No. 24-

IN THE

Supreme Court of the United States

DR. RONALD LUBETSKY,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The Circuits have applied vastly different interpretations of the ambiguous phrase "outside the usual course of his professional practice, other than for a legitimate medical purpose." *Ruan v. United States*, 597 U.S. 450, 459 (2022); *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006); *United States v. Moore*, 423 U.S. 122, 135 (1975). Circuits applying this phrase in the disjunctive have convicted physicians of a "knowing or intentional" deviation from an unenumerated "standard of care." The questions presented are:

Whether the phrase to measure authorization under 21 U.S.C. § 841(a) can be applied in the disjunctive.

If the phrase is applied in the disjunctive, whether the prosecution of a physician for a deviation of an unenumerated "standard of care" is an improper exercise of the Commerce Clause.

PARTIES TO THE PROCEEDING

Petitioner, defendant-appellant below, is Dr. Ronald Lubetsky.

Respondent is the United States of America, appellee below.

RELATED PROCEEDINGS

United States v. Ronald Lubetsky, No. 23-10142, United States Court of Appeals for the Eleventh Circuit. Judgments entered February 13, 2024 and May 7, 2024.

United States v. Ronald Lubetsky, No. 22-14087, United States Court of Appeals for the Eleventh Circuit, Judgment entered December 10, 2022.

United States v. Ronald Lubetsky, No. 1:21-cr-20485-DMM-1, United States District Court for the Southern District of Florida, Judgment entered January 11, 2023.

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The opinion of the Court of Appeals is not reported. See Petitioner's Appendix ("App. 1a-4a"), *infra*, 1a-4a. The order of the Eleventh Circuit denying rehearing is not reported. See App., *infra*, 5a-6a.

JURISDICTION

The Eleventh Circuit entered judgment on February 13, 2024. The court of appeals denied rehearing on May 7, 2024. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Section 841(a)(1) of the Controlled Substances Act, 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) provides:

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

Fla. Stat. Ann. § 456.44(3)(a) provides:

> (3) STANDARDS OF PRACTICE FOR TREATMENT OF CHRONIC NONMALIGNANT PAIN.—The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.

> (a) A complete medical history and a physical examination must be conducted before beginning any treatment and must be documented in the medical record. The exact components of the physical examination shall be left to the judgment of the registrant who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of previous medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance. Each registrant must develop a written plan for assessing each patient's risk of aberrant drug-related behavior, which may include patient drug testing. Registrants must assess each patient's risk for aberrant drug-related behavior and monitor that risk on an ongoing basis in accordance with the plan.

INTRODUCTION

The 91st Congress passed the Controlled Substances Act ("CSA") which was signed into law by President Richard Nixon in 1970. The CSA was intended to strengthen rather than weaken existing law enforcement authority in the field of drug abuse. *Moore*, 423 U.S. at

132. That intent, however, existed alongside the desire to more clearly delineate the boundaries of authorized prescribing. *See Id.* at 144 ("The practicing physician has . . . been confused as to when he may prescribe narcotic drugs for an addict. Out of a fear of prosecution many physicians refuse to use narcotics in the treatment of addicts except occasionally in a withdrawal regimen lasting no longer than a few weeks. In most instances they shun addicts as patients.") (citing Report of the President's Advisory Commission on Narcotic and Drug Abuse 56-57 (1963), quoted in H. R. Rep. No. 91-1444, pp. 14-15). Whereas criminal prosecutions in the past had turned on the opinions of federal prosecutors, the CSA provided that "[t]hose physicians who comply with the recommendations made by the Secretary will no longer jeopardize their professional careers. . . ." *Id.* (citing H. R. Rep. No. 91-1444, p. 15).

The CSA was structured as a closed system of distribution, making it unlawful for "any person knowingly or intentionally . . . to manufacture, distribute, or dispense" a controlled substance, "[e]xcept as authorized by this subchapter." 21 U.S.C. § 841(a)(1). "[T]his subchapter" authorizes persons who have registered with the Attorney General to distribute controlled substances "to the extent authorized by their registration." *Id.* § 822(b). The Act also directs the Attorney General to accept the registration of a medical doctor or other practitioner if he is "authorized to dispense . . . controlled substances under the laws of the State in which he practices." 21 U.S.C. § 823(f).

