United States Court of Appeals FOR THE DISTRICT OF COLUMBIA CIRCUIT

Norman Clement,

Case: No. 21-1262

Petitioner

v.

Drug Enforcement Administration,

Respondent

PETITIONER'S DISPOSITIVE MOTION TO VACATE ADMINISTRATIVE JUDGES FINDINGS AND DEA ADMINISTER'S ORDERS, RESTORE CSA REGISTRATION of PRONTO PHARMACY LLC AN AWARD DAMAGES, AMEND INDEX OF RECORD

Pursuant to the Court's Order of December 20, 2021 and D.C. Circuit Rule 30 (c), Petitioners Norman Clement pro-se in Case No. 21-1262 files this Dispositive Motion and Amend Petitioner's Certified Index Record to include blog youarewithinthenorms.com, hereby states,

STATEMENT

The decision in this case will have far-reaching deleterious effects on the professions of Medicine, Nursing and other Mid-Level Practitioners and Pharmacists.

After reading the TRIAL TRANSCRIPT and ALJ DECISION many glaring errors became apparent. This document is intended to enlighten the court as to the true nature of the STANDARD of CARE as it pertains to the practice of PHARMACY.

The practice of Pharmacy has many traditional and emerging roles and a one size fits all standard cannot apply. The proof of this is that certain facets are known as retail establishments, institutional establishments, healthcare organizations and others. Within these broad categories there are subdivisions.

ARGUMENT

The Controlled Substances Act (CSA) and its implementing regulations established a closed system of distribution to ensure appropriate medical care and to maintain the integrity of the system through an accountability process.

One of the most important principles underlying the CSA and its implementing regulations is that to be valid, every prescription for a controlled substance must be based on a determination by an individual practitioner, that the dispensing of the controlled substance is for a

legitimate medical purpose in the usual course of professional practice. *United States v. Moore*, 423 U.S.C. 122 (1975) and 21 CFR 1306.04(a).

Federal regulations do not define the term legitimate medical purpose nor do they set forth the standards of medical practice. It is up to each DEA-registered practitioner authorized by DEA to do so, to treat patients according to his or her professional medical judgement in accordance with a standard of medical practice that is generally recognized and accepted in the United States.

DEA has not promulgated any new regulations regarding the treatment of pain. Federal law and DEA regulations do not impose a specific quantitative minimum or maximum limit on the amount of medication that a practitioner may prescribe on a single prescription, or the duration of treatment intended for a particular patient.

What is clear here is that Pronto Pharmacy is acting as a specialty pharmacy which specializes in pain management as well as non-sterile compounding.

Since DEA expert, Dr. Sullivan seems not to have any experience in pain management nor non-sterile compounding it is understandable that he does not grasp of the fine nuances in these fields. Since THE PETITIONER has experience in the fields listed above the following is submitted to enlighten the court.

REFLECTING THE DISTINCT ROLES OF PRESCRIBERS AND PHARMACIST, § 1306.04 IMPOSES LIABILITY ONLY ON PHARMACIST WHO "knowingly" fill an illegitimate prescription.

Although § 1306.04(a) regulates both prescribers and pharmacists, the two roles are far from inter- changeable, including for purposes of determining potential liability. With different licenses, education, skill sets, responsibilities, and workplaces from physicians, pharmacists play a vital but distinct role in a patient's care. (see Amicus Curiae Brief

National Association Chain Drug Stores, US Supreme Court Case No. 20-1410, *Ruan vs. United States of America*)

Specifically, when dispensing a controlled substance to a patient, as prescribed by a physician, a pharmacist relies on the physician's assessment of the patient's needs. The pharmacist has neither examined nor diagnosed the patient, and lacks the information the physician has collected on the patient's medical situation, records, and history, including such things as x-rays, ultrasounds, lab results, and treatment plans.

The CSA recognizes pharmacists' circumscribed role in dispensing controlled substances. It provides that pharmacists may not dispense Schedule II con- trolled substances "without the written prescription of a practitioner," 21 U.S.C. § 829(a), and that they risk criminal and civil liability if they do, see id. §§ 841(a), (c), 842.

The CSA's implementing regulations further explain that a prescription for a controlled substance "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 separately provide that such a prescription "may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed" by a registered entity. 21 C.F.R. § 1306.06.

Consistent with the division of responsibility be- tween prescribers and pharmacists, § 1306.04 limits when pharmacists may be held liable for filling controlled-substance prescriptions to situations where a pharmacist knows a prescription is illegitimate:

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corre- sponding 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 C.F.R. § 1306.04(a) (emphasis added). A pharmacist violates this provision only if the pharmacist "knowingly fill[s]" a "purported" prescription—i.e., a prescription that was not written "in the usual course of professional treatment."

These critical limitations on a pharmacist's possible liability under § 1306.04 are no accident. They were added to the regulation intentionally to avoid the un- warranted and counterproductive imposition of liabiity.

When first proposed in 1971, the regulation lacked the word "knowingly," which would have allowed penalties for any "person filling [an illegitimate] prescription." Purpose of Issue of Prescription, 36 Fed. Reg. 4847, 4948 (Mar. 13, 1971).

Pharmacists protested such an expansive rule, however, and during the comment period specifically "objected to the responsibility placed upon a pharmacist under § [1306.04] to determine the legitimacy of a prescription."

Comments and Objections to Part 306, 36 Fed. Reg. 7776, 7777 (Apr. 24, 1971).

The DEA agreed with these comments and changed the legal standard in the final regulations, noting the "language [was] revised to require knowledge."

DEA DISPLAYS LACK OF KNOWLEDGE AND OF IN THE PHARMACEUTICAL MEDICAL PRACTICE

The warrant issued identified Items that are evidence of violations of 21 U.S.C. §§ 841(a)(1) (possession with the intent to distribute and distribution of oxycodone and hydromorphone.

The intent of this law implies that it shall be unlawful for any person knowingly or intentionally— to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

The DEA use the law with intent to imply a licenses Pharmacist and medical professionals as a person that illegally distribute, or dispense, a controlled substances.

The DEA has deliberately reinterpreted the law to support their effort to attack Pharmacist, in essence the DEA willfully and knowingly misguided the courts that the petitioner a license pharmacist was in violations of 21 U.S.C. §§ 841(a)(1) (possession with the intent to distribute and distribution of oxycodone and hydromorphone. The officers should be charged under Giglio.

As a licensed pharmacist, the Petitioner carried out his fiduciary responsibility of Petitioner, Norman J Clement was acting in the capacity of a license's pharmacist. Whereby a Pharmacist is a person who is professionally qualified to prepare and dispense medicinal drug.

This definition and is a statue within the Florida Administrative Code & Florida Administrative Register. The officer acted upon an oath to enter

the premises to secure evidence of violations of 21 U.S.C. §§ 841(a)(1) (possession with the intent to distribute and distribution of oxycodone and hydromorphone.

The DEA agents removed files with the intent of searching to discover items to suggest a criminal act took place or is taking place. This is not implied within the warrant and the act of looking to find a criminal act is not supported by probable cause.

In this and other cases DEA Diversion Investigator falsely established diversion based solely on the use of googles maps and performed absolutely no follow up investigation as found in *Wheatland Pharmacy,* 78 FR 69441, 69445 (2013) to establish diversion or evidence that any patients had diverted any prescription medication filled by pharmacist from Pronto Pharmacy LLC.

Similar misconduct by DEA Diversion Investigation is on the record in investigations of At Cost Pharmacy Rx., Ft. Myers Fl, Lincourt Pharmacy LLC, Clearwater Florida, Superior Pharmacy, Tampa, Fl., Gulf-Med Pharmacy, Cape Coral, Florida.

Such acts to search to find without stated cause for the search is an investigative function that violates the premise of a search warrant and violated the basis of Probable Cause, and elements of Reasonable Suspicion. The search conducted was not specific in nature whereby the agents confiscated items not specific to the warrant.

The removal of such documents and items serves no purpose of criminal activity but only to developing a case beyond the scope and statues of the search. The intent that a person and not a sold medication and criminalizing the job of a licenses Pharmacist.

The Fourth Amendment was intended to create a constitutional buffer between U.S. citizens and the intimidating power of law enforcement. The officers failed to indicate within their search warrant the components of what was to be seized. The officers exercised undue discretion when they choose to search and seize.

Therefore, the interest of the defendant was violated when the search and seizures became "unreasonable" and not authorized by the warrant based upon probable cause, to remove personal artifacts such as documents of academic research. This binder contained copyrighted academic research.

THE CONDUCT OF DEA'S PECULIAR COURT SYSTEM NEEDS SERIOUS JUDICIAL REVIEW

The Court System of the Drug Enforcement Agency (DEA), has slipped through both Judicial review and Congressional oversight, and operates outside the Federal Rules of Civil and Criminal Procedures not bounded by *Giglio* and in contempt and violation of those protections of the Constitution of The United States of America.

