ORIGINAL

22-6000

In the
Supreme Court of the United States

NORMAN J CLEMENT,

Petitioners,

v.

DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia

PETITION FOR A WRIT OF CERTIORARI

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OCTOBER 7, 2022

QUESTION PRESENTED

On May 25, 2022, a three-judge panel of the United States Court of Appeals District of Columbia DEA Administrator's decision to revoke Pronto 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. Under this approach, even if a physician prescribed drugs in a good faith effort to promote a patient's well-being.

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 Administrative Court explained, however, he exceeded his limited authority under the Act. *Id.* More recently, the Court. *Ruan v. United States,* 597 U.S. ___ (2022) (slip op.). determine to whether "knowingly" applied to "except as authorized" under the CSA brought the regulation back before

This Petition raises a fourth 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 (see APP-25,97). *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. However "red flags" are guidelines created by DEA in which the agency "**lacks the authority to issue guidelines that constitute advice relating to the general practice of medicine** and further lacks authority to **promulgated new regulations regarding the treatment of pain. (see APP-19-21)** *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:

1.Whether a pharmacy violates its corresponding responsibility under 21 C.F.R. § 1306.04(a) by being required to operate beyond licensing requirement and training and deny filling prescription(s) for a controlled substance issued by an authorized prescribing provider, for a medical disease purpose(s) where the prescription's legitimacy remains undetermined?

2. Whether the record as a whole establishes by a preponderance of the evidence base on an evidentiary standard of "red flag" as a guideline that Pronto Pharmacy's DEA Certificate of Registration Number FP2302076 should be revoked and any pending applications for renewal or modification of such registration and

applications for any other pending DEA registrations should be denied pursuant to 21 U.S.C. 824(a) (4) and 21 U.S.C. 823(f)?

3. We further ask this Court to determine whether a Pharmacists refusal to fill a prescription for a "legitimate medical purpose" under the Pharmacists

"corresponding responsibility," provision, constitute and violates the Eight Amendment prohibition against cruel and usual punishment?

4. Whether it was the intent Congress for DEA to regulate the field and practice of medicine and pharmacy auger deference awarded to administrative agencies ?

PARTIES TO THE PROCEEDINGS

Petitioners

- Pronto Pharmacy

- **Respondent**

- Drug Enforcement Administration

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, neither Pronto Pharmacy 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

86 FR 647,14 (2021).....195app

Pronto Pharmacy LLC v. *Drug Enforcement Administration,* Defendant

Date Decision Issued: Nov. 18, 2021
Date Decision Effective: December 18, 2021

Direct Appeal

United States Court of Appeals for the District of Columbia No.: 21-1262

Pronto Pharmacy LLC, Plaintiff, v. *Drug Enforcement Administration,* Defendant

Date of Judgment: June 27, 2022

Date of Rehearing Denial: September 19, 2022

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OPINIONS BELOW

The opinion of the U.S. Court of Appeals for the District of Columbia Circuit appears in the Appendix at App.1a and can be found at Norman Clement, pro se Pronto *Pharmacy LLc v. DEA*, No. 21-1262, 2022 U.S. App. (District of Columbia Circuit, May 25, 2033). (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.17 and can be found in the Federal Register at Fed. Reg. 73753.

JURISDICTION

On May 25, 2022, a three-judge panel of the United States Court of Appeals District of Columbia entered its opinion in Norman Clement and Pronto *Pharmacy v. DEA*, No. 21-1262, 2022 U.S. App. (11th Cir. Feb. 14, 2022). (App.1a). Petitioner Norman Clement, Pronto Pharmacy LLC filed a Petition for Panel Rehearing, or alternatively, En Banc Rehearing, which the Court denied on September 27, 2022 (App.). This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Section 841(a)(1) of the Controlled Substances Act ("CSA"), 21 U.S.C. § 841(a)(1), provides:

(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[.]

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 profes- sional 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 included in the appendix at App-1

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 pro- vider registration. 21 U.S.C. § 871; *Gonzales*, 546 U.S. at 262; *Final Rule: Redelegation of Functions; Dele- gation 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 Adminis- trator, however, has exceeded his limited authority of overseeing provider registration and has instead created a new category of "unauthorized prescriptions". With-out 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 deci- sions,

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—

author- ity 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 to declare an entire class of activity outside "the course of professional practice," and there- fore a criminal violation of the CSA. (citation omitted)).

RED FLAGS
1. " **Red Flags"** are not described in : 1) the CDC Guidelines ,

either the 2016, 2017, or the 2022 version, 2) HHS Best Pain

Practice
2. " **Red Flags"** are not part of a generally accepted, nationally-

approved medical standard.
3. " **Red Flags"** represent " reasonable suspicion" and not, proof

beyond a reasonable doubt.
4. " **Red Flags"** are arbitrary and capricious , because the

" alleged red flags" do not proactively, clearly and

objectively, describe the prohibited conducts
5. **"Red Flags"** are necessary but not sufficient, to serve as

evidence beyond a reasonable doubt, of criminality.
6. " **Red Flags"** falls below the knowing and intentional mens

rea, evidence standard, set under Ruan. (*Ruan v U.S. Supreme Court of the United States,* (No. 20–1410. Argued March 1, 2022—Decided June 27, 2022)

The question here in this case is the Rule of Law. The most fundamental concept of our country, without which our society crumbles. The authority the DEA Administrator lays claim too 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, An Administrative Law Judge has the power to receive evidence and to issue subpoenas to compel the attendance of witnesses and the production of materials "necessary" for the hearing. See 21 C.F.R. §1316.52(d). However, DEA administrative revocation hearings do not include the type of discovery process that is available to civil litigants in this Court and are prevented from presenting witnesses such as the prescribing practitioners.** As is found in Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order, 85 Fed. Reg. at 73776-77 (on Petition for a Writ of Certiorari to the US Supreme Court) at no point did the Acting Administrator determine the legitimacy of the underlying controlled

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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).