This Court, in *Moore*, acknowledged that the CSA "does not spell out . . . in unambiguous terms" when physicians may be subject to prosecution for federal

narcotics offenses. 423 U.S. at 140. Nonetheless, drawing on 21 C.F.R. § 1306.04(a) and the CSA's predecessor statute (the Harrison Anti-Narcotic Law, 38 Stat. 785), the Court held that a physician registered with the Attorney General may be prosecuted under Section 841(a)(1) if his "activities fall outside the usual course of professional practice." *Id.* at 124; *see id.* at 136 n.12, 138-143. The Court noted, however, that "the usual course of professional practice" stopped where "drug trafficking" began. *See Id.* at 137 (noting that the harsh penalties for unlawful distribution were deemed by Congress to be an appropriate sanction for *drug trafficking* by a registered physician).

That distinction between "the usual course of professional practice" and "drug trafficking" was what initially animated CSA prosecutions. In *United States v. Badia*, 490 F.2d 296 (1st Cir. 1973), for example, a physician was convicted of unauthorized prescribing where a federal agent testified that, on three occasions, he was provided controlled substance prescriptions without any physical examination. *Id.* at 297. The agent also established that the physician knew the controlled substances were not intended nor used for therapeutic or medical purposes. *Id.* at 298 n.3 (testifying that the physician tried to sell the agent Ionamin because it was great for parties). Moreover, in *United States v. Green*, 511 F.2d 1062 (7th Cir. 1975), a physician was convicted of unauthorized prescribing where agents testified that they were prescribed Ritalin despite not having their medical history taken or a physical examination performed at any of their patient visits. *Id.* at 1066. The agents also testified that they informed the physician that they intended to use the Ritalin prescriptions for nonmedical purposes, for example, to "get high." *See Id.* One of the agents even

specifically informed the physician that he never used his prescriptions but instead sold them, to which the doctor replied: "Everybody has to make a living." *Id.*

There are, in fact, many cases through the 1970s to early 2000s where physicians were prosecuted and convicted for prescribing controlled substances in the complete absence of charting the patient's medical history, failing to administer any physical examinations, and prescribing despite unequivocal notice that the medications were not intended nor used for a legitimate medical purpose.[1] Or, in other words, these physicians

1. *United States v. Rosenberg*, 515 F.2d 190, 192 (9th Cir. 1975) (affirming unauthorized prescribing convictions where no physical examination was given, and undercover agents plainly stated that they had no medical problem for which they needed controlled substances but instead they had been buying the medications on the street but wanted a safer source).

United States v. Fellman, 549 F.2d 181, 182 (10th Cir. 1977) (affirming unauthorized prescribing convictions where physician never took undercover agent's medical history nor gave the agent a physical examination).

United States v. Potter, 616 F.2d 384, 386 (9th Cir. 1979) (affirming unauthorized prescribing convictions where little to no medical examination was given and where controlled substances were prescribed in exchange for sexual relations).

United States v. Blanton, 730 F.2d 1425, 1428 (11th Cir. 1984) (affirming unauthorized prescribing convictions where physician issued Schedule II N prescriptions for methaqualone even though he was not registered to do so).

United States v. Chin, 795 F.2d 496, 498 (5th Cir. 1986) (affirming unauthorized prescribing convictions where physician issued controlled substance prescriptions to numerous undercover

agents even though no valid medical reasons were given, and agents admitted that their spouse was abusing their prescriptions).

United States v. Hitzig, 63 Fed. Appx. 83, 84 (4th Cir. 2003) (affirming unauthorized prescribing convictions where physician never conducted physical examinations, failed to take adequate medical histories, violated patient confidentiality by sharing medical information with others, encouraged patients to share medications, used drugs and alcohol in the presence of patients, and engaged in improper sexual behavior with patients).

United States v. Jong Hi Bek, 493 F.3d 790, 796 (7th Cir. 2007) (affirming unauthorized prescribing convictions where physician provided no physical examination of undercover agents body or limbs, prescribed an undercover female officer Viagra despite not having any authorized indications for women, never requested past medical records or diagnostic imaging, and where assistant instructed the agents to simply ask the physician which drugs they wanted and directed the same agents where they could secure controlled substance prescriptions that the physician did not prescribe).

United States v. Merrill, 513 F.3d 1293, 1298 (11th Cir. 2008) (affirming unauthorized prescribing convictions where physician performed no or very minimal physical examination, did not obtain prior medical records, did not run tests to confirm compliance, issued prescriptions to patients that altered prescriptions, wrote a prescription for at least one patient that overdosed on controlled substances during his care, increased the dosage of patient prescriptions even though there were no new complaints of pain, and ignored warnings of possible addiction from insurance companies, pharmacies, and even previous doctors without taking any corrective action).

United States v. Maynard, 278 Fed. Appx. 214, 215 (3d Cir. 2008) (affirming unauthorized prescribing convictions where physician