This Administrative Court acts in the capacity as both Criminal and Civil Court. The Judges of this peculiar court system make their own decision and rules which permits DEA Agents, and Diversion Investigators to act as rogues to which no Federal or Constitutional protection are they bound to respect or abide by.

Associate Supreme Court Justice Gorsuch wrote April 20, 2020, Ramos v Louisiana

"Imagine a constitution that allowed a "jury trial" to mean nothing but a single person rubber stamping convictions without hearing any evidence but simultaneously insisting that the lone juror come from a specific judicial district "previously ascertained by law….And if that's not enough, imagine a constitution that included the same hollow guarantee twice—not only in the Sixth Amendment but also in Article III.8 No: The text and structure of the Constitution clearly suggest that the term "trial by an impartial

jury" carried with it some meaning about the content and requirements of a jury trial"

The officers of this peculiar Court system, mission is not to seek out the truth and but to promote injustice by eliminating the truth supporting junk science and unscientific bias.

Thus this DEA Court System has allowed this Federal Agency to gain the powers over the entire field of medicine (healthcare science) and permitted the Agency to redefine medical procedures medical science.

IMPROPER DOSING FOR PAIN MANAGEMENT AND CONSTRUCTION OF THE CSA THAT CRIMINALIZE MEDICAL ERROR IMPROPERLY INTRUDES ON THE STATES' POWER TO REGULATE THE PRACTICE OF MEDICINE. *(See BRIEF OF AMICI CURIAE PROFESSOR OF HEALTH LAW AND POLICY IN SUPPORT OF PETITIONER DR. XIULU RUAN V. UNITED STATES OF AMERICA CASE NO. 20-1410, IN THE SUPREME COURT OF THE UNITED STATES .....24)*

Federal law and DEA regulations do not impose a specific quantitative minimum or maximum limit on the amount of medication that a practitioner may prescribe on a single prescription, or the duration of treatment intended for a particular patient.

According to the Office of the Inspector General's report on the DEA as prescription opioids has remained relatively flat the increase of heroin use has been skyrocketing. Death by fentanyl, which was once a

rarity, is becoming a big player in the death of Americans due to opioids. If Pronto Pharmacy were actually in the business of diversion, I would applaud the DEA's effort to rid the profession of bad actors. However, in this case it seems that there are too many irregularities to come to that conclusion. Not only is there no evidence to the level of "more likely than not" but the level of "preponderance of evidence" has not been met either.

However as noted from the record both federal and Florida law require a pharmacist to identify and address red flags of drug abuse or diversion including over- utilization and under-utilization. See 21 CFR 1306.04(a); 21 CFR 1306.06; Fla. Admin. Code. Ann. r. 64B16–27.810.

21 C.F.R. § 1306.04(a) (emphasis added). A pharmacist violates this provision only if the pharmacist "knowingly fill[s]" a "purported" prescription—i.e., a prescription that was not written "in the usual course of professional treatment."

These limitations sensibly reflect the very real constraints on pharmacists presented with prescriptions for controlled substances. To be sure, pharmacists can do things like inspect prescriptions for indicia of facial invalidity to determine if they can be filled—e.g., tampering, missing or incorrect information, a forged signature, or a prescribing physician who is not DEA-registered. See 21 C.F.R. § 1306.05(a).

HIGH DOSE OPIOIDS

When presented with a facially valid prescription, however, a pharmacist cannot be expected to second-guess the prescriber's medical judgment that the prescribed medicine is appropriate, to interrogate the patient re-

garding whether they actually need the prescribed medication, or to obstruct the patient's care by with- holding it.

The law should not unduly chill a pharmacist's performance of her/his duties to make medications safely available to patients who need them. The knowledge requirement in § 1306.04 properly reflects this circumscribed role.

Any construction of Section 841(a)(1) that permits the federal government to criminalize good faith med- ical errors raises alarming federalism implications.

The states that have primary authority to regulate the practice of medicine under their reserved Tenth Amendment police powers. *See*, *e.g.*, *Linder v. United States*, 268 U.S. 5, 18 (1925) ("[D]irect control of medical practice in the states is beyond the power of the federal government."); *Barsky v. Bd. of Regents*, 347 U.S. 442, 449 (1954) ("The state's [broad power to establish and enforce standards of conduct within its borders relative to health] extends naturally to the regulation of all professions concerned with health."); *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985) (The regulation of health and safety is "primarily, and historically, a matter of local concern[.]"); *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 387 (2002) (espousing that establishing "standards of reasonable medical care" is a "quintessentially state-law" function).

The preservation of a proper balance between fed- eral and state powers is central to our constitutional design and the protection of fundamental liberties. As this Court has explained:

This federalist structure of joint sovereigns preserves to the people numerous advantages. It assures a decentralized government that will be more sensitive to the diverse needs of a heterogenous society; it increases opportunity for citizen involvement in democratic processes; it allows for more innovation and experimentation in government; and it makes government more responsive. . . . Just as the separation and independence of the coordinate branches of the Federal Government serve to prevent the accumulation of excessive power in any one branch, a healthy balance of power between the States and the Federal Government will reduce the risk of tyranny and abuse from either front.

Gregory v. Ashcroft, 501 U.S. 452, 458 (1991).

Consequently, the federal-state balance of power cannot be dramatically reconstrued by either judicial supposition or a federal law enforcement agency's in- terpretation of a statute that runs afoul of its plain text. *Raygor v. Regents of University of Minnesota*, 534

U.S. 533, 543 (2002) ("When Congress intends to alter the usual constitutional balance between the States and the Federal Government, it must make its inten- tion to do so unmistakably clear in the language of the statute.").

The federal government has no right to interfere with a state's authority to regulate medical practice without "a clear indication that Congress intended that result." *Solid Waste Agency of Northern Cook County v. United States Corps of Engineers*, 531 U.S. 159, 172 (2001); *Pegram v. Herdrich*, 530 U.S. 211, 237 (2000) ("[I]n the field of health care, a subject of traditional state regulation, there is no . . . preemption without clear manifestation of congressional purpose.").

In cases involving "Congressional regulation of core state functions," the clear statement canon has been characterized as a "super-strong rule" of statutory construction that carries weightier force than ordi- nary preemption. William N. Eskridge, Jr. & Philip P. Frickey, *Quasi-Constitutional Law: Clear Statement Rules as Constitutional Lawmaking*, 45 Vand. L. Rev. 593, 623-24 (1992); *see also Pa. Dep't of Corr. v. Yeskey*, 524 U.S. 206, 208–09 (1998) ("[A]bsent an unmistakably clear expression of intent . . . we will interpret a statute to preserve rather than destroy the States' substantial sovereign powers.") (quotation marks and citations omitted).

The rule of lenity, a "time-honored interpretive guideline," also applies when Courts construe an am- biguous criminal statute. *United States v. Kozminski*, 487 U.S. 931, 952 (1988).

Under the rule, when choosing between two constructions of a crime, the statute shall be construed in favor of the defendant. *United States v. Universal C.I.T. Credit Corp*., 344 U.S. 218, 221-22 (1952) ("We should not derive criminal out- lawry from some ambiguous implication"). The rele- vant provision of the CSA at issue here, however, is unambiguous.

CSA Section 841(a)(1) cannot be interpreted as criminalizing good faith medical mistakes under per- tinent precedent because the statute lacks any sug- gestion that Congress intended to delegate to the Department of Justice (DOJ) breathtaking authority over the practice of medicine. Instead, Congress ex- plicitly left to the states the authority to regulate the medical professions. *See* 21 U.S.C. § 823(g)(2)(H)(i) ("Nothing in such regulations or practice guidelines may authorize any Federal official or employee to ex- ercise supervision or control over the practice of medi- cine or the manner in which medical services are provided.").

This Court has long recognized that the state's protection of "the health of its citizens . . . is at the core of its police power," *Sporhase v. Neb. ex rel. Douglas*, 458 U.S. 941, 956 (1982), and has expressly rejected the notion that the CSA grants either DOJ or DEA the broad authority to regulate the practice of medicine:

[t]he [CSA] and our case law amply support the conclusion that Congress regulates medi- cal practice *insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally. The silence is understandable given the structure and limitations of federalism, which allow the [s]tates "[ ]great latitude un- der their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.[ ]"*

Gonzales, 546 U.S. at 269-70 (emphases added).

Not only does Congress know how to explicitly delegate the authority to regulate controlled substance prescribing to a federal agency, it has done so in one— and only one—narrow category: opioid use disorder (OUD) treatment. *Id*. at 271 (holding that 42 U.S.C. § 290bb-2a is the only arena in which Congress has set federal medical standards and "indicates that when Congress wants to regulate medical practice in the given scheme, it does so by explicit language in the statute"); *see also* Anderson et al. at 98 ("Despite the longstanding norm of federal noninterference in medicine, . . . the federal government can regulate medical practice if it makes its intention to do so clear and unambiguous.").