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 whom had DEA registrations and are authorize to prescribe control substances for a legitimate medical purpose and the usual course of professional practice for prescription 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 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 so-called "illegitimate" controlled substances that Sun- tree Pharmacy filled. (9)(10)

In the case of Pronto Pharmacy LLC, Suntree Pharmacy are similarly situated and nexus that Dr. Donald Sullivan professors at the Ohio State University College of Pharmacy working from home was **used by DEA** as the Pharmacy Expert consultant and used "red flags" as a proxy to conclude the prescriptions were 'illegitimate.' (See Decision and Order, Fed. Reg.86 FR 64714 (2021) id. at https:// www.federalregister.gov/d/2021-25133/p-87)

Similarly in this case, not only did the DEA Administrator fail to determine the legitimacy of the prescriptions Pronto Pharmacy filled, but he also discouraged such a determination by preventing Pronto Pharmacy from calling the physicians to testify (see App.205-220). The Administrator further failed to gather testimony from patients who were prescribed these controlled substances. All of the prescribing physicians, dentist had DEA registrations and were authorize to prescribe control substances for a legitimate medical purpose and the usual course of professional practice for prescription, whom prescribed the controlled substances prescriptions Pronto Pharmacy Llc., filled. *See Pronto 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). Whether and to what extent an agency can use a subjective non-statutory standard, "redflags," compelling pharmacist(s) to second guest the prescribing providers diagnosis, treatment and licensing authority based on DEA's own manufactured rules and misinterpretation of laws, medical procedures guidelines, creating their own intrusion to regulate medical science. Most-importantly, whether the record as a whole establishes by a preponderance of the evidence base on an evidentiary standard of, "red flag" that Pronto Pharmacy's DEA Certificate of Registration Number FP2302076 should be revoked and whether any pending applications for renewal or modification of such registration and applications for any other pending DEA registrations should be denied pursuant to 21 U.S.C. 824(a) (4) and 21 U.S.C. 823(f).

In the June 27, 2022 *Ruan v United States* opinion, the Court provided much-needed clarity regarding when a physician can be subject to criminal conviction for writing improper prescriptions for controlled substances.[1] By narrowing the scope of criminal liability, to requires proving beyond a reasonable doubt that the physician knowingly or intentionally prescribed controlled substances without a legitimate medical purpose. The "beyond a reasonable doubt" standard for conviction requires that the jury must be virtually certain of the defendant's guilt this decision will benefited both physicians, pharmacist and patients, especially patients seeking treatment for pain.

The great fear at this moment here is the United States Drug Enforcement Administration (DEA) has operated unchecked, as a rogue sub agency of government operating outside the rule of law. Creating their own medical science (Auer-deference) seizing property using omnipotent authority of ill gotten gain over the field of medicine and medical science.

Specifically, mis-identifying the dosages and purposes of legally and medically prescribed FDA approved Narcotic Analgesic medications, "having a useful and legitimate medical purposes," to be re-defined as "illegitimate." mis-labeling all as "opioids."

While, the original intent of Congress in the Controlled Substances Act (CSA) was made clear Congress determined Federal law enforcement agencies are unqualified to determine whether drugs "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. § 801(1).

"As a Law Enforcement agency, DEA is not a position to authorize or **dictate what a doctor prescribes to a patient.** DEA cannot grant waivers of any kind when it comes to the practice of medicine because no such wavier exists. As the United States' component body charged with the management of controlled substances and chemicals for scientific, medical research, and industrial applications; DEA regulates the flow of control substances, not the practice of medicine. (see App 16-19 App 72,73,74,92,93)

The DEA lacks the authority to issue guidelines that constitute advice relating to the general practice of medicine. The DEA has not promulgated 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 may be prescribed on a single prescription on the duration of treatment intended with the prescribed controlled substance."[10] (see App.375-380)

B. 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.

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9. The owner of Suntree Pharmacy is both a pharmacist and licensed practicing Attorney. 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.(https://www.wesh. com/article/new-allegations-made-on-dea- s-role-in-pain-prescription-denials/ 4443955#)

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). OTSC warrants repeatedly refers to Pronto Pharmacy as prescriber.(App.-375-380)

The regulations separately provide that such a prescription "may only be filled by a pharmacist, acting in the usual course of his/her professional practice and either registered individually or employed" by a registered entity. 21 C.F.R. § 1306.06. Consistent with the division of responsibility between 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 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 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."

The purpose of the CSA's regulations governing prescribing is to prevent physicians from using their prescribing powers to engage in drug trafficking; for example, by effectively selling prescriptions to individuals who misuse drugs. The Supreme Court's decision in Ruan v United States represented a critical step in remedying these problems. Accordingly, the Court concluded that to convict a physician for writing improper prescriptions, "the Government must prove beyond a reasonable doubt that the defendant knew that he or she was acting in an unauthorized manner or intended to do so."

In other words, rather than simply showing that a physician's prescriptions did not conform to professional standards, prosecutors must prove the physician intentionally wrote prescriptions without any legitimate medical purpose. The Court acknowledged that deviating from prevailing standards, such as prescribing pain medications for certain off-label uses or in unusually large doses, can be relevant in determining whether a physician intended to act unlawfully. But these practices should not establish criminal liability on their own. Rather, prosecutors must show other evidence of a physician's intention to act as a drug trafficker, such as prescribing drugs with high potential for misuse without examining patients or charging patients according to the volume of drugs prescribed. (see App249-253)

Here in Ruan, the Court categorically rejected the idea that physicians could be convicted as drug traffickers merely by showing they prescribed outside the usual course of practice, regardless of their intent. The Court observed that such a standard would "criminalize a broad range of apparently innocent conduct" and risk deterring physicians from using their best judgment to benefit patients.

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 unwarranted and counterproductive imposition of liability. 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). (see App. 237-249)

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."

However "red flags" are guidelines creating by DEA which has stated to Congress and public that DEA "lacks the authority to issue guidelines that constitute advice relating to the general practice of medicine(see APP-19-21,72,73,74,92,93). The DEA has not promulgated new regulations regarding the treatment of pain," this of course is false.

STATEMENT OF FACTS

On August 23, 2019, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), the DEA issued an Order to Show Cause ("OSC") to Pronto Pharmacy. R. 1. The OSC alleged that Pronto Pharmacy filled prescriptions in contra- vention of its corresponding responsibility under 21 C.F.R. § 1306.04(a). R. 1 at 2. Specifically, the OSC claimed that Pronto Pharmacy 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."

