prescriptions for J.M. and M.M. on the same day 15 times between January 7, 2014 and March 31, 2015. FF 138. Furthermore, in Dr. Gordon's opinion, many of the prescriptions filled by the Pharmacy constituted drug cocktails. FF 140.

Dr. Clark testified that J.M. and M.M. are long-time customers of the Pharmacy and came to the Pharmacy together and that she knows them well. Tr. 677. J.M. and M.M. see the same doctor in Orlando.[49] Tr. 680; GE-21, at 145, 147. Dr. Clark also testified that she had a conversation with M.M.'s prescribing

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[49] Dr. Clark's testified about why J.M. and M.M. saw the same doctor in Orlando. Tr. 680. That testimony is hearsay. Because there is no indicium of reliability for that testimony, it is given no weight. Further, the reason was not documented.

physician and it resolved her concerns of M.M. traveling to Orlando to see the doctor. Tr. 681. There, however, is nothing in M.M.'s file that documents that conversation. GE-21; RE-H, at 485-527.

While the Respondent erroneously argued that the Government had not presented any evidence that J.M. and M.M. were visiting the Pharmacy as a group, the Respondent did. ALJ-36, at 36; RE-H, at 484, 527. Clearly the pharmacist filling the prescriptions for J.M. and M.M. had to have known that they saw the same doctor in Orlando on the same day, that they were receiving the same controlled substance, that they had different addresses, and that they were presenting to the Pharmacy at about the same time to get their prescriptions of oxycodone filled.

Although GE-21 contains letters from J.M. and M.M.'s prescribing doctor, and some medical records pertaining to them, those documents do not resolve any of the red flags raised by the prescriptions. Tr. 181-83; GE-21, at 143-50. These documents do not explain why the patients were paying cash, why they were traveling together a long distance to obtain similar prescriptions for an opioid, or why they were in need of a drug cocktail. GE-21, at 143-50.

The Pharmacy did not fulfill its corresponding duty to ensure that the prescriptions contained in GE-21 were issued for a legitimate medical purpose, and the Pharmacy did not dispense them within the normal course of professional practice. Tr. 183-84; FF 136-43. Accordingly, the Government's allegations that the Pharmacy violated its corresponding responsibility by filling the prescriptions contained in GE-21 to J.M. and M.M. are SUSTAINED and weigh in favor of revocation of the Pharmacy's DEA registration.

6. H.B.

Finally, the Government argues that the Pharmacy violated its corresponding responsibility under 21 C.F.R. § 1306.04(a), Fla. Stat. § 893.04, and Fla. Admin. Code r. 64B16-27.800 and r. 64E16-27.810 by dispensing oxycodone, Adderall, alprazolam, clonazepam, Carisoprodol, and zolpidem to customer H.B. The Government argues that the Pharmacy filled prescriptions to H.B. without resolving the following red flags: (1) the prescriptions were for well-known highly diverted/abused controlled substances; (2) H.B. travelled an unusual path and distance to obtain the prescriptions and have them filled; (3) H.B. frequently sought to pay for the prescriptions in cash; (4) H.B. frequently received early refills of medication; (5) in January 2015, H.B. obtained twice the amount of oxycodone as she had received the moth before[50]; (6) H.B. presented prescriptions constituting therapeutic duplication; and (7) H.B. presented combinations of prescriptions constituting highly abused prescription drug cocktails. ALJ-1, at 8-9, para. 10(s).

There were several red flags raised by the prescriptions the Pharmacy filled for H.B., contained in GE-22. First, H.B. lives about 54 miles from his prescribing physicians. FF 144. Additionally, the types of medications prescribed to H.B. raise significant red flags. Specifically, H.B. was prescribed both "uppers" and "downers," which, accordingly to Dr. Gordon, have contradicting effects on the patient. FF 145-146. Additionally, H.B. sought multiple early refills from the

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[50] I find no support for this red flag. H.B. received 116 tablets of oxycodone 20 m.g. in December 2014, and only 4 more tablets in January 2015. *Compare* GE-22, at 96-99, *with* GE-22, at 107-108.

Pharmacy, which should have raised a red flag. FF 147. Furthermore, GE-22 contains evidence of three different drug cocktails that the Pharmacy filled for H.B. FF 148.