And even then, Congress expressly delegated the authority to set federal medical standards regarding OUD treatment to the Department of Health and Human Services (HHS) and not a federal law enforcement agency. 42 U.S.C. § 290bb-2a ("The Secretary of Health and Human Services, after consultation with the Attorney General . . . shall determine the appropriate methods of professional practice in the medical treatment of the narcotic addiction. . . .").

Federal law enforcement agencies are unqualified to determine whether drugs "have a useful and legiti- mate medical purpose and are necessary to maintain the health and general welfare of the American people."

21 U.S.C. § 801(1). Congress, therefore, did not even leave it to DEA to perform one of its core CSA functions—the scheduling of controlled substances— without health care agency oversight and evaluation. *See id*. § 811(b) ("The Attorney General shall, before in- itiating proceedings . . . [to schedule or reschedule a drug] . . . request from the [HHS] Secretary a scientific and medical evaluation, . . . The recommendations of the Secretary to the Attorney General shall be binding . . . as to such scientific and medical matters.").

Furthermore, this Court has expressly held that DOJ cannot criminally prosecute OUD prescribers under CSA Section 841(a)(1) unless they sell "drugs, not for legitimate purposes but 'primarily for the profits to be derived therefrom' " and are acting outside the usual course of professional practice such that their behavior is akin to that of a "large-scale [drug] pusher, not as a physician." *Moore* at 345.

Congress's refusal to permit a federal agency to regulate the practice of medicine beyond illegal trafficking is further evidenced by the Narcotic Addict Treatment Act (1974) (NATA), which

amended the CSA to permit HHS to regulate OUD treatment. NATA's legislative history demonstrates that the Senate Judiciary Committee carefully weighed the states' long-standing authority to regulate "the general practice of medicine" against "the specialized circumstances within the purview of the bill [e.g., OUD treatment], which entail inordinate *risks of di- version and unethical profiteering*." S. Rep. No. 93-192, at 13 (1973).

The Committee report further explains that the purpose of the NATA amendments was to "re- affirm the commitment Congress made to the nation when it passed the [CSA] by . . . facilitating the pros- ecution of those who engage in the criminal distribution of legitimate narcotic drugs *for profit*." *Id*. at 15.

In sum, the CSA permits the federal prosecution of prescribers who operate as drug traffickers as tradi- tionally understood and, thereby, knowingly or intentionally engage in prescribing conduct that exceeds the bounds of professional practice. Congress never intended to delegate to law enforcement the authority to regulate the practice of medicine by criminalizing good faith medical mistakes. *See* 21 U.S.C. § 903.

The CSA also *depends on state law* to determine which medical professionals constitute "practitioners" acting "in the course of professional practice" and are, therefore, presumptively eligible for federal controlled substance registration. 21 U.S.C. § 823(f) provides that "[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled sub- stances *under the laws of the State in which he practices*") (emphasis added); *id*. § 802(21) (defining "practitioner" to include "a physician . . . licensed by the United States *or the jurisdiction*

in which he practices . . . to . . . dispense . . . a controlled substance in the course of professional practice") (emphasis added).

The CSA further mandates that DOJ defer to state medical licensing authorities before denying, suspending, or revoking a state-licensed prescriber's registration. *Id*. § 823(f)(1) (explaining that the Attorney General may deny, suspend, or revoke a state-licensed prescriber's registration if doing so is in "the public interest" and that the first of the five factors that the Attorney General must consider in making such a de- termination is "[t]he recommendation of the appropriate State licensing board or professional disciplinary authority").

In a 1998 letter to the House Judiciary Committee Chairman, Attorney General Janet Reno explained that the CSA was not "intended to displace the states as the primary regulators of the medical pro- fession or to override a state's determination as to what constitutes legitimate medical practice." *Oregon v. Ashcroft*, 368 F.3d 1118, 1123 (2004).

Consistent with Congress's long-standing policy of leaving the regulation of medical practice to the states was its refusal to enact the Pain Relief Promotion Act (PRPA), which would have made illicit the con- trolled substances used in physician-assisted suicide and, thus, delegated to the DEA the authority to regulate medicine. **Pointing to the DEA's lack of requisite medical and scientific expertise, Congress rejected PRPA. S. Rep. No. 106-299, at 61 (2000) ("[T]his poorly writ- ten, poorly thought-out statute would wreak havoc on States' traditional police authority to regulate their own doctors—an authority they have enjoyed for more than 200 years. . . . In our view, the DEA is not qualified to handle investigations into**

allegation [sic] of the misuse of pain management drugs.") (emphasis added).

Congress has refused to extend the right to interfere with the states' regulation of medical practice even to those federal agencies with significant scientific and medical expertise.

The Food Drug and Cos- metics Act (FDCA) expressly provides that it should not "be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device . . . within a legitimate health care practitioner-patient relation- ship." 21 U.S.C. § 396; *see also United States v. Regenerative Sci*., *LLC*, 878 F. Supp. 2d 248, 255 (D.D.C. 2012).

This express limitation of the FDCA is of significant practical import. If the FDCA pre-empted the regulation of medical practice, prescribers would be stripped of their traditional right to prescribe Food and Drug Administration (FDA) approved drugs "off-label," that is, for non-approved uses to benefit their patients.

The Supreme Court has expressly endorsed the off-label practice of medicine. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (off-label use is an "accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine"). The United States Congress has taken precisely the same view:

In general, the FDA has no authority to regu- late how physicians prescribe approved drugs in the context of their medical practice.

Physicians prescribing off-label uses of ap- proved drugs is not within the jurisdiction of the FDA.

H.R. Rep. No. 105-310, at 60 (1997).

The Social Security Amendments of 1954 also make clear federal non-interference with the states' health-related police powers, providing that "[n]othing in this title shall be construed as authorizing the Commissioner of Social Security . . . to interfere in any way with the practice of medicine. . . ." 42 U.S.C. § 416.

The federal Medicare statute, the Fertility Success Rate and Certification Act of 1992, and the Drug Addiction Treatment Act of 2000 each included similar expansive and express prohibitions on federal interference with the practice of medicine. 42 U.S.C. § 1395 ("Nothing in [the Medicare statute] shall be construed to authorize any Federal officer or employee to exercise any super- vision or control over the practice of medicine."); 42 U.S.C. § 263a-2(i)(1) ("[HHS] may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine"); 21 U.S.C. § 823(g)(2)(H)(i) ("Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise super- vision or control over the practice of medicine or the manner in which medical services are provided.").

Congress's long-standing and express prohibition on federal interference with state authority to regu- late the medical professions is grounded in the un- controversial notion that it is the states that are the laboratories of inventive "social and economic experiments" in our dual sovereignty system of government. *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("It is one of the happy inci- dents of the federal system that a single courageous State may, if its citizens

choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."). Permitting state heterogeneity in medical practice bolsters medical inno- vation and benefits public health. *Gregory*, 501 U.S. at 458 (explaining that the very purpose of the clear statement rule is to preserve a "federalist structure of joint sovereigns . . . that will be more sensitive to the diverse needs of a heterogeneous society" and that "in- creases opportunity for citizen involvement in demo- cratic processes; [and] allows for more innovation and experimentation in government").

Medical innovation is necessarily wrought from medical practitioners' discretion to deploy their specialized training and expertise to pioneer new treatment approaches that may improve patients' well-being. This is likely why there is not a single federal statute that indicates that Congress intended to permit a federal law enforcement agency to criminalize good faith yet mistaken attempts to revolutionize medical practice. *United States v. Lopez*, 514 U.S. 549, 583 (1995) (Kennedy, J., concurring) (cautioning against "foreclos[ing] the States from experimenting in an area to which States lay claim by right of history and expertise").

Eliminating the *Mens Rea* Requirement from 841(a)(1) Stifles Innovation, Harms Patients, and Compromises Practitioners' Ethical Integrity

In the absence of a *mens rea* requirement, the national standards of practice used in Section 841(a)(1) prosecutions to determine the usual course of professional practice is a dangerous precedent for criminal liability. Standard of care inquiries in civil matters evaluate the reasonableness of practitioner treatment decisions and measure prevailing customs, with tolerance for "respectable minority" approaches, including innovative medical practices. Sandra H. Johnson,

Customary Standards of Care, 43 HASTINGS CTR. REP. 6, 9-10 (2013). In civil matters, liability does not implicate more than reputational and pecuniary interests. On the other hand, using one component of a civil standard to determine criminal liability will further fuel practitioners' reasonable fears of the kinds of legal scrutiny that can end not only practitioners' careers but deprive them of basic liberties. Dineen & DuBois. In self-interest, practitioners are incentivized to avoid innovation and the care of patients with unique or complex needs. Instead of comporting with the ethical duties to maximize their patients' well-being, practitioners over-comply with perceived legal norms to avoid any possible legal entanglement at those patients' expense. *Id*.; Dineen, *Definitions Matter*.