An administrative hearing was held from January, 28-29, 2020, following which, on May 5, 2020, the Administrative Law Judge ("ALJ") filed his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision. Pronto Pharmacy *LLC; Decision and Order*, 86 FR 647,14 (2021). On November 9, 2021, the Administrator rendered her decision, finding Pronto Pharmacy LLC had violated its corresponding responsibility under § 1306 .04(a), and issuing an Order revoking Pronto Pharmacy's registration, effective November 18, 2021. *Id.* (App.17a).

In her decision, the Administrator determined that Pronto Pharmacy actions of filling "hundreds" of prescriptions in the face of "red flags" was egregious conduct that necessitated revocation. At no point did the Administrator determine the illegitimacy of the underlying controlled substance prescriptions that Pronto Pharmacy LLC., filled, nor did any qualified healthcare professional comment on whether the prescriptions were issued for a legitimate medical purpose.

Accordingly, nor did the Administrator conclude that the physicians were writing improper prescriptions, or that prosecutors convicted the prescriber by using the standard beyond a reasonable doubt or that the Petitioner knew that he or she was acting in an unauthorized manner or intended to do so."

In other words, rather than simply showing that a physician's prescriptions did not conform to professional standards, prosecutors must prove (or had proven) the physician intentionally wrote prescriptions without any legitimate medical purpose. The Court acknowledged that deviating from prevailing standards, such as prescribing pain medications for certain off-label uses or in unusually large doses,

can be relevant in determining whether a physician intended to act unlawfully. But these practices should not establish criminal liability on their own. Rather, prosecutors must show other evidence of a physician's intention to act as a drug trafficker, such as prescribing drugs with high potential for misuse without examining patients or charging patients according to the volume of drugs prescribed. In this case the Administrator used "red flag" as a proxy to unjustly manufacture an Order to Show Cause, to seize Pronto Pharmacy's records, property and money.(see App. 374-378)

Most, importantly, in the same way the Administrator used "red flags" as a proxy to determine the illegitimacy of a controlled substance prescription (without actually making such a determination; either by herself or via a medical expert), Instead, the Acting Administrator simply relied on "red flags" identified by Dr. Donald L Sullivan, consultant (*i.e.*, not a retail pharmacist), and used these "red flags" as a proxy to conclude the prescriptions were illegitimate. (see App-162-163,)

Pronto Pharmacy appealed the Administrator decision to the United States Court of Appeals for the District of Columbia. It had jurisdiction to challenge the DEA Administrator's Order pursuant to 21 U.S.C. § 877, or the in the Eleventh Circuit Court of Appeals pursuant to 21 U.S.C. § 877, in which Pronto Pharmacy's principal place of business is located. 21 U.S.C. § 877. (see App-333-373)

On May 25, 2022 a three Judge Panel issued its decision upholding the Acting Administrator's revocation of Pronto Pharmacy's registration, finding the Petitioner has not shown that the Drug Enforcement Administration ("DEA") see decision published November 18, 2021, (11)

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10. The Acting Administrator's factual findings were supported by "substantial evidence" and thus conclusive. 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. Relying on his—and the DEA's —prior deci- sions, 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 ibid 1, 2

11. see decision published November 18, 2021, revoking Pronto Pharmacy, LLC's registration to dispense controlled substances, was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." pursuant to; 5 U.S.C § 706(2)(A); Morall v. DEA, 412 F. 3d 165, 177 (D.C. Cir. 2005). The DEA's conclusion

that revocation was warranted because the pharmacy had committed acts rendering its registration inconsistent with the public interest was supported was supported by substantial evidence. See 21uU.S.C. § § 823(F), 824 (a)(4); Masters Pharm., Inc v. DEA, 861 F. #d 206, 215 (D.C. Cir 2017). In a addition petitioner has not shown that the DEA's interpretation of the Controlled Substances Act 21 U.S.C. § 801, et seq., was "arbitrary, capricious or manifestly contrary to the statute, "Wedge-wood Vill. Pharmacy v. DEA, 509 F 3d 541, 549 (d.C. Cir 2007), or that the DEA subjected Pronto Pharmacy LLC to unfair or unequal treatment. (see App 334-338)

SUMMARY OF THE ARGUMENT

The DEA has set up a system of dictating medical through which encourages Pharmacists to profiling patients by the Processes of "RED FLAGGING." The term Red Flag used and enforced by DEA is both subjective, arbitrary and capricious and has no statutory meaning in the areas of pharmacy and or within the medical profession. Those pharmacists who merely question these DEA policies risk loss of employment and/or administrative sanctions. The DEA can impose these errant actions because they possess unchecked authority and weapons the ability to intimidate by seizings property and assets. Under this interpretation, a golf ball can become a football and baseball bat can enforced as a hockey stick. 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.

The question we seek out as pharmacist here in is when does a golf ball become a football, at what point in the game does a baseball bat become a hockey stick and at what point does the umpire call a strike across the plate third down?

When does the referee call a prescription written for a "legitimate medical purpose" illegal so that a pharmacy violates its corresponding responsibility whether or not there is evidence of a prescription's illegitimacy? At what point on the mile marker does a prescription written by a licensed authorized provider to treat a medical disease of a disease state become illegal or can the Umpire convert the rules of the game into scienter as an financial incentive to issue more fines and expand his/her authority?

In this case is whether the record as a whole establishes by a preponderance of the evidence that Pronto Pharmacy's DEA Certificate of Registration Number FP2302076 should be revoked and whether any pending applications for renewal or modification of such registration and applications for any other pending DEA registrations should be denied pursuant to 21 U.S.C. 824(a) (4) and 21 U.S.C. 823(f).

Whether a pharmacy violates its corresponding responsibility under 21 C.F.R. § 1306.04(a) by being compelled to operate beyond their subject matter expertise and knowingly fills a prescription for a controlled substance issued for a legitimate medical purpose where the prescription's legitimacy remains undetermined?