Dr. Clark testified that she knows H.B. well, and she has had interaction with H.B. concerning her medical condition and treatment. Tr. 682, 755. Dr. Clark, however, only filled prescriptions for H.B. on three different days, spread out over five months. GE-22, at 41-42, 49-52, 71-74. While Dr. Clark did not consider it an issue that H.B. was receiving both Adderall from one doctor and pain management medications for another doctor, the only prescriptions Dr. Clark filled for H.B. was for oxycodone. Tr. 687; GE-22, at 41-42, 49-52, 71-74. Dr. Clark testified that based on her conversations with H.B. she knew that the two doctors were aware of the different prescriptions. Tr. 688. Nothing in HB's file, however, documents those discussions.[51]

Although GE-22, contains letters from two of H.B.'s prescribing doctors, those documents do not resolve any of the red flags. Tr. 189-90; GE-22, at 123-25. For example, these documents do not explain: why H.B. was traveling a long distance to obtain prescriptions for an opioid; why it was necessary for H.B. to use drug cocktails or prescriptions for two different strengths of oxycodone; why H.B. obtained early refills; or whether

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[51] Assuming Dr. Clark discussed this matter with H.B., it would appear that she was aware that it was a red flag to have H.B. receiving controlled substances from two different doctors, where the two substances created a drug cocktail. Nevertheless, Dr. Clark did not document this discussion. *But see infra* note 52.

the two doctors were aware of the other doctor's prescriptions for H.B. Further, there is no indication in the record that the Respondent ever contacted any of H.B.'s doctors to determine if they were aware that she was obtaining prescriptions from other doctors, which would be normal practice of a pharmacy. Tr. 189. Dr. Clark testified that she talked to H.B. about whether her doctors were aware of what the other doctor was prescribing.[52] Tr. 688.

The Pharmacy did not fulfill its corresponding duty to ensure that the prescriptions contained in GE-22 were issued for a legitimate medical purpose, and the Pharmacy did not dispense them within the normal course of professional practice. Tr. 191; FF 144-49. Accordingly, the Government's allegation that the Pharmacy violated its corresponding responsibility by filling the prescriptions contained in GE-22 to H.B. is SUSTAINED and weighs in favor of revocation of the Pharmacy's DEA registration.

DISCUSSION AND CONCLUSIONS OF LAW

Although I have not sustained the Government's allegations regarding the "office prescriptions," I find that the Pharmacy violated its corresponding responsibility on numerous occasions by dispensing controlled substances outside the normal course of professional practice. Significantly, the Pharmacy dispensed highly abused controlled substances to many of its

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[52] I do not find this testimony credible. Dr. Clark did not fill a prescription for H.B. until May 8, 2014, and only two dates after that. GE-22, at 41-42, 49-52, 71-74. More important, the only prescriptions Dr. Clark filled for H.B. were those written by Dr. Skolnik. *Id.* Further, nothing on H.B. profile would have alerted Dr. Clark to the fact that H.B. was seeing multiple doctors.

customers without resolving numerous red flags raised by the prescriptions. First, the Pharmacy dispensed controlled substances to J.S.3, a doctor who wrote the prescription for himself, in violation of Florida law. The Pharmacy also dispensed oxycodone and hydromorphone to a group of five customers (S.P., A.J., J.S.1, D.G., and E.H.). All of these customers appeared to be travelling extremely long distances, in groups, from their physician, Dr. Richard, in Miami, Florida, to the Pharmacy. Next, I find that the Pharmacy violated its corresponding responsibility by dispensing controlled substances to five other patients of Dr. Richard's (J.S.1, J.S.2, C.C., P.P., K.P.) without resolving similar red flags such as the type of controlled substance, distance travelled, customers seeking to pay cash, and customers travelling in groups to obtain their prescriptions and have the filled on the same day.

Additionally, I find that the Pharmacy violated its corresponding responsibility by filling questionable prescriptions by other physicians without resolving red flags raised by the prescriptions. I find the prescriptions the Pharmacy filled for J.C. particularly troubling. The Pharmacy dispensed large quantities of oxycodone, Oxymorphone, morphine, fentanyl, and diazepam to J.C. The Pharmacy even filled five prescriptions of short-acting oxycodone on multiple occasions for J.C. Tr. 115, 833; FF 100. The Pharmacy also provided J.C. with drug cocktails, all without resolving the red flags raised by the prescriptions. FF 101.