The fear of criminal scrutiny, including the deter- rent effect of investigations alone, motivates practitioners to avoid prescribing controlled substances as

well as the care of the patients who might benefit from them. Sandra H. Johnson, *Regulating Physician Behavior: Taking Doctors' "Bad Law" Claims Seriously*, 53 ST. LOUIS U. L.J. 973 (2009); *see also* Cara L. Sedney et al., *"The DEA Would Come In And Destroy You": A Qualitative Study of Fear And Unintended Consequences Emerging From Restrictive Opioid Prescribing Policies In West Virginia* (Oct. 25, 2021), https://www.researchsquare.com/article/rs-991531/ v1 (conducting qualitative interviews with prescribers who repeatedly identified the fear of the DEA as motivating patient avoidance). According to Michael Barnes,

DOJ raids and searches . . . interrupt the de- livery of health care, put patients' lives at risk, and unjustly destroy careers and livelihoods. They also create confusion and fear among professionals serving or considering serving similar patient populations. A reluctance to practice and prescribe controlled medications when medically necessary is es- pecially troublesome given rising rates of suicide, the availability of

increasingly lethal black-market alternatives, and in the case of OUD, the federal objective of increasing, rather than decreasing, prescribing.

Michael C. Barnes, *A More Sensible Surge: Ending DOJ's Indiscriminate Raids of Healthcare Providers*, 8 LEG. & POLICY BRIEF 7, 21 (2019).

See BRIEF OF AMICI CURIAE PROFESSOR OF HEALTH LAW AND POLICY IN SUPPORT OF PETITIONER DR. XIULU RUAN V. UNITED STATES OF AMERICA CASE NO. 20-1410, IN THE SUPREME COURT OF THE UNITED STATES……14)

EARLY FILLS

Narcotic prescriptions are not refillable and thus cannot be refilled early. There has never been a C-2 narcotic refilled at Pronto Pharmacy. That said, let's look at early fills. **Intractable pain** is a very complex syndrome complete with changing dynamic clinical states.

These changes in morbidity can mean that a patient may be stabilized on a particular regimen and suddenly fall out of pain control and as such need higher doses of pain medications. The opposite is true also. A patient may find that after reaching steady state blood levels they would find that they could tolerate the pain for longer times between medication.

Drug interactions play an important role in these changes. Therefore, for a patient to require an early fill of their medication is not uncommon, nor is a gap in treatment for several months. The goal of therapy is the reduction of pain to tolerable levels. If a patient runs out of the medication anxiety can often lead to an increased sensation of pain.

This is why patients, especially ones that have to travel far for their medications often come in 2 –7 days early from time to time. In fact, the insurance companies have set up override codes for this very fact. Every Pharmacy system in America has the ability to track override codes.

However, since the DEA destroyed the data in the Pronto Pharmacy computer these codes, which are no more than 6 characters spread out over 3 different fields cannot be presented.

The malfeasance of the DEA could be considered contributory negligence in this case. Other places that such documentation could be found are on the front or back of the original prescriptions. Not to mention the electronic patient profiles, all of which were available to the DEA but not presented at trial.

RED FLAGS OF DIVERSION

In recent enforcement actions it has filed across the country, accusing pharmacists and pharmacies of unlawfully dispensing medicines, the U.S. Department of Justice (DOJ) has aggressively attempted to sidestep § 1306.04's knowledge requirement. Citing pharmacists' "corresponding responsibility," DOJ has argued that pharmacists are liable for filling prescriptions that allegedly present so- called "red flags"—factors that do not necessarily bear on a prescription's facial validity but that, in DOJ's opinion, suggest the prescriber may have written it for an illegitimate purpose.

Under DOJ's theory, the presence of one or more "red flags" not only proves that a prescription is illegitimate but that a pharmacist who fills it must be doing so "knowingly." (see Amicus Curiae Brief National Association Chain Drug Stores, US Supreme Court Case No. 20-1410, *Ruan vs. United States of America*)

The "red flags" advanced by DOJ include patients seeking to fill "[n]ew prescriptions for controlled sub- stances a patient has never received before";(2) certain combinations of prescribed drugs; 3 providing physi- cian ordered refills when "one to three days of supply

remained";(4) late filling of prescriptions;5 dispensing the same medications "for the same patients over long periods of time";6 prescriptions for doses above "90 [morphine milligram equivalents]/ day";(7) and prescriptions for more than one "immediate release opioid[ ] …sufficiently close in time that the supplies would have overlapped."(8)

Even though in many circumstances these supposed "red flags" have legitimate explanations (medical or otherwise), DOJ has gone so far as to argue that the presence of one or more of these elements is "near conclusive[ ] evidence of a prescription's invalidity."(9)

According to DOJ, when faced with a prescription presenting one or more "red flags," a pharmacist must identify each issue, take steps to resolve it, and document in writing how it was resolved—no matter how many times the same patient has presented the prescription. Until and unless each "red flag" is resolved, DOJ says, a pharmacist must second-guess the prescription's appropriateness, override the

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prescriber's medical judgment, and refuse to fill it—or else face the threat of liability.

There are many problems with DOJ's "red flags" theory. It has no basis in the CSA or it's implementing regulations, or even in the DEA's Pharmacist's Manual. It imprudently dismisses the individualized, case-by-case approach that pharmacists take when filling prescriptions in favor of a categorical approach to culpability.(10) And it traps pharmacists in an untenable position—either face liability under the CSA for filling a facially valid prescription that raises a "red flag," or face state-based professional liability,(11) and even civil suits,(12) for refusing to fill such a prescription.

But the critical point here is that § 1306.04 pro- vides a protection for pharmacists that the Court should not inadvertently eliminate: a

pharmacist may only be held liable if the pharmacist "knowingly fill[s]" a "purported" prescription.

In other words, unless a pharmacist subjectively knows that a facially legitimate prescription has been prescribed for illegitimate reasons, the pharmacist should not face potential liability for dispensing medication based on that prescription.

A strict adherence to this knowledge element is critical to ensuring that pharmacists acting in good faith are not punished for filling facially valid prescriptions written by licensed and registered prescribers—punishment that, if rendered, would chill other pharmacists from performing their duties.

In addressing the related issues raised in these cases, the Court should be careful not to undermine this important safeguard.

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2. Compl. ¶ 79, United States v. Ridley's Family Markets, Inc., No. 1:20-cv-00173-TS-JCB (D. Utah Dec. 4, 2020), ECF No. 2.
3. See, e.g., id. ¶¶ 68–72.
4. Compl. ¶ 67, United States v. Shaffer Pharmacy, No. 3:21- cv-00022-JZ (N.D. Ohio Jan. 6, 2021), ECF No. 1.
5. See, e.g., Compl. ¶ 72, United States v. Howen, No. 1:21-cv- 00106-DAB-SAB (E.D. Cal. Jan. 26, 2021), ECF No. 1.
6. Compl. ¶ 66, United States v. WeCare Pharmacy, LLC, No. 8:21-cv-00188-MSS-AEP (M.D. Fla. Jan. 26, 2021), ECF No. 1.
7. Compl. ¶ 75, United States v. Chip's Discount Drugs, Inc., No. 2:20-cv-00010-LGW-BWC (S.D. Ga. Feb. 12, 2020), ECF No. 1.

8. Compl. ¶ 361, United States v. Walmart Inc., No. 1:20-cv- 01744-CFC (D. Del. Dec. 22, 2020), ECF No. 1.
9. Mem. in Opp'n to Def.'s Mot. to Dismiss at 5 (emphasis added), 8, United States v. Ridley's Family Markets, Inc., No. 1:20- cv-00173-TS-JCB (D. Utah Mar. 8, 2021), ECF No. 31.
10. See Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52716, 52720 (Sept. 6, 2006) (noting that "each case must be evaluated based on its own merits in view of the totality of circumstances").
11. See, e.g., Wis. Pharmacy Examining Bd., Administrative Warning, Division of Legal Services and Compliance Case No. 17 PHM 095 (Dec. 6, 2018).

12. See, e.g., First Amended Compl. ¶ 2, Fuog v. CVS Pharmacy, Inc., No. 1:20-cv-00337-WES-LDA (D.R.I. Aug. 26, 2020), ECF No. 6 (challenging "corporate wide discriminatory practices in refusing to fill, without a legitimate basis, valid and legal prescriptions for opioid medication"); Reasor v. Walmart Stores E., L.P., No. 3:19-CV-27-CRS, 2019 WL 5597302, at *3 (W.D. Ky. Oct. 30, 2019) (defamation suit by physician asserting that "the failure to fill his patient's prescriptions necessarily imputed illegal con- duct because pharmacists are required to fill prescriptions unless the Pharmacist has reason to know of some irregularity").