That these DEA policies are applied so arbitrarily and capriciously makes them violate the right of patients to seek healthcare treatment for acute, chronic pain care. This misguided thinking of "redflags" has led to abuses by the DEA, and the needless suffering and deaths of thousand of chronic disease patients such as Sarcardosis, Amyotrophic lateral Sclerosis, Sickle Cell (SCD) because pain has been criminalized by this massive over-reach of the DEA. There are no amount of words any healthcare providers can write in any petition when learning of the needless suffering deaths of their chronic pain patients or love ones being subjected to inadequate narcotic analgesic medication treatment because of fear being targeted by DEA-DOJ as drug seekers and their doctors, "drug dealers in white coats." (see App 12, 21,17, 354,356)

This fear is real, my brother Walter R. Clement a 34 year veteran Detroit Police Dept., passed September 19, 2022, peacefully and in horrific agonizing untreated pain from ALS because his doctors feared over-prescribing. Then their is Gilinda Dame-Fincher 63, Cleveland , OH., with the Kincaid Kindred Spirits, (www.kks4scd.org) whose suffered all her life of the horrific pain from Sickle Cell Disease, (a condition exempt from the 2016 CDC Guidelines) a graduate of the University of Cincinnati requires two units of blood every month to sustain her life, requiring Oxycontin and being denied by pharmacies as a "Red Flag."

Further knowing there are only twenty (20) Adult Sickle Cell hematology physician specialist in all of America remaining to care for SCD adult patients because these doctors whom are authorized to prescribe are targeted.

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, and the original intent of Congress' not to dictate the practice of medcine and does not "unjustly punish" 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 Pronto Pharmacy's registration *Decision and Order*, 86 FR 647,14 (2021) 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]."). The Supreme Court's decision in *Ruan v United States* represents a critical step toward

remedying these problems. The Court categorically rejected the idea that physicians could be convicted as drug traffickers merely by showing they prescribed outside the usual course of practice, regardless of their intent. The Court observed that such a standard would "criminalize a broad range of apparently innocent conduct" and risk deterring physicians from using their best judgment to benefit patients.

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.* In other words, rather than simply showing that a physician's prescriptions did not conform to professional standards, prosecutors must prove the physician intentionally wrote prescriptions without any legitimate medical purpose. The Court acknowledged that deviating from prevailing standards, such as prescribing pain medications for certain off-label uses or in unusually large doses, can be relevant in determining whether a physician intended to act unlawfully. But these practices should not establish criminal liability on their own. Rather, prosecutors must show other evidence of a physician's intention to act as a drug trafficker, such as prescribing drugs with high potential for misuse without examining patients or charging patients according to the volume of drugs prescribed.

The DEA though is willfully blind of this requirement and has instead interpreted § 1306.04(a) to penalize pharmacies, like Pronto Pharmacy, *Decision and Order*, 86 FR 647,14 (2021) regardless of the underlying legitimacy of the prescriptions it filled, so long as there are unresolved "red flags". See Colautti v. Franklin, 439 U.S. 379 (1979) (12)

This is deeply unfair to both physicians, and pharmacist who could face draconian penalties without any evidence that they intended to engage in criminal activity. The risk has been particularly acute for both physicians who treat patients for pain and pharmacist who fill such prescriptions relying upon the prescribers "good faith" and having verified the legitimacy of each prescription through the Prescription Drug Monitoring Program (PDMP). Identifying the "usual course of practice" for treating pain is especially challenging because patients' experiences of pain and treatment needs are so varied. Moreover, although physicians are trained to trust their patients (and patient self-report is the standard approach for assessing pain), both physicians and pharmacist could be convicted for failing to detect that their patients were misusing or diverting their prescribed drugs.

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. However, the review, reveals the DEA's interpretation is not entitled to deference because it is unreasonable, thereby exceed- ing the zone of ambiguity identified by this Court's prior cases and the original intent of Congress. The DEA's interpretation were reasonable, 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 (13)

Here, the question we seek out before this body as pharmacist, under what law, rule or authority does the Umpire have to dictate a golf ball as a football? At what point during the game does a baseball bat become a hockey stick and the Umpire has authority dictate and change the rules, regulations and procedures of the game into scienter and criminal offenses ?

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12. *The viability determination requirement of § 5(a) is void for vagueness. Pp. 439 U. S. 390-397.Though apparently the determination of whether the fetus "is viable" is to rest upon the basis of the attending physician's "experience, judgment or professional competence," it is ambiguous whether that subjective language applies to the second condition that activates the duty to the fetus, viz., "sufficient reason to believe that the fetus may be viable." Pp. 439 U. S. 391-392. (b) The intended distinction between "is viable" and "may be viable" is elusive. Apparently those phrases refer to distinct conditions, one of which indeterminately differs from the definition of viability set forth in Roe v. Wade, 410 U. S. 113, and Planned Parenthood of Central Missouri v. Danforth, 428 U. S. 52. Pp. 439 U. S. 392-394. (c) The vagueness of the viability determination requirement is compounded by the fact that § 5(d) subjects the physician to potential criminal liability without regard to fault. Because of the absence of a scienter requirement in the provision directing the physician to determine whether the fetus is or may be viable, ...faith," United States v. Ragen, 314 U. S. 513, 314 U. S. 524, and the perils of strict criminal liability are particularlyacute here because of the uncertainty of the viability determination itself. Pp. 439 U. S. 390-397*

13. https://youarewithinthenorms.com/2022/09/24/pain-and-the-rules-of-law/

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

The warrant issued identified as "red flags." 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 licensed Pharmacist and medical professionals as a person that illegally distribute, or dispense, a controlled substances. (see App 374-385)

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.")

The DEA 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 and authorized. (see App 382-396). Mr.Clement nor his staff or any drug whole-saler was ever arrested or charged or brought before a grand jury.

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.) *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).

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 "red flag," googles maps and performed absolutely no follow up investigation as found in *Wheatland Pharmacy,* 78 FR 69441, 69445 (2013)(see app 376-380) to establish diversion or evidence that any patients had diverted any prescription medication filled by pharmacist from Pronto Pharmacy LLC. (see App 345-352)

Similar misconduct by DEA Diversion Investigation is on the record in investigations of Sun Tree Pharmacy and Superior Pharmacy, Tampa, 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. (see App-21-27)

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.