Similarly, I find that the Pharmacy filled numerous prescriptions for patients, such as M.B., D.B., J.D. which constituted "drug cocktails." FF 106, 113, 117. The Pharmacy also filled these prescriptions in light

of red flags, such as, prescriptions written for the highest dosage available, distance travelled, customers paying with cash, and customers presenting with early refills. The Pharmacy also filled prescriptions for C.A., K.B.2, and K.B.3 that all raised similar red flags.

I find the prescriptions written for A.G. were also of significant concern. Specifically, the Pharmacy consistently filled prescriptions presented by A.G. for oxycodone, which enabled A.G. to receive, over 11 occasions, a total of 110 extra tablets of oxycodone 30 mg than what had been prescribed. FF 129. Additionally, the Pharmacy filled prescriptions for A.G., as well as for customers K.B.1, C.K., J.M., and M.M., that were written by a physician who completed her residency in OB-GYN, although all but one of these patients were male. The Pharmacy did not resolve any of these red flags prior to filling the prescriptions.

I also find that the Pharmacy filled prescriptions to additional groups of patients, which raised significant red flags. Specifically, the Pharmacy frequently filled prescriptions for K.B.1 and C.K., who travelled a long distance to see the same physician on the same day, obtain similar prescriptions for the highest dosage available of oxycodone, and had them filled on the same day by the Pharmacy. FF 131-33. The prescriptions the Pharmacy filled for J.M. and M.M. raised similar red flags. J.M. and M.M. also travelled long distances to see the same physician on the same day, and have these prescriptions filled by the Pharmacy on the same day. FF 137-39. Additionally, the Pharmacy filled numerous of J.M. and M.M.'s prescriptions for highly abused prescription drug cocktails. FF 140.

Finally, I find the Pharmacy's actions regarding H.B. egregious. The Pharmacy filled prescriptions for H.B. that had contradictory effects on the human body. FF 144-46. Additionally, the Pharmacy filled many early refills that H.B. presented. FF 147.

Accordingly, I find that there is sufficient evidence in the Administrative Record to establish that the Pharmacy has violated its corresponding responsibility. Specifically, the Pharmacy repeatedly filled numerous prescriptions for highly abused and diverted controlled substances in the face of blatant red flags. The Pharmacy did little to nothing to resolve these numerous red flags, but instead relied on "rubber stamped" types of letters of medical necessity that were often not tailored towards a particular patient, and were obviously missing information. While it is not the responsibility of a pharmacist to practice medicine, the pharmacist does have a corresponding responsibility to ensure that prescriptions are written within the scope of medical practice. *See United States v. Hayes*, 595 F.2d 258, 261 (5th Cir. 1979) ("The pharmacist is not required to have a 'corresponding responsibility' to practice medicine. What is required of him is the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute because he knows that the issuing practitioner issued it outside the scope of medical practice."). The numerous unresolved red flags identified in this case are sufficient circumstantial evidence to establish that these prescriptions were not written for a legitimate medial purpose. *See Hills Pharmacy, LLC*, 81 Fed. Reg. 49816, 49836 n.33 (2016).

Further, while nothing in the DEA regulations specifically requires a pharmacist to document the

resolution of a red flag, Florida laws specifically require that a pharmacist maintain records that include discussions with licensed health care practitioners and information about a patient's drug therapy and information peculiar to a specific patient. In light of these requirements, the absence of such documentation is circumstantial evidence that those requirements were not met. Certainly, the pharmacist filling a follow-up prescription would have nothing in the patient's file to show that red flags had been resolved. In short, it was not documented; therefore, it was not done.[53]

Accordingly, Factors Two and Four strongly weigh in favor of revoking the Pharmacy's COR. Considering the public interest factors in their totality, I find that the Government has made *a prima facie* case showing that the Pharmacy's registration would be inconsistent with the public interest

After the Government presents *a prima facie* case for revocation, the Respondent has the burden of production to present "sufficient mitigating evidence" to show why he can be entrusted with a DEA registration. *See Medicine Shoppe—Jonesborough*, 73 Fed. Reg. 364, 387 (2008) (quoting *Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. 23848, 23853 (2007)). To rebut the Government's *prima facie* case, the Respondent must both accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *Patrick W. Stodola, MD.*, 74 Fed. Reg. 20727, 20734-35 (2009).

