UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

Norman Clement,

Petitioner

Case: No. 21-1262

Drug Enforcement Administration,

Respondent

OUT OF A MOUNTAIN OF DESPAIR COMES A STONE OF HOPE

MOTION FOR A REHEARING UNDER FEDERAL RULES OF APPELLATE PROCEDURE, RULE 35

The Appellant moves, pro se, submits this Petition request under Rule 35 before entire Panel for Rehearing En Banc from a May 25, 2022 decision , barring a summary reversal of the DEA Administrative court and further based on United States Supreme Court ruling in Ruan-Khan vs. United States case: No- 20-1410.

STATEMENT AT ISSUE

Based on a June 27, 2022 U.S. Supreme Court Finding, the appellant moves pro se to request a reconsideration, in support of vacating the revocation of his pharmacy DEA license.

FACTUAL BACKGROUND

Pronto Pharmacy was searched and seized by the DEA. Pronto Pharmacy lacked requisite scienter and/or an intent to defraud. The DEA searched and seized video exculpatory equipment that has not been returned. Using an evidentiary standard of preponderance of evidence, the DEA revoked Pronto's Pharmacy 's DEA registration. Such action by the DEA, was improper. The Court can redress the harm.

Issue:
Was the proper evidentiary standard followed in the case of the revocation of Pronto Pharmacy DEA registration.

Rule
In *Ruan v. United States* (United States Supreme Court No. 20-1410, Decided June 27, 2022), the Supreme Court held that the proper evidentiary standard in cases alleging violations of the Controlled Substance Act, is beyond a reasonable doubt.

Analysis

Ruan provides : " A strong scienter requirement helps reduce the risk of "overdeterrence," i.e., punishing conduct that lies close to, but on the permissible side of, the criminal line."
Pursuant to an evidentiary standard of " preponderance of evidence, " Pronto Pharmacy's DEA registration was revoked . Furthermore, the basis for the opinions expressed by the DEA's expert witness allegations, were speculative. An objective standard of care was not proven. The revocation used the improper evidentiary standard and thus, improper.
As an actual and proximate cause of the revocation, Pronto Pharmacy was closed . Pronto's inventory and financial assets were seized by the DEA. The Apllelant suffered serious property and economic damage. The Court can redress the harm.

Conclusion
The Appellant requests that the Court vacates the Order of Revocation of Pronto's Pharmacy DEA registration. In the alternative, remand the case back to the trial court for adjudication under the proper evidentiary standard.

1. Did the Administrative Law Judge err in the DEA failing prove that the prescribing practitioners acted outside the bounds of professional medical practice to find PRONTO PHARMACY was and imminent danger, and having conducted No Investigation of any prescribing practitioner?

2. Did the Administrative Law Judge err by failing to examine the physician pharmacist role and the act upon the "good faith" of the prescribing practitioner and the DEA mere accusation of diversion without an investigation is speculation which is not sufficient in removing Pronto Pharmacy Controlled substance

Registry, and a life time sanction on the owners ability to practice pharmacy?

3. Did the Administrative Law Judge err by admitting expert testimony on a legal issue when the government expert testified as to the ultimate legal fact that prescriptions filled by Pronto Pharmacy were outside the bounds of a medical practice, the practice of pharmacy and being diverted without having interviewed any patients, prescribers. or conduct any meaningful investigation?

SUMMARY OF THE ARGUMENT

SCOTUS sides with the petitioner and Health Law Professors in Ruan v. United States 9-0 ruling that CSA Section 941 has a scienter requirement. Opinion by Justice Breyer here: https://supremecourt.gov/opinions/21pdf/20-1410_1an2.pdf (1)

According to Professor Jennifer Oliva of Heath Care Law amicus brief Ruan vs. United States, once a doctor proves that they are authorized to prescribe a controlled substance (e.g., has state & federal registration), the government must PROVE BEYOND A REASONABLE DOUBT that doc KNEW or INTENDED that their prescribing conduct was unauthorized under the CSA.

This means that the doc must have known or intended to prescribe outside the legit bounds of medical practice. Not enough for DEA to say "we think this is outside the bounds." Must prove that doc knew it was outside the bounds.

Oliva, who co-authored an amicus brief in support of the doctors in the case, said that the DEA has increasingly been given authority to punish providers for whatever it deems to be improper practice,

when that should be under the jurisdiction of state medical boards. (2)

RUAN, KHAN vs. DOJ-DEA 9-0 RULING BEFORE SUPREME COURT UNITED STATES

THE CONTROLLED SUBSTANCES ACT ONLY CRIMINALIZES ACTIVITIES OUTSIDE THE USUAL COURSE OF A DOCTOR'S PROFESSIONAL PRACTICE.