B. FAMILIARIZING AND HELPING THIS COURTS UNDERSTANDING, ALL DRUG MEDICATIONS ARE DANGEROUS ESPECIALLY WHEN

TAKEN BEYOND THEIR THERAPEUTIC PRESCRIBED DOSE AND NOT ALL OPIOIDS ARE CREATED EQUAL, ESPECIALLY IN THE BODY

The DEA and the drug war system on physicians and pharmacist have fails to recognize a peoples chronic disease conditions of intractable pain, while further failing to understand or comprehend human suffering, the science of clinical treatment and the value of human life. While the comparison may seem silly, in today's anti-opioid climate a subjective standard of "one-size-fits-all" mindset has become the foundation of government-dictated medicine. And it's very bad medicine 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 medical care.

Theses deeply flawed policies that are being enacted as law all over the country are based on the "one-size-fits-none" subjective unscientific concept of morphine milligram equivalents (MME) - the maximum amount of an opioid medication than is permitted per patient per day. Anyone with even a passing knowledge of pharmacology would immediately be skeptical of data in the chart. Let's take, for example, the two drugs at the bottom.

While MME values are touted as useful predictors of the total "opioid load" that a patient can receive, they are nothing of the sort. And MME-based policies don't just fail because of differences in the size of patients; they fail for multiple reasons.

FLAWED SCIENCE YIELDS MEANINGLESS RESULTS

Below is a chart published by the CDC, a "guide" **(2)** for physicians who prescribe pain drugs. Morphine is normalized to 1.0 and the conversion factor reflects the relative potency of other opioid drugs. So, if the daily MME - the maximum dose of drug allowed - is 90 mg **(3)** then a patient may receive no more than 90 mg of morphine, 90 mg of hydrocodone, 60 mg of oxycodone, or 30 mg of oxymorphone per day. (see App-128-134)

Although the conversion table seems to be straightforward enough, it is based on an assumption that all opioids behave similarly in the body. But this assumption could not be less accurate. Once we see the profound differences in the properties of the drugs and the difference between individuals who take them it becomes clear that

not only is the CDC chart flawed, but the MME is little more than a random number.

The CDC MME chart, in fact, the entire concept of morphine milligram equivalents may be convenient for bureaucrats but because of differences in the absorption of different drugs into the bloodstream, half-life of different drugs, the impact of one or more other drugs on opioid levels, and large differences of the rate of metabolism caused by genetic factors, is not only devoid of scientific utility, but actually causes far more harm than help by creating "guidelines" that are based upon a false premise. When a policy is based on deeply flawed science, the policy itself will automatically be fatally flawed. It cannot be any other way.

Although Table 1 tells us that Oxymorphone is twice as "strong" as oxycodone it does not take into account a number of critical properties that paint a more complete picture of the fate of the drug once swallowed. In other words, there is no information about pharmacokinetics - the effect of the body on the drug.

The overall opioid prescribing rate in the United States peaked and leveled off from 2010-2012 and has been declining since 2012, but the amount of opioids in morphine milligram equivalents (MME) prescribed per person is still around three times higher than it was in 1999. (14), (15),(16)

(1) MME is a deeply flawed science used by DEA as a way to calculate the total amount of opioids, accounting for differences in opioid drug type and strength.

(2) There was a more than 19% reduction in annual prescribing rate from 2006 to 2017. The declines in opioid prescribing rates since 2012 and high-dose prescribing rates (≥90 MME) since 2008 suggest that healthcare providers have become more cautious in their opioid prescribing practices.

Some opioid drugs will be absorbed and pass to the bloodstream very well and some will do so very poorly.

- Even opioids that appear to be structurally and functionally similar will be metabolized at very different rates.

- Other drugs can drastically alter the physiological response of a pain patient to a given opioid; the second drug may increase a person's response to the opioid or it may decrease it.

Even under ideal conditions - two people taking the same opioid drug at the same dose, at the same interval, and taking no other drug - huge variations of innate metabolism from one individual to another will necessarily result in a wide range in clinical response to that drug.

- It is the single most heinous governmental agency whose tactics have led to the increased cost of medications and healthcare across America, by mis-interpreting the purpose and roles of medications needed to treat acute, chronic, neuropathic and psychological pain.

(3) DEA has waged a subjective campaign of misinformation to persuade the public that these medications are dangerous drugs whose dosages are "RED FLAGS" indicating abuse and trafficking, which contributes to the so-called Opiod crisis in America.

The DEA has become a rogue agency based on flawed science and subjective misinterpretations of medical procedures (which is outside their Congressional authority) **that has lost their mission,** using threats and intimidation such as;
1. Tactics of no-knock raids and arrest,
2. Forfeiture,

3. Threat of prison time
They impose their will onto the medical profession (nurses, pharmacists, physicians, dentists, and especially drug wholesalers) and their patients.

OPIOID (doses in mg/day except where noted)	CONVERSION FACTOR
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1-20 mg/day	4
21-40 mg/day	8
41-60 mg/day	10
≥ 61-80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3

14. Josh Bloom, PhD, "Comments to the FDA – Opioid Dosing Based on Milligram Morphine Equivalents is Unscientific", *American Council on Science and Health*, May 24, 2021, https://www.acsh.org/news/2021/05/24/ comments-fda-opioid-dosing-based-milligram-morphine-equivalents-unscientific-15561

15. h2ps://www.acsh.org/profile/josh-bloom

16. Sally Satel, MD, "The Truth About Painkillers" *National Affairs*, Nr 47, Spring 2021. https://nationalaffairs.com/publications/detail/the- **truth-about-painkillers**

ARUGUMENT

II. U.S. v. Levin 973 F.2d 463 (6th Cir. 1992) Decided Aug 7, 1992

In Levin, the undisputed evidence established that the government issued letters which were circulated to the defendant stating the government's approval of the activity charged in the indictment the United States Supreme Court in *Raley v. State of Ohio,* 360 U.S. 423, 79 S.Ct. 1257, 3 L.Ed.2d 1344 (1959). Holding that

"convicting a citizen for exercising a privilege which the State had clearly told him was available to him" was "the most indefensible sort of entrapment by the State" and violated due process (3) (see App-16-17)