The Respondent may accept responsibility by providing evidence of his remorse, his efforts at rehabilitation, and his recognition of the severity of his

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[53] I adopt the position of Dr. Gordon, the Government's expert. She testified, "if it's not documented, it didn't happen. Tr. 211.

misconduct. *See Robert A. Leslie, MD.*, 68 Fed. Reg. 15227, 15228 (2003). To accept responsibility, a respondent must show "true remorse" for wrongful conduct. *Michael S. Moore, MD.*, 76 Fed. Reg. 45867, 45877 (2011). An expression of remorse includes acknowledgment of wrongdoing. *See Wesley G. Harline, MD.*, 65 Fed. Reg. 5665, 5671 (2000). A respondent must express remorse for all acts of documented misconduct, *Jeffrey Patrick Gunderson, MD.*, 61 Fed. Reg. 26208, 26211 (1996), and may be required to acknowledge the scope of his misconduct, *Arvinder Singh, MD.*, 81 Fed. Reg. 8247, 8250-51 (2016). Acceptance of responsibility and remedial measures are assessed in the context of the "egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others." *David A. Ruben, M.D.*, 78 Fed. Reg. 38363, 38364 (2013) (citation omitted).

There is nothing in the Administrative Record that suggests the Respondents, through their owner Dr. Clark, have accepted responsibility for their actions. During the hearing, Respondents' counsel, Mr. Chapman, made it clear on numerous occasions that his clients had not accepted responsibility and were not offering any evidence of remedial actions of the Pharmacy. For example, when I asked Mr. Chapman during the hearing if he was introducing evidence for remedial purposes, he indicated: "I won't be discussing anything done in remediation as a result of this case unless I specifically say that." Tr. 548. Mr. Chapman then went on to clarify: "Everything I've referred to and will refer to is related to things that were in place during the time of the allegations or sometime just prior to." Tr. 548. Then, later on during the hearing, when

replying to an objection raised by Government counsel, Mr. Chapman indicated: "I'm well aware that I can't go into remediation unless we were to accept responsibility, Your Honor. And we won't unless we do." Tr. 567. At no point throughout the rest of the hearing did the Respondents indicate that they were accepting responsibility. Furthermore, nothing in the Respondents' Post-Hearing Brief indicates that the Respondents have accepted responsibility for any of the allegations against them. *See* ALJ-36.

Since I have determined that the Government has met its *prima facie* burden, and that the Respondents have not accepted responsibility, I must next determine whether it is consistent with the public interest for the Pharmacy to maintain its DEA registration. When considering whether a registrant's continued registration is consistent with the public interest, the ALJ must consider both the egregiousness of the registrant's violations and the DEA's interest in deterring future misconduct by both the registrant as well as other registrants. *Ruben*, 78 Fed. Reg. at 38364; *see also Richard J. Settles, D.O.*, 81 Fed. Reg. 64940, 64945 n.17 (2016) ("In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct" (quoting *Jayam Krishna-Iyer, MD.*, 74 Fed. Reg. 459, 462 (2009)).

Here, I find that the misconduct proven in the Administrative Record is egregious and supports the revocation of the Pharmacy's registration. Specifically, pharmacists employed by the Pharmacy, as well as Dr.

Clark, dispensed numerous prescriptions of controlled substances in violation of their corresponding responsibility. I further find that the DEA's interest in deterring future misconduct by the Pharmacy, as well as by other pharmacies, supports revocation of the Pharmacy's registration.

Relationship Between the Pharmacy and Suntree Medical

The Respondents accurately argue that the OSC did not list a single violation against Suntree Medical. ALJ-36, at 77. Further, the Respondents argue that "the Government failed to present any evidence, statute, or rule suggesting that revocation of Suntree Medical Equipment's registration is appropriate simply because both companies share common ownership." ALJ-36, at 77. Thus, the Respondents argue, the allegations against Suntree Medical should be dismissed because they are not supported by the evidence. ALJ-36, at 77. The Respondents' arguments ignore the obvious, that the Pharmacy and Suntree Medical are essentially one and the same. *See* FF 150-60.

The DEA treats "two separately organized business entities as one integrated enterprise . . . based on the overlap of ownership, management, and operations of the two entities." *Jones Total Health Care Pharmacy, L.L.C., and SND Health Care, L.L.C.*, 81 Fed. Reg. 79188, 79222 (2016) (citing *MB Wholesale, Inc.*, 72 Fed. Reg. 71956, 71958 (2007)). In this case the evidence clearly established that there is an overlap in ownership, management, and operations.