MULTIPLE PRESCRIBERS

Although the case glossed over this red flag, a patient going to multiple prescribers to obtain high dose opioid medications is a well-established red flag of diversion. The basis of this is that the patient, prescriber, pharmacy relationship is not present. Although the presence of this is not proof of diversion, it has been highly touted as suspicious.

However, there are many reasons that this could be explained or cleared. On the PDMP dataset if a patient goes to a clinic and sees several prescribers in that clinic it will show up as multiple prescribers, but, on closer examination the fact that the prescribers are at the same address could be determined.

If the prescriber has multiple offices and the patient is seen at different offices or the information is entered into the computer incorrectly the PDMP data could appear to be that of drug seeking behavior or merely that of convenience for the patient or the prescriber.

What is glaring in this case is that every patient noted in the allegation only got medications from one specific prescriber for that individual patient. So, this firmly establishes for each patient the prescriber, patient, pharmacy relationship and should be the firm foundation that this case should be based upon.

This is important for several reasons because when relationships are formed it causes variations in behavior that do not happen without a relationship.

If a pharmacy acts only as a source of medication for a particular patient, then they are more likely to obtain whatever they need wherever they find convenient. Often, such a patient will seek out the lowest cost. On other occasions that type of patient will be concerned specifically with service. However, when there is a relationship such as with a specialist, that patient will reasonably travel higher distances, and avoid other specialists in the field. Pronto Pharmacy is a compounding pharmacy which is a specialty. Pronto Pharmacy is a pain management pharmacy which is a specialty. A reasonable and prudent medical observer of the actions of the patients, prescribers and pharmacists involved would see this relationship as normal everyday specialty practice.

DISTANCE

The red flag of distance serves as a discussion point in Pharmacy. If a patient, travels so far that they pass several Pharmacies to get to a specific Pharmacy many issues may be in play. One is cost. Since many patients have insurance and many Pharmacies take most insurances the cost to the patient is most likely the same. However, more than 8.5 % of Americans are without insurance now and 13.5 % were at the time of the Affordable Care Act according to the census bureau (https://khn.org/news/number-of-americans-without-insurance-rises-in-2018/).

Coupled with that are the increasing number of American Nationals that are not counted and the illegal immigrants who for the most part do not have insurance would make this red flag an unreliable indicator of actual diversion. In fact, in light of the current trend of insurance companies, bolstered by the Pharmacy Benefit Managers (PBM's) this is likely to become increasingly irrelevant if it is not already.

The business practices of these near monopolies are akin to those of Standard Oil before it was broken up by the Sherman Antitrust Act (https://en.wikipedia.org/wiki/Standard_Oil). The PBM's attack smaller retail Pharmacies with substandard reimbursement while paying their larger Pharmacy chain operations a premium for the same medications on the same day (https://communityoncology.org/march-30-what-cvs-is-doing-to-mom-and-pop-pharmacies-in-the-us-will-make-your-blood-boil/) .

This effectively leads to small retail Pharmacies being forced to charge larger copayments and the chains being able to charge lower copayments. Kickbacks and Rebates between wholesalers, insurers and

PBM's which are hidden in convoluted pricing schemes all the while under the secrecy of "Trade Secrets" threaten to undermine the patient's overall Freedom of Choice (42 CFR sec 431.51).

According to the Pharmacy trade publication which is one authority in standard of care in Pharmacy practice:

> https://www.pharmacytimes.com/contributor/jeffrey-fudin/2017/10/opioid-red-flags-for-consideration-
>
> "Of late, some community pharmacy chains have changed policies that have been developed around the pretext of patient safety. Such policies include limited-day supply of opioids for acute pain. However, this may present a bitter inconvenience for patients who **legitimately require** opioids for a major acute injury and also maximizes the profitability associated with multiple copays and dispensing fees for drugs that cost pennies. To our knowledge, there is no evidence to support that limited supplies for legitimate patients improves safety or mitigate risk. In fact, there is sufficient data to support that placing such barriers, at least for patients requiring long-term opioids, may actually contribute to the heroin epidemic."

It would be reasonable for a patient to travel outside of their local area when faced with such discrimination by the Chain Pharmacies such as CVS, Walgreens, Rite-Aid and others if they have chronic pain. With their combined market share it would be, almost impossible for such a patient to be, treated properly at all times.

Because Pronto Pharmacy is a specialty Pharmacy that specializes in pain management and compounding it is reasonable for their clientele to

travel distances that normal Pharmacy patients without intractable pain and are low income or without insurance would travel.

DEA TARGETING AND RACIAL PROFILING OF BLACK OWNED PHARMACIES INCLUDING PRONTO PHARMACY

Most, importantly all patients list in Certified Index list continued to receive the same control, medication in the same or increase dosage amounts, from the same practitioners after the DEA August 29, 2019 incursion into Pronto Pharmacy from other Small White own Pharmacies and large chain store operations to this very day.

There is one company the Petitioner currently works for in the State of Florida that sends control testosterone medicals patients various nationwide. To single out pain management as criminal while ignoring the vast number of therapies is improper intrusion of government into a patient's constitutionally guaranteed right of life, liberty, and the pursuit of happiness.

The State of Florida is a big player in the practice of **Mail Order Pharmacy** and as such provides medications (controlled and non-controlled) to patients in other states. This in and of itself should **invalidate the red flag of distance** since this practice is condoned and supported by the Florida State Legislature and the Florida Board of Pharmacy. To discriminate against Florida Pharmacies treating Florida patients is grotesque.

In terms of documentation, I have personally seen patient interviews that were conducted between Dr. Clement and his patients that were in intractable pain. As an expert in the field of diversion as well as pain management, it is clear that without clear cut guidelines from the DEA,

FDA, JCAHO or ISMP the steps were reasonable and prudent. Other similarly practicing Pharmacists would concur with my conclusions.

The DEA removed **all of the documentation** from Pronto Pharmacy as well as the backups but did not return them to Dr. Clement intact. In fact, because of the **negligence of the DEA** some of the data was never retrievable, thus making it impossible for Dr. Clement to present the necessary notations on the prescription images, patient notes, patient profiles, and physician notes therein. Then accused him of not having the proper documentation. In some circles this would be considered tampering with evidence. This is a very suspicious activity on the part of the DEA.

DRUG COCKTAILS

In this case the DEA continually referred to combinations of medications as Drug Cocktails, which has no basis in clinical pharmacy nor medicine. It might be a street term but since we as Pharmacists do not operate in the street the use of that terminology is more akin to propaganda than actual medical practice.

Many patients with chronic pain have comorbidities and as such require medications to treat other issues. To cherry pick out two or three conditions and to assign criminality to them without benefit of knowing what the patient's condition is rises to the height of absurdity and should be discounted.

There is a plethora of double-blind, prospective and retrospective studies that conclude that the combination of several combinations of

oxycodone, hydrocodone, gabapentin, cyclobenzaprine, ibuprofen, ketoprofen, alprazolam, temazepam, oxazepam, baclofen and others have increased efficacy in terms of pain management and the management of comorbidities commonly associated with inflammation, pain and paralysis.

There are competing step care **protocols** as well as **empirical therapy** in use in hospitals, home infusion and community Pharmacy and therefore to criminalize the ones being used in these cases without benefit of the patient interview or prescriber input would raise serious doubts about this red flag. The current information that the DEA uses to evaluate the use of opioids in the treatment of chronic pain is geared towards primary care practitioners and not specialists.

> CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016 https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm

Even still because of the fear of retribution by the DEA most prescribers went too conservative in their approach. Indeed, the CDC as well as the FDA agree that these standards may be too constricting in a majority of pain patients.

> Feds issue new warning to doctors: Don't skimp too much on opioid pain pills
>
> https://www.usatoday.com/story/news/health/2019/04/24/opioid-pain-pills-crackdown-doctors-prescriptions-cdc-fda/3562373002/

This has left too many patients not getting the pain relief that they deserve. In fact, pain relief is a fundamental human right according to

the International Treaty on Human Rights that the United States is a signatory to.

> Pain management: a fundamental human right.
>
> https://www.ncbi.nlm.nih.gov/pubmed/17578977

One of the most exciting developments in pain management is **opioid rotation**. In this technique short acting opioids are rotated or alternated in patients that have developed tolerance. Analgesic tolerance is defined pharmacologically as a reduced potency of the analgesic effects of opioids after repeated administration or the need for higher doses to maintain the same effect. Tolerance is such a factor that State Legislatures nationwide and Congress are grappling with the clinical ramifications of their directives for example: The Intractable Pain Treatment act of Texas indicates that there is overwhelming evidence that all types of pain, either of malignant or nonmalignant origin, are under treated and reluctance to use narcotics for selected patients with nonmalignant painful medical conditions stems from the **mistaken belief** that they will become narcotic "addicts." Data from the medical literature do not support such a contention.