In this case we previously demonstrated in Dispositive Motions, Addendums and Supplements (see App-110, App 168-170) the DEA issued letters to Citizens, Providers, a US Congress Member stating:

"The DEA lacks the authority to issue guidelines that constitute advice relating to the general practice of medicine(see APP-19-21). **The DEA has not promulgated 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 may be prescribed on a single prescription on the duration of treatment intended with the prescribed controlled substance."** (See App-73-74 **exhibit 5-4D September 14, 2022, US Court of Appeals DC ,** letter dated November 04, 2019, from: **Thomas W. Prevoznik, Deputy Assistant Administrator Diversion Control Division**, to: Kevin N. Nicholson, R.Ph., J.D.Vice President, Public Policy and Regulatory Affairs National Association of Chain Drug Stores1776 Wilson Boulevard Suite 200 Arlington, Virginia 22209) (see App-73-74 also App-15 thru App-21). However, "red flags" are guidelines that constitute advice in medicine.

DEA's , letter to Congresswoman Grace Meng,

"As a Law Enforcement agency, DEA is not a position to authorize or **dictate what a doctor prescribes to a patient.** DEA cannot grant waivers of any kind when it comes to the practice of medicine because no such wavier exists...." (See APP- 72, 73,74) **exhibit 5-3c filed September 14, 2022, US Court of Appeals DC,** Congresswoman Grace Meng, Member of Congress Sixty District of New York, December 18, 2019).

DEA's, letter to **Richard Lawhern**,

" 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.

While DEA is the agency responsible for enforcing the CSA, DEA does not act as the Federal equivalent of a state medical board overseeing the general practice of medicine and lacks the authority to issue guidelines that constitute advice relating to the general practice of medicine..."

(See APP-92-93, **exhibit 5-6F,** Letter dated February 12, 2021, from: **Thomas W. Prevoznik, DEA Deputy Assistant Administrator Diversion Control Division,** to: Richard A. Lawhern, Ph.D. 3691 Nestling Lane Fort Mill, South Carolina 29708 lawhern@hotmail.com) (17)

In sum, the district court concluded from the *undisputed extrinsic evidence,* initially introduced during the court's pretrial hearing addressing the defendants' 12(b) motion to dismiss the indictment, including the HCFA letters, that the sales inducements did not constitute criminal activity in violation of § 1395nn(b)(1)(B), and that the defendants and those similarly situated could not, as a matter of law, have formulated the necessary intent to participate in a criminal act in violation of § 1395nn(b)(1)(B). (17),(18)

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, the Administrator 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)); (18)

The letters of DEA Thomas W. Prevoznik, DEA Deputy Assistant Administrator Diversion Control Division, act as a command exercising a privilege. The Court reaffirmed its pronouncements in Raley v. State of Ohio, in United States v. Laub, 385 U.S. 475, 87 S.Ct. 574, 17 L.Ed.2d 526 (1967), where it stated: Ordinarily, citizens may not be punished for actions undertaken in good faith reliance upon authoritative assurance that punishment will not attach. As this Court said in Raley v. State of Ohio, 360 U.S. 423, 438, 79 S.Ct. 1257, 1266, 3 L.Ed.2d 1344, we may not convict " a citizen for exercising a privilege which the State clearly had told him was available to him." As Raley emphasized, criminal sanctions are not supportable if they are to be imposed under "vague and undefined" commands (citing Lanzetta v. State of New Jersey, 306 U.S. 451, 59 S.Ct. 618, 83 L.Ed. 888 (1939)); or if they are "inexplicably contradictory" (citing United States v. Cardiff, 344 U.S. 174, 73 S.Ct. 189, 98 L.Ed. 200 (1952); and certainly not if the Government's conduct constitutes " active misleading language".

Thus we have based our argument here that the DEA Administrator has attained "omnipotent powers" not granted by Congress and has been wrongfully excersizing the use of their ill-attained authority to regulate the practice of medicine by criminalizing good faith medical mistakes being freely able to move the goal post backward and forward generate rules policy and law without proper notice or hearing required by Congress See 21 U.S.C. § 903., and further act as the Federal equivalent of a state medical board overseeing the general practice of medicine while they have lacked the authority to issue guidelines that constitute advice relating to the general practice of medicine."...dictating what a doctor prescribes to a patient, promulgating regulations regarding the treatment of pain, imposing specific quantitative minimum or maximum limit (a subjective standard of 90MME) on the amount of medication that may be prescribed on a single prescription on the duration of treatment intended with the prescribed controlled substance, simply

"The DEA lacks the authority to issue guidelines that constitute advice relating to the general practice of medicine. (see App. 16-19 App. 72,73,74,92,93)

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17. The assignment of error confronting this appellate review was initially resolved by the United States Supreme Court in *Raley v. State of Ohio,* 360 U.S. 423, 79 S.Ct. 1257, 3 L.Ed.2d 1344 (1959). In that action defendants had been convicted for refusing to answer certain questions before the "Unamerican Activities Commission of the State of Ohio". The defendants had invoked the privilege against self-incrimination after various commission members, including the chairman, erroneously advised them that the enabling legislation extended them the right against self- incrimination. Subsequently, defendants were indicated in the state court for exercising the privilege. They were convicted. The conviction was affirmed by the Supreme Court of Ohio.

18. In reversing the defendants' conviction, the United States Supreme Court concluded that: "the judgments of convictions rendered below violate the Due Process Clause of the Fourteenth Amendment. . . . [H]ere the Chairman of the Commission, who clearly appeared to be the agent of the State in a position to give such assurances, apprised three of the appellants that the privilege in fact existed, and by his behavior toward the fourth obviously gave the same impression. . . . [H]ere the crime said to have been committed by the appellants, as defined by the State Supreme Court, was simply that of declining to answer any relevant question on the ground of possible self-incrimination.....While there is no suggestion that the Commission had any intent to deceive the appellants, we repeat that to sustain the judgment of the Ohio Supreme Court on such a basis after the Commission had acted as it did *would be to sanction the most indefensible sort of entrapment by the State — convicting a citizen for exercising a privilege which the State clearly had told him was available to him. Cf. Sorrells v. United States,* 287 U.S. 435, 442, 53 S.Ct. 210, 212, 77 L.Ed. 413. "

19. A state may not issue commands to its citizens, under criminal sanctions, in language so vague and undefined as to afford no fair warning of what conduct might transgress them. *Lanzetta v. State of New Jersey,* 306 U.S. 451, 59 S.Ct. 618, 83 L.Ed. 888. Inexplicably contradictory commands in ....*United States v. Cardiff,* 344 U.S. 174, 20. 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.")