In terms of ownership, it is clear from the record that Dr. Clark owns both entities. FF 150. Further, Dr. Clark is listed with the Florida Department of

Health as the supervising practitioner for Suntree Pharmacy, and its sole Officer/Director (President) with the Florida Department of State, Division of Corporations. Stip. 4. Similarly, Dr. Clark is listed with those same Florida offices as the supervising practitioner for Suntree Medical Equipment, LLC, and as its sole Officer/Director (Manager). Stip. 6.

As the supervising practitioner of both the Pharmacy and Suntree Medical, which are co-located, Dr. Clark is normally in the building when it is open. FF 152. Thus, she would be available to provide almost constant management and supervision of both the Pharmacy and Suntree Medical. Dr. Clark is assisted in managing both businesses by Mr. Peterson. FF 154-59. While Peterson testified that he works for Suntree Medical, he does extensive work for the Pharmacy, considered Dr. Clark his boss, and during the last two quarters of 2016, he was listed as the only employee of Suntree Medical. FF 154-59. Peterson engages in "managing, marketing, and developing the Pharmacy" as well as handing its human resources, discipline, interviewing and payroll. FF 155, 158. Similarly, Peterson described himself as the manager of Suntree Medical, where his duties include: business development, marketing, sales, human resources, ordering medical equipment, and the oversight of the day-to-day operations. FF 154. When Peterson was presented a Notice of Inspection for the Pharmacy in September 2013, he signed the notice, writing the title "manager" as his position. FF 156. Peterson also turned over the Pharmacy's records to the DEA following the September 2013 inspection. FF 157.

As far as operations go, the Pharmacy and Suntree Medical share office spaces, as well as managers—Dr.

Clark and Peterson. FF 150-52, 154-55; *see also* GE-30, at 2 (a photo depicting the entrance). The attorney for the Pharmacy and Suntree Medical testified that he considered the Pharmacy and Suntree Medical to be "one client." FF 160.

Because of the obvious commonality of ownership, management and operations, it is abundantly clear that if the Pharmacy's COR. was revoked, but Suntree Medical was allowed to keep its COR, Suntree Medical could pick up where the Pharmacy left off without missing a beat. Accordingly, due to that commonality, it is appropriate to treat the Pharmacy and Suntree Medical as one integrated enterprise.

RECOMMENDATION

In this case, the Government has established a *prima facie* case for revocation of the Pharmacy's Certificate of Registration. It did so by demonstrating that the Pharmacy repeatedly violated its corresponding responsibility between October 2013 and March 2015 by filling prescriptions that contained red flags of diversion and/or abuse, without addressing or resolving those red flags. Further, those red flags were so flagrant that they established by circumstantial evidence that the prescriptions were not issued for a legitimate medical purpose by a doctor acting in the usual course of the doctor's professional practice. The red flags were also so flagrant as to put the pharmacists who filled the prescriptions on notice that the prescriptions lacked a legitimate medical purpose. Time after time, however, pharmacists who worked at the Pharmacy filled the prescriptions without resolving those red flags.

The evidence is clear in this case that the Pharmacy has taken no responsibility for its egregious and repeated failure to fulfill its corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances. The evidence is clear because the Pharmacy has specifically denied responsibility.

There has been no allegation, or evidence presented, that Suntree Medical violated any portion of the Controlled Substances Act, or any of its implementing regulations. Because of a commonality in ownership, management, and operations of the Pharmacy and Suntree Medical, however, they are considered to be one enterprise.

Therefore based upon my review of the entire Administrative Record, I recommend that the Certificate of Registration of Suntree Pharmacy, COR number BS7384174, and that the Certificate of Registration of Suntree Medical Equipment LLC, COR number FS2194289, be REVOKED. I further recommend that any pending application for renewal of modification of these Certificates of Registration be DENIED.

/s/ Charles Wm. Dorman
U.S. Administrative Law Judge

Dated: August 15, 2017

ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT DENYING PETITION FOR REHEARING EN BANC (MAY 5, 2022)

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

SUNTREE PHARMACY AND
SUNTREE MEDICAL EQUIPMENT, LLC,

Petitioner,

v.

DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

No. 20-14626-DD

Petition for Review of a Decision
of the Drug Enforcement Agency

Before: NEWSOM, LUCK, and ANDERSON,
Circuit Judges.