June 27, 2022, in a separate and related case ruling 9-0 of the United States Supreme Court Justice Stephen Breyer in summary wrote for the majority that prosecutors must prove that doctors knew they were illegally prescribing powerful pain drugs in violation of the federal Controlled Substances Act.

When Congress enacted the Controlled Substances Act, it recognized that many drugs and substances regulated under the statute "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). Congress, therefore, established five schedules to classify drugs and substances based on their accepted medical use for treatment, the relative potential for abuse, and the likelihood of dependence if abused. S e *id.* § 812.

Scienter requirements advance fundamental principles of criminal law by helping courts "separate those who understand the wrongful nature of their act from those who do not." *Rehaif* v. *United States*, 139 S. Ct. 2191, 2196 (2019) (internal quotation marks omitted).

Congress prohibited a doctor from "knowingly or intentionally" dispensing a controlled substance except as authorized by relevant

provisions of the Controlled Substances Act. 21 U.S.C. § 841(a). violations of this provision may result in felony convictions. *United States* v. *Moore*, 423 U.S. 122, 134 (1975). Congress specifically criminalized "the diversion of drugs from legitimate to illegitimate channels," *id.* at 135, recognizing that no doctor may knowingly act "as a drug pusher," *id.* at 138 (internal quotation marks omitted). (3)

STATEMENT OF FACTS

The Administrative Court committed plain error , deprivation of rights under a quasi-judicial setting when it allowed testimony from DEA Diversion Investigator Albert and pharmacist expert Don Sullivan failed to investigate whether the prescriptions were issued in good faith by the practitioners or that they were assisting in the maintenance of a drug habit or simply put, whether issuing a prescription under the suspicion that the patients might be misusing them is that is outside the bounds of professional medical practice. A pharmacist is licensed to fill prescriptions base on the "good faith" of the prescribing practitioners engaged in the lawful practice of medicine and dentistry.

Notably to convict a practitioner under 841(a) the government must prove that the practitioner acted with intent to distribute the drugs and with intent to distribute them outside the course of professional practice, that wasn't done on this case. (see United States v. Brizuela Case No-19-4656 (4th Cir Court of Appeals vacated June 20, 2020)

In order words, the jury must make a finding of intent not merely with respect to distribution , but also with respect to the doctors intent to act as a pusher rather than a medical professional. United States v. Feingold. 454 F3d 1001, 1008 (9th Cir. 2006) (emphasis in original). The CSA prohibits the knowing distribution of prescriptions issued without a legitimate medical purpose or outside

the usual course of professional practice." Unites States v. Lovern, 590 F.3d 1095, 1109 (10th Cir. 2009) (emphasis in original).

FEDERAL LAW ENFORCEMENT AGENCIES ARE UNQUALIFIED TO DETERMINE WHETHER DRUGS "HAVE A USEFUL AND LEGITIMATE MEDICAL PURPOSE

The Supreme 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 us- ing 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 un- ambiguous."). 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 diversion 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 prosecution 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 determination is "[t]he recommendation of the appropriate State licensing board or professional disciplinary authority").

Conclusion

The Appellant requests that the Court vacates the Order of Revocation of Pronto's Pharmacy DEA registration. In the alternative, remand the case back to the trial court for adjudication under the proper evidentiary standard.

WHEREFORE, WE REQUEST UPON THIS COURT:

1. Grant this motion and reverse these 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 $587 million U.S. dollars, I've lost my life savings

RESPECTFULLY SUBMITTED

July 3, 2022

Norman J Clement

Norman J Clement, pro se

Table of Authorities

1. https://youarewithinthenorms.com/2022/07/02/doj-dea-acting-with-scienter-in-484-million-dollars-healthcare-fraud-allegations-

against-pain-center-exposed-and-defeated-by-team-of-attorneys-led-by-chapman-law-firm/

2. https://supremecourt.gov/opinions/21pdf/20-1410_1an2.pdf

3. https://filtermag.org/supreme-court-pain-dea/?utm_source=twitter&utm_medium=social&utm_campaign=filter

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on July 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 July 03, 2022. I certify further that Petitioner is *pro se*, and that service will is accomplished by electronic mail to

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