Since Dr. Sullivan is not practicing in the field of pain management or hospital or long-term care it is not unexpected that these new treatment modalities are not on his radar.

> Opioid rotation for cancer pain – Americn Cancer Society Journal
> https://acsjournals.onlinelibrary.wiley.com/doi/full/10.1002/(SICI)1097-0142(19991101)86:9%3C1856::AID-CNCR30%3E3.0.CO;2-G

Other Examples:

- 2009 Clinical Guidelines from the American Pain Society and the American Academy of Pain Medicine on the use of chronic opioid therapy in chronic noncancer pain: what are the key messages for clinical practice? https://www.ncbi.nlm.nih.gov/pubmed/19776687
- Negative mood mediates the effect of poor sleep on pain among chronic pain patients. https://www.researchgate.net/publication/43148187_Negative_Mood_Mediates_the_Effect_of_Poor_Sleep_on_Pain_Among_Chronic_Pain_Patients
- The intractable pain treatment act of Texas https://europepmc.org/abstract/med/1348377
- Opioid Cumulative Daily Morphine Milligram Equivalents (MME) Limit – MME Decrease – Alabama Medicaid. https://medicaid.alabama.gov/alert_detail.aspx?ID=13378

CASH PAYMENTS

As was stated before **suspicion of diversion is not actual diversion**. However, as a diversion expert I am aware that there are people who attempt to fraudulently obtain narcotics from Pharmacies and one thing that tips a Pharmacist off is that the patient attempts to purchase the medication by using cash.

This is particularly concerning when it is known that the patient has insurance available. But there are many reasons that this so called “red flag” may be investigated and cleared. By checking the PDMP data it is possible to see that a patient has, in the past, obtained the medication in question by using insurance.

If this is found to be true it is possible that the patient is trying to divert, especially in the face of other red flags such as distance, early fill, unreasonable therapy and the like. However, in this case the historical PDMP data was not produced by the DEA at trial, so it is impossible to say for sure that this condition of ignoring past payment methods existed for any of the patients in question.

This is crucial information. There are so many legitimate reasons that a patient would pay cash that were not addressed at trial. The patient in question could not have insurance at all. The patient could have a lapse in coverage. The patient might have insurance that is provided by their employer and they might not want the employer to know that they have chronic pain. Examples of that might be truck drivers or medical personnel or heavy equipment operators.

The local pharmacies might not accept their insurance. Pronto Pharmacy could not have a contract with the patient's insurance. This item was proven at trial. If there is no PBM contract there is no insurance contract. It is common knowledge that Pronto Pharmacy's business model includes the principle of not accepting insurance company contracts.

It is also proven at trial that there is no law, Federal, State, or Local that requires contracting with a PBM for a Pharmacy. In fact, I used to be the Supervising Pharmacist of a place called Cash Rx Plus Pharmacy in New York City, who did not take insurances either. Many Pharmacies take a few insurances and not others. With the shrinking margins that are forced upon community pharmacies nationwide many are cherry-picking which insurance companies to contract with. Some are avoiding them altogether. This is an increasing trend in the marketplace.

The USD or United States Dollar, which is the fiat currency of the THE UNITED STATES OF AMERICA has a statement on every denomination. It says, "THIS NOTE IS LEGAL TENDER FOR ALL DEBTS PUBLIC AND PRIVATE." According to 31 U.S. Code § 5103 United States coins and currency (including Federal reserve notes and circulating notes of Federal reserve banks and national banks) are legal tender for all debts, public charges, taxes, and dues. Foreign gold or silver coins are not legal tender for debts.

The prevailing sentiment on this is that all United States money as identified above are a valid and legal offer of payment for debts when tendered to a creditor. There is, however, no Federal statute mandating that a private business, a person or an organization must accept currency or coins as for payment for goods and/or services. Private businesses are free to develop their own policies on whether or not to accept cash unless there is a State law which says otherwise. For example, a bus line may prohibit payment of fares in pennies or dollar bills. In addition, movie theaters, convenience stores and gas stations may refuse to accept large denomination currency (usually notes above $20) as a matter of policy.

Currently, there is no law in this country that contravenes 31 U.S. Code § 5103. Therefore, if a patient offers to pay in cash it might seem suspicious but does not necessarily rise to the level of actual diversion. This is important because any patient has the right to expect that the Pharmacy will act within the law in this matter and in light of their freedom of choice and fundamental human right suspicion may be present but does not require that the patients, themselves to be subject to this requirement.

If a Pharmacist does not reasonably believe that the medication is going to be diverted there is no reason not to accept cash. Currently, the

PDMP system at present cannot **distinguish between cash, credit, debit or healthcare payment cards**. All, of these things come up on the system as cash. With the growing cost of medications, the payment of copayments as well as full prices by credit or debit cards is increasing.

Healthcare payment cards often are the form that employers use to decrease their overall healthcare costs by limiting the benefit to their employees. The employer matches contributions to the funds made through payroll deductions with specific limitations and these are in fact insurance in a broad sense. It removes the bureaucracy of insurance companies, PBM's and switches from the overall cost of healthcare.

COMPOUNDING VS MANUFACTURING

Pharmaceutical Compounding licensed by the State of Florida

"Compounding" is the professional act by a pharmacist or other practitioner authorized by law, employing the science or art of any branch of the profession of pharmacy, incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or the practitioner's agent; and shall specifically include the

professional act of preparing a unique finished product containing any ingredient or device defined by Sections 465.003(7) and (8), F.S.

The term also includes the preparation of nuclear pharmaceuticals and diagnostic kits incident to use of such nuclear pharmaceuticals. The term "commercially available products," as used in this section, means any medicinal product as defined by Sections 465.003(7) and (8), F.S., that are legally distributed in the State of Florida by a drug manufacturer or wholesaler.

(1) Compounding includes:

(a) The preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns.
(b) The preparation pursuant to a prescription of drugs or devices which are not commercially available.
(c) The preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis, and the patient has been made aware that the compounded product will be prepared by the pharmacist.
The reconstitution of commercially available products pursuant to the manufacturer's guidelines is permissible without notice to the practitioner.

If the officers were asked the difference between compounding and manufacturing, they must know what they are being asked. A reasonable officer could not support or testify to the facts of any item or file that was within the seized computer or secondary storage systems. In the warrant the DEA deliberately misinterpreted compounding as manufacturing control substance.

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, was legislatively negotiated to strike "a balance between two potentially competing policy

interests—inducing pioneering development of pharmaceutical formulations and methods and facilitating efficient transition to a market with low-cost, generic copies of those pioneering inventions at the close of a patent term." The Hatch-Waxman Act was, at least according to two economists, the first change in patent terms since 1861. So, one of the pillars of the generic drug push by Congress was to ensure that patients had low cost alternatives to brand name drugs.

Compounding has been a primary facet of the practice of Pharmacy since the beginning of the profession. Prior to that it was only done legally by physicians or their assistants.

In the United States, compounding pharmacies are licensed and regulated by their respective states like all other pharmacies. National standards have been created by Pharmacy Compounding Accreditation Board (PCAB). However, accreditation is not mandatory and inspections for compliance occur only every three years for particular facets of compounding. As mentioned, some confusion has arisen when the traditionally patient-specific nature of compounding gets blurred by the making the multi-product "batches" such as in anticipation of similar orders.

Notably, the Food and Drug Administration (FDA) has always had authority to regulate "manufacturing" – which is when drug products are not made or modified as to be *tailored in some way to the individual patient* – regardless of whether this is done at a factory or at a pharmacy. And conversely, truly legitimate/traditional compounding does not cease to be so merely by having a high *frequency* or occurrence – indeed, progressing towards *more* prevalent drug product customization is an appealing aspect of personalized medicine. https://en.wikipedia.org/wiki/Compounding

DEFINITION OF MANUFACTURING:

21 U.S. Code § 802

> (15) The term "manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. **The term "manufacturer" means a person who manufactures a drug or other substance**.

DEFINITION OF COMPOUNDING:

Section 503A of the Federal Food, Drug, and Cosmetic Act SEC. 503A.

> PHARMACY COMPOUNDING.
>
> (a) In General.--**Sections 501(a)(2)(B), 502(f)(1), and 505 <u>shall not</u> apply** to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing

practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding--

(1) is by--

(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

(B) a licensed physician, on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

(2) (A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between--

(i) the licensed pharmacist or licensed physician; and

(ii) (I) such individual patient for whom the prescription order will be provided; or

(II) the physician or other licensed practitioner who will write such prescription order.