C. THE GOVERNMENT FAILED TO PROVE BY A PREPONDERANCE OF THE EVIDENCE THAT THE PETITIONER DISPENSED PRESCRIPTIONS WITHOUT RESOLVING "RED FLAGS"

The regulation at the heart of this case, 21 C.F.R. § 1306.04(a), provides: "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 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. In this case 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. Supreme Court 9-0 Ruan-Khan vs United States could not be met to establish criminal negligence and falsely established diversion based solely on the use of "red flags "and performed absolutely no investigation in Ruan v. United States holding that "§841(a)(1) and § 1306.04(a) require the government to provide that a practitioner-defendant either:

(1) subjectively knew a prescription was issued not for a legitimate medical purpose; or

(2) issued a prescription that was objectively not in the usual course of professional practice." Going strictly by "pill," numbers is not enough to support a prosecution. The government must prove that a doctor prescribed controlled substances for no "legitimate medical reason" to impose criminal liability as a violation of Section 841(a) of the Controlled Substances Act. United States v. Outler, 659 F.2d (see Ruan v. United States, App-14)

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.

The Government's expert, Dr. Sullivan, testified at length that the prevailing professional standard of care applicable to the Petitioner requires the Petitioner and its pharmacists to conduct a prospective drug utilization review and attempt to resolve "red flags" – i.e., indicia of diversion or abuse – before filling (or refusing to fill) a prescription for controlled substances. Dr. Sullivan opined that there are many options available to a pharmacist to address "red flags," including, *inter alia*, speaking with, observing, or even conducting a physical examination of the patient, communicating with the prescriber, and reviewing PDMP data. He also emphasized that there is no "one size fits all" approach to conducting a prospective drug utilization review, as each patient and prescription may present different circumstances that the pharmacist, in the exercise of his or her independent professional judgment regarding whether a prescription was issued for a legitimate medical purpose, must consider. Dr. Sullivan was adamant that, whatever efforts a pharmacist may make to resolve "red flags," the prevailing standard of professional care absolutely and unequivocally requires that the pharmacist must document his efforts somewhere, whether in the pharmacy's patient record management system (a/k/a, the "patient profile") or, notably, on the face of the prescription itself. It is in this regard that the Government's first contention falls short.

It is beyond peradventure that the Government seized data from the Petitioner during the execution of the OSC. It is also unquestionable that these data included images of the actual prescriptions filled by the Petitioner during the relevant time period. Indeed, in the pre-hearing phase of this proceeding, the parties extensively briefed this Tribunal on the whereabouts of the prescription image data seized by DEA.

The Petitioner alleged that when the DEA eventually returned Petitioner's computer equipment several months after the initial seizure, the Petitioner discovered that the data were corrupted and/or rendered inaccessible in its computer system and certain items of hardware had been destroyed while in DEA custody. Through these pre-hearing proceedings, it became clear that the Government was able to obtain images of the actual prescriptions filled by the

Petitioner. In fact, the Government included excerpts of certain prescription images in the demonstrative exhibit it used extensively at the hearing.

Remarkably, though it clearly had these documents in its possession, the Government did not seek to introduce **any** of the original prescriptions, or even electronic images thereof, into evidence at the hearing. The Government's expert also testified that he had not reviewed any of the actual prescriptions or images thereof, and had not asked the DEA to provide those documents to him for review. Instead, the Government relied solely upon PDMP data – spreadsheet reports that DI Albert testified were generated from the PDMP and/or E-FORSCE databases.

The Government's exclusive reliance on PDMP data and its expert's review thereof to prove that "red flags" were not resolved was insufficient for at least one glaring reason: its own expert testified that the prevailing standard of professional care required the Petitioner to document the resolution of "red flags" in one of two places – either in the "patient profile" (i.e., in the Appellant's patient management computer system), or *on the face of the prescription itself.* It would confound logic to conclude, as the Government invites us to do, that the evidence demonstrates that Appellant failed to resolve "red flags" when the record is utterly devoid of even so much as a single, actual prescription. Stated differently, if the Petitioner had the option to document resolution of "red flags" on the face of the prescriptions, but there is no record evidence before this Tribunal to suggest whether the Respondent documented resolution of "red flags" on the prescriptions (i.e., because there are no prescriptions in evidence), then it cannot be said that the Appellant, in fact, failed to document its resolutions or attempted resolutions of "red flags." At best, the likelihood that the Petitioner resolved the "red flags" is equal to the likelihood that it failed to do so. We reach this conclusion because, as noted above, only half of the relevant evidence on this question is before us. To prove a factual assertion by a preponderance of the evidence, the Government must, at a minimum, show that it is more likely that not that the Petitioner failed to resolve the "red flags" in question. It has not done so.

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.

In this 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.

Further 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 Pronto Pharmacy filled were not issued for a legitimate medical purpose.