PER CURIAM:

The Petition for Rehearing En Banc is DENIED, no judge in regular active service on the Court having requested that the Court be polled on rehearing en banc. (FRAP 35) The Petition for Panel Rehearing is also denied. (FRAP 40)

REGULATORY AND STATUTORY PROVISIONS INVOLVED

21 C.F.R. § 1306.04
Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the

Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in § 1301.28 of this chapter.

(d) A prescription may be issued by a qualifying practitioner, as defined in section 303(g)(2)G)(iii) of the Act (21 U.S.C. 823(g)(2)(G)(iii), in accordance with § 1306.05 for a Schedule III, IV, or V controlled substance for the purpose of maintenance or detoxification treatment for the purposes of administration in accordance with section 309A of the Act (21 U.S.C. 829a) and § 1306.07(f). Such prescription issued by a qualifying practitioner shall not be used to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients.

21 U.S.C. § 824
Denial, revocation, or suspension of registration

(a) Grounds

A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II;

(2) has been convicted of a felony under this subchapter or subchapter II or any other

law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of title 42.

A registration pursuant to section 823(g)(1) of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(g)(1) of this title.

(b) Limits of revocation or suspension

The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

(c) Service of show cause order; proceedings

(1) Before taking action pursuant to this section, or pursuant to a denial of registration under section 823 of this title, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended.

(2) An order to show cause under paragraph (1) shall—

(A) contain a statement of the basis for the denial, revocation, or suspension, including specific citations to any laws or regulations alleged to be violated by the applicant or registrant;

(B) direct the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but not less than 30 days after the date of receipt of the order; and

(C) notify the applicant or registrant of the opportunity to submit a corrective action plan on or before the date of appearance.

(3) Upon review of any corrective action plan submitted by an applicant or registrant pursuant to paragraph (2), the Attorney General shall determine whether denial, revocation, or suspension proceedings should be discontinued, or deferred for the purposes of modification, amendment, or clarification to such plan.

(4) Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in

accordance with subchapter II of chapter 5 of title 5. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter or any other law of the United States.

(5) The requirements of this subsection shall not apply to the issuance of an immediate suspension order under subsection (d).

(d) Suspension of registration in cases of imminent danger

(1) The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in section 823(g)(1) of this title may be treated under this subsection as grounds for immediate suspension of a registration granted under such section. A suspension under this subsection shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

(2) In this subsection, the phrase "imminent danger to the public health or safety" means that, due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under this subchapter or

subchapter II, there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration.

(e) Suspension and revocation of quotas

The suspension or revocation of a registration under this section shall operate to suspend or revoke any quota applicable under section 826 of this title.

(f) Disposition of controlled substances or list I chemicals

In the event the Attorney General suspends or revokes a registration granted under section 823 of this title, all controlled substances or list I chemicals owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be placed under seal. No disposition may be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded except that a court, upon application therefor, may at any time order the sale of perishable controlled substances or list I chemicals. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances or list I chemicals (or proceeds of sale deposited in court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled

substances or list I chemicals in accordance with section 881(e) of this title. All right, title, and interest in such controlled substances or list I chemicals shall vest in the United States upon a revocation order becoming final.

(g) Seizure or placement under seal of controlled substances or list I chemicals

The Attorney General may, in his discretion, seize or place under seal any controlled substances or list I chemicals owned or possessed by a registrant whose registration has expired or who has ceased to practice or do business in the manner contemplated by his registration. Such controlled substances or list I chemicals shall be held for the benefit of the registrant, or his successor in interest. The Attorney General shall notify a registrant, or his successor in interest, who has any controlled substance or list I chemical seized or placed under seal of the procedures to be followed to secure the return of the controlled substance or list I chemical and the conditions under which it will be returned. The Attorney General may not dispose of any controlled substance or list I chemical seized or placed under seal under this subsection until the expiration of one hundred and eighty days from the date such substance or chemical was seized or placed under seal.

(h) Order to prohibit registration based on prior history

The Attorney General may issue an order to prohibit, conditionally or unconditionally, and permanently or for such period as the Attorney

General may determine, any person from being registered under this subchapter to manufacture, distribute, or dispense a controlled substance or a list I chemical, if the Attorney General finds that—

(1) such person meets or has met any of the conditions for suspension or revocation of registration under subsection (a); and

(2) such person has a history of prior suspensions or revocations of registration.