At trial, Mr. Sullivan indicated his opinion that compounding should be narrowly drawn. This flies in the face of 200 years of Pharmacy Practice standards. In fact, what he defines as when it is proper to compound is based upon his opinion and that of the manufacturers.

However, Pharmacists nationwide would not agree. If a patient is unable to afford their medication their clinical outcomes are less than optimal. Price can be a major factor in compliance, so when Pronto Pharmacy minimizes the

impact of price, they are acting within the spirit of the law that created generics in the first place. Because the batches are small it could be inferred that the danger is also decreased.

Manufacturers' errors lead to nationwide recalls (Cimetidine), but small batch compounding can only affect a few people, and therefore safer for the public. When I started in the profession all Pharmacies were required to have compounding supplies as a condition of registration in every state in the union. However, as the manufacturers gained more of a stranglehold on the government with their bribes and corruption, compounding in Pharmacy began to diminish. We found that as insurance penetration into the profession increased the reimbursement for compounding decreased.

But Congress and the State Boards of Pharmacy have not totally abandoned the profession and compounding still has its place as a pillar of Pharmacy. Without compounding there will be no intravenous admixtures, specialized solutions to complex problems or innovation.

In this case all the things that are required for compounding instead of manufacturing are present. Each prescription for a compound is for a specific patient. There is a Physician – Pharmacist relationship. There is a Patient – Pharmacist relationship. In the anticipatory compounding reasonable, limited quantities are being compounded and the necessary prescriptions do actually show up in reasonable time frames. All over the country anticipatory compounding is done and a typical limit is about **3 weeks** but may actually loom as high as **3 months** in some cases. This is the standard of care in compounding Pharmacy.

For Mr. Sullivan not to realize this is further proof of his lack of experience and thus, he is not an expert in this realm. Diversion Expert Alpert admitted at trial that he has absolutely no understanding of compounding. The DEA did not produce even one piece of evidence that shows mastery of the subject of compounding.

ANTICIPATORY COMPOUNDING OF CONTROLLED SUBSTANCES

The DEA contended that Pronto Pharmacy illegally manufactured controlled substances. However, without mastery of the laws concerning compounding their contention fails on its face. Let's look at the pertinent statutes:

> **21 U.S. Code § 841.Prohibited acts**
> **(a)Unlawful acts** Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—
>
> > **(1)**to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense a controlled substance

Taken by itself I could see their point. However, there are exceptions in play.

This information is available on the DEA website, Findlaw, website and elsewhere. Since the wording in this part is particularly voluminous and Pronto Pharmacy was in possession of a valid DEA license at the time that was without blemish and not expired this is the only pertinent part that might be under question.

> **21 USC § 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities**
>
> (iii) **Dispensing or** Instructing (includes… Retail Pharmacy…) A Pharmacist may manufacture aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in a proportion not exceeding 20 percent of the complete solution, compound or mixture,

Business Activity – (iv)	Dispensing or instructing (includes Practitioner, Hospital/Clinic, **Retail Pharmacy**, Central Fill Pharmacy, Teaching institution)
Controlled substances	**Schedules ll-V**
DEA Application Forms	New – 224 Renewal – 224a
Application Fee	$731
REGISTRATION PERIOD	3 years
Coincident Activities allowed	May conduct research and instructional activities with those substances for which registration was granted, except that a mid-level practitioner may conduct such research only to the

> extent expressly authorized under state statute. ***A Pharmacist <u>may manufacture</u> an aqueous or oleaginous solution or solid dosage form consisting a narcotic controlled substance in Schedule ll – V in a proportion not exceeding 20% of the complete solution, <u>compound</u> or <u>mixture</u>***. A Retail Pharmacy may perform central fill activities

As can be seen the when the DEA contended that Pronto Pharmacy needed to be registered as a manufacturer the law says otherwise. Compounding of controlled substances takes place in every state of the union and has since the beginning. If the prohibition is against a certain substance the law could be changed such as it was in the case of heroin, laudanum, opium and so many others. If it were meant to restrict C-2 medications the law could have been changed long before now. The reporting of the C-2 medications in question to PDMP was proper according to the silence on the part of the DEA who brought this case. The question of exceeding the 20% maximum was not a point of contention in the case and therefore is not in question here.

To remove anticipatory compounding from Pharmacy Practice would have many far-reaching negative consequences for patient care and an exponential increase in unnecessary waste. After all, to pierce anticipatory compounding would too broadly define the issue. It would include antibiotics, antipsychotics, neuroleptics, vitamins, tablets, capsules, pills, troches, solutions, emulsions, creams, lotions, macerations, decoctions, ointments, suppositories and all the other dosage forms that exist. It is highly unlikely that the Legislature would have as its intent such an egregious threat to public safety or such burdensome costs to be placed on the American people. The FDA regulates compounding and manufacturing. The DEA is in charge of

administration and enforcement of the Controlled Substances Act. The State Boards of Pharmacy regulate compounding. Therefore, a practicing pharmacist would need to be abreast of sometimes overlapping jurisdictions and subsequently possible contradictory information.

THE BLOG AND VIDEOS BARES WITNESS AND ALLOWS THE SYSTEM TO BE HELD ACCOUNTABLE

YOUAREWITHINTHENORMS.COM

It was apparent that the Administrative Law Judge (Mr. Dowd), the Diversion Expert (Mr. Alpert), the Prosecutor (Mr. Beerbower), as well as the Expert Witness (Mr. Sullivan) are not likely to understand the level of care and clinical issues.

The Petitioner created a blog *youarewithinthenorms*.com, which the Respondent's Counsel introduced as evidence in court and Judge Dowd made in part his decision from this blog.

This Blog consisting of 350 article has served as a National Platform for many health practitioner finding themselves Targets of DOJ_DEA

CONCLUSION SUMMARY

These are but a few indicators that the search for truth was not existent in this procedure. Everything presented here is common knowledge and available to the DEA and was available before the proceedings.

It seems that prosecutorial myopathy was in play here and when the Respondent realized the Petitioner had documenting all of their work with video, his blog youarewithinthenorms.com the DOJ-DEA backed off its attempts to maliciously pursue this case beyond administrative.

But, because the DEA has an agenda which is based upon incomplete information and a desire to combat the so called "Opioid Epidemic" and has had their feet held to the fire by the Office of the Inspector General's Report on the DEA https://oig.justice.gov/reports/2019/e1905.pdf their focus on diversion could be seen as overzealous.

Unfortunately, individual practitioners have been made the scapegoat of this misguided witch hunt. The biggest issue is that suspicion of diversion is not necessarily actual diversion.

Before starting this case, the DEA could have interviewed the prescribers and found out about the individual patient's needs. However, they did not. Had they done so, and wrongdoing was found they could have censured the prescriber and notified the Pharmacists in the state to avoid the narcotic prescriptions of that prescriber. If no wrongdoing had been found the DEA could have concentrated its resources in other areas.

Before starting this case, the DEA could have looked at the PDMP data and surmised that these patients were stabilized on pain management therapies. Even if they didn't fully understand the effects of enzyme induction, drug interactions, tolerance, or comorbidity protocols there is ample information to figure these things out in the public space. However, they did not focus their gaze on possible treatment of patients but rather on suspicion and innuendo.

A reasonable and prudent individual might conclude that discovering the truth was not the goal in this investigation.

WHEREFORE, WE REQUEST UPON THIS COURT:

1. Grant this motion and reverse to findings and decision of the Administrative Court, return and restore all privileges of the DEA Control Registration Certificates of Pronto Pharmacy LLC.
2. Further, Dismiss the Decision of the Administrative Judge Mark Dowd in agency case No: 19-42, Federal Registry filed 1927282 on December 20, 2021with extreme prejudice.
3. Return all Files, Equipment, Medication to Pronto Pharmacy Llc and its owner Norman J Clement of Tampa, Florida.
4. Reward damages and penalties of amounts greater than $187 million U.S. dollars

RESPECTFULLY SUBMITTED

February 03, 2022

Norman J Clement
Norman J Clement, pro se

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on February 03, 2022 a true and correct copy of the foregoing was electronically filed via ECF and/or served via e-mail upon the following:

I, Norman J Clement, hereby certify that I electronically filed and agree to utilize jointly the foregoing Respondent's Notice of Filing the Certified List of the Record with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit, by using the appellate CM/ECF system, on February 03, 2022. I certify further that Petitioner is *pro se*, and that service will is accomplished by electronic mail to

Anita Gay, Esq United States Department of Justice
Criminal Division/ Narcotic and Dangerous Drugs Section
145 N Street, NE, Room 2E-404 Washington, D.C. 20002
(202) 353-7629 anita.gay2@usdoj.gov

Norman J Clement
Norman J Clement pro. se
prontopharmacy@aol.com

CERTIFIED LIST OF
MATERIAL COMPRISING THE RECORD OF PROCEEDINGS
DOCKET NO. 21-1262

Drug Enforcement Administration (DEA)
Docket No. 2019-42

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge dated May 5, 2020

Letter Transmitting Record from Administrative Law Judge Mark M. Dowd to Acting Administrator Timothy Shea dated June 10, 2020

Docket Sheet

Corrected Index of Transmitted Record dated July 30, 2021

Administrative Law Judge's Exhibits 1-44

Government's Exhibits 1-44, 46-68

Government's Demonstrative Exhibit

Transcripts of Hearing held on January 28-29, 2020

Record Copy of Exhibit List

Government's Exceptions to the Administrative Law Judge's Recommended Decision dated May 26, 2020

Respondent's Exceptions to the Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge dated May 26, 2020

Amicus Brief Concerning the Standard of Practice in Pharmacy, Law, and Decision of the Administrative Law Judge dated June 9, 2020

Order Regarding Respondent's Amicus Brief dated June 10, 2020

Order to Show Cause and Immediate Suspension of Registration

Government's Notice of Service of Order to Show Cause and Immediate Suspension of Registration

Request for Hearing

Order for Prehearing Statements

Respondent's Unopposed Motion for Extension of Time to File Prehearing Statements

Order Granting Respondent's Unopposed Motion for Extension of Time to File Prehearing Statements

Order Rescheduling Prehearing Conference

Government's Prehearing Statement

Respondent's Second Unopposed Motion for Extension of Time to File Prehearing Statements

Order Granting Respondent's Unopposed Motion for Extension of Time to File Prehearing Statements

Respondent's Brief in Response to Order Granting Respondent's Unopposed Motion for Extension of Time to File Prehearing Statements

Government's Response to the Tribunal's October 17, 2019 Order

Respondent's Third Unopposed Motion for Extension of Time to File Prehearing Statements

Order Granting Respondent's Third Unopposed Motion for Extension of Time to File Prehearing Statements

Respondent's Prehearing Statement

Prehearing Ruling

Government's Motion for Adjustment of the Tribunal's Prehearing Deadlines

Respondent's Opposition to Government's Motion for Adjustment of Supplemental Prehearing Statement Deadlines

Order Granting Government's Motion for Adjustment of Supplemental Prehearing Statement Deadlines

Respondent's First Supplemental Prehearing Statement

Government's Supplemental Prehearing Statement

Notice of Hearing

Government's Motion for Official Notice

Government's Motion to Limit and Exclude Certain Testimony and Witnesses

Respondent's Motion to Compel Production of Documents

Letter to Judge from Government's Counsel re: Government's Exhibits 1 – 68

Government's Response to Respondent's Motion to Compel

Respondent's Request for Issuance of Subpoenas for Hearing

Government's Request for Issuance of Subpoenas

Respondent's Opposition to Government's Motion for Official Notice

Respondent's Opposition to Government's Motion to Limit and Exclude Certain Testimony and Witnesses

Order Granting In Part Government's Motion to Limit and Exclude Certain Testimony and Witnesses

Government's Motion for Leave to Keep Record Open

Order Granting In Part Government's Motion to Limit and Exclude Certain Testimony and Witnesses

Order Denying Government's Motion for Leave to Keep Record Open

Letter w/ Enclosures to Counsel from Secretary re: Transcript

Respondent's Motion for Extension of Time to File Proposed Findings of Fact and Conclusions of Law

Exhibit #	Exhibit Description	Admitted	Offered But Not Admitted
1	DEA Certificate of Registration No. P2302076	1/28/20	
2	DEA e222 Forms for Purchases from Auburn Pharmaceutical	1/28/20	
3	Ordering Forms for Purchases from B&B Pharmaceuticals	1/28/20	
4	Order Forms for Purchases from Fagron Inc.	1/28/20	
5	Non-Sterile Manufacturing Batch Records for Hydromorphone (January 2017 to September 2017)	1/28/20	
6	Non-Sterile Manufacturing Batch Records for Oxycodone (January 2017 to September 2017)	1/28/20	
7	Respondent's Closing Inventory (dated September 10, 2018)	1/28/20	
8	Florida PDMP Data from Respondent for September 10, 2018 to May 7, 2019	1/28/20	
9	Florida PDMP Data from Respondent for January 9, 2018 to January 7, 2019	1/28/20	
10	Florida PDMP Data from Respondent for September 21, 2016 to June 27, 2018	1/28/20	
11	Respondent's Prescription Log for June 1, 2017 to September 7, 2018	1/28/20	
12	Pronto "Three Month Dispensing Report" for November 2, 2015 to February 1, 2016	1/28/20	
13	Respondent's Dispensing Report (September 2017 to September 2018)	1/28/20	
14	PDMP Report for Patient A.G.	1/28/20	
15	Patient Report for Patient A.G.	1/28/20	
16	Dispensing Report for Patient A.G.	1/28/20	
17	Prescription Log Report for Patient A.G.	1/28/20	

GOVERNMENT EXHIBITS

18	Documents Produced for Patient A.G. in Response to May 2019 Subpoena	1/28/20	
19	PDMP Report for Patient A.H	1/28/20	
20	Patient Report for Patient A.H.	1/28/20	
21	Prescription Log Report for Patient A.H.	1/28/20	
22	PDMP Report for Patient B.S.	1/28/20	
23	Patient Report for Patient B.S.	1/28/20	
24	Prescription Log Report for Patient B.S.	1/28/20	
25	PDMP Report for Patient C.R.	1/28/20	
26	Patient Report for Patient C.R	1/28/20	
27	Prescription Log Report for Patient C.R	1/28/20	
28	PDMP Report for Patient J.D.	1/28/20	
29	Patient Report for Patient J.D.	1/28/20	
30	Prescription Log Report for Patient J.D.	1/28/20	
31	PDMP Report for Patient J.M.	1/28/20	
32	Patient Report for Patient J.M.	1/28/20	
33	Prescription Log Report for Patient J.M.	1/28/20	
34	PDMP Report for Patient M.M.	1/28/20	
35	Patient Report for Patient M.M.	1/28/20	
36	Prescription Log Report for Patient M.M.	1/28/20	
37	PDMP Report for Patient N.B.	1/28/20	
38	Patient Report for Patient N.B.	1/28/20	
39	Prescription Log Report for Patient N.B.	1/28/20	
40	PDMP Report for Patient R.B.	1/28/20	
41	Patient Report for Patient R.B.	1/28/20	
42	Dispensing Log for Patient R.B.	1/28/20	
43	Prescription Log Report for Patient R.B.	1/28/20	
44	Documents Produced for Patient R.B. in Response to May 2019 Subpoena	1/28/20	

46	PDMP Report for Patient R.G.	1/28/20	
47	Patient Report for Patient R.G.	1/28/20	
48	Dispensing Log for Patient R.G.	1/28/20	
49	Prescription Log Report for Patient R.G.	1/28/20	
50	PDMP Report for Patient R.L.	1/28/20	
51	Patient Report for Patient R.L.	1/28/20	
52	Prescription Log Report for Patient R.L.	1/28/20	
53	Curriculum Vitae for Donald L. Sullivan	1/28/20	
54	Google Maps Printout showing approximate distances between cities	1/28/20	
55	Google Maps Printout showing distance between A.G.'s residence and Respondent's registered location	1/28/20	
56	Google Maps Printout showing distance between A.H.'s residence and Respondent's registered location	1/28/20	
57	Google Maps Printout showing distance between B.S.'s residence and Respondent's registered location	1/28/20	
58	Google Maps Printout showing distance between C.R.'s residence and Respondent's registered location	1/28/20	
59	Google Maps Printout showing distance between J.D's residence and Respondent's registered location	1/28/20	
60	Google Maps Printout showing distance between J.M's residence and Respondent's registered location	1/28/20	
61	Google Maps Printout showing distance between M.M.'s residence and Respondent's registered location	1/28/20	
62	Google Maps Printout showing distance between N.B.'s residence and Respondent's registered location	1/28/20	

63	Google Maps Printout showing distance between R.B.'s residence and Respondent's registered location	1/28/20	
64	Google Maps Printout showing distance between R.G.'s residence and Respondent's registered location	1/28/20	
65	Google Maps Printout showing distance between R.L.'s residence and Respondent's registered location	1/28/20	
66	FDA Safety Announcement regarding combining opioids and benzodiazepines, dated August 31, 2016	1/28/20	
67	Administrative Subpoena, dated September 5, 2018	1/28/20	
68	Administrative Subpoena, dated May 10, 2019	1/28/20	

Amend Petitioner's Certified Index List:

To Included the Petitioner's entire Blog youarewithinthenorms.com