A state may not issue commands to its citizens, under criminal sanctions, in language so vague and undefined as to afford no fair warning of what conduct might transgress them. *Lanzetta v. State of New Jersey,* 306 U.S. 451, 59 S.Ct. 618, 83 L.Ed. 888. Inexplicably contradictory commands in statutes ordaining criminal penalties have, in the same fashion, judicially been denied the force of criminal sanctions. *United States v. Cardiff,* 344 U.S. 174,

D. THE GOVERNMENT FAILED TO PROVE THAT THE RESPONDENT "MANUFACTURED," RATHER THAN "COMPOUNDED," SCHEDULE II CONTROLLED SUBSTANCES

The other theory advanced by the Government is that the Appellant engaged in illegal "manufacturing" of Schedule II controlled substance, as opposed to permissible "compounding" of those materials. Applying the legal framework of the CSA, the Government thus contends that under factor 2 of § 823(e), the Respondent has not complied with applicable federal, state and local law. Accordingly, before

turning to a consideration of the evidence before us, we must consider the requirements of applicable federal, state, and local law. (see. APP-52-54)

The Appellant is registered with the DEA to "dispense" Schedule II controlled substances. The CSA defines "dispense" to mean "to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or **compounding** necessary to prepare the substance for such delivery." 21 U.S.C. § 802(10) (emphasis supplied). (see. APP 138-150)

The statute also defines the term "manufacture" to mean "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.** 21 U.S.C. § 802(15) (emphasis supplied). (see App 30-35)

The CSA does not supply a definition of "compounding." However, because the CSA refers to the "compounding . . . of a drug . . . in conformity with applicable State or local law," we can look to State law to supply the relevant definition.

Under Florida law, "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." FAC Rule 64B16-27.700. Pursuant to Rule 64B16-27.700, compounding specifically includes the following three (3) activities:

- The preparation of drugs or devices **in anticipation of prescriptions based on routine, regularly observed prescribing patterns.**

- The preparation pursuant to a prescription of drugs or devices which are not commercially available.

- **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.

FAC Rule 64B16-27.700(1) (emphasis supplied).
Another federal law also provides guidance regarding the circumstances under which a pharmacist may compound drugs. The Federal Food, Drug, and Cosmetic Act (hereinafter, the "FDCA") imposes certain requirements upon those who produce drugs for human use. *See* 21 U.S.C. §§ 301-392, *et seq.* Sections 501, 502, and 505 of the act set forth the obligations of human drug producers with respect to the implementation of current good manufacturing practices, drug labeling and directions for use, and the approval of new drug applications or abbreviated new drug applications. 21 U.S.C. §§ 351, 352, 355.

However, a licensed pharmacist in a State licensed pharmacy who compounds human drug products is exempt from the aforementioned requirements of the FDCA if certain conditions are met. 21 U.S.C. § 353a(a). Specifically, there are two (2) circumstances in which the compounding exemption applies, to wit-

- If the drug is compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, on the prescription

- order for an individual patient made by a licensed physician or other licensed practitioner authorized by state law to prescribe drugs, or

- If the drug is compounded by a licensed pharmacist or licensed physician **in limited quantities before the receipt of a valid prescription order** for such individual patient if the compounding is **based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the human drug product,** and the orders have been generated solely within an **established**

- **relationship between the licensed pharmacist or licensed physician and either such patient for whom the prescription order will be provided or the physician or other licensed practitioner who will write such prescription order.**

21 U.S.C. § 353a(a)(2)(A) (emphasis supplied).

The latter practice described above, known as "anticipatory compounding," can be beneficial not only because larger batch sizes can increase efficiency and reduce the likelihood of human error associated with small batch compounding, but also because the limitations set forth in the statute serve to distinguish licensed pharmacists practicing permissible "compounding" under 503A of the FDCA from conventional manufacturers, who generally produce larger quantities of drugs that are distributed without a prescription.

With all of the foregoing framework in mind, it would be fair to summarize the distinction between "manufacturing" and "compounding," for purposes of applying the CSA in the instant proceeding, as follows:

- "manufacturing" means the production of drugs, but does not include "compounding" in conformity with State and local law.

Neither the CSA nor the FDCA expressly defines "compounding," but Florida law supplies the definition:

- Under Florida law, "compounding" is the incorporation of ingredients to create a finished drug product for dispensing to a patient, and specifically includes, *inter alia*, anticipatory compounding and preparation of commercially available products from bulk. (see APP-145-158, 374-378)

- Anticipatory compounding may be practiced, in compliance with each of the federal and state laws referenced herein, by a licensed pharmacist in a State licensed pharmacy so long as the conditions of 21 U.S.C. § 353a(a)(2)(A) are satisfied. (see App 136-144, 368-373) (see OTSC App- 381-383)

Turning to the evidence before us, we cannot conclude that the Appellant was engaged in "manufacturing" as that term is defined by the CSA. The evidence

included approximately 51 pages of batch records for limited quantities of two (2) different strengths of hydromorphone, a Schedule II controlled substance. GE 5, 6. DI Albert was unable to identify the signatures and initials contained on these batch records and did not compare the number of doses of capsules reflected in the batch reports to the amount of drugs dispensed by the Appellant. There was no evidence that Appellant produced significantly large quantities of any drug, nor was there any evidence that Appellant sold or wholesaled any drug, in any quantity, to any distributor or reseller (such as would be expected in the case of a traditional drug manufacturer, whose business model typically involves the distribution of drugs to third parties without a prescription). (App. 137-139)

There was also no evidence to suggest that the single drug compounded by Appellant was not compounded in anticipation of receipt of valid prescriptions based upon established historical relationships with patients to whom the drug was prescribed and providers who prescribed it.

In fact, the evidence of record demonstrates that the Appellant dispensed a significant amount of hydromorphone, and Dr. Sullivan testified about the dispensing of this drug by Appellant on several occasions. In short, the evidence appears to suggest that the Petitioner's Pronto Pharmacy engaged in permissible anticipatory compounding in compliance with applicable federal and state law. (see APP-137-138) Such practice is, according to the CSA, not encompassed within the definition of "manufacturing." 21 U.S.C. § 802(15).

In order to prosecute a pharmacist does the DEA have the authority to move the goal post backward and forward, redefine a golf ball as a football, change the rules of the game while in the game, to regulate the practice of medicine and pharmacy by unenumerated "red flags," not developed by notice and comment, statues or medical expertise and enforcing such authority thru forfeiture laws, revocations certificates of registration while, "lacking the authority to promulgate rules." (see APP-139,149,150, see also App 16-19, App 72,73,74,92,93)

CONCLUSION

For the foregoing reasons, the revocation of Pronto Pharmacy's registration should be reversed and the Court should grant Petitioner's writ of certiorari as the decision in this case by this Court will have far-reaching effects on the professions of Medicine, and Pharmacy. The Petitioner is a Pharmacist Not a Street Drug Dealer.

Respectfully submitted

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OCTOBER 26, 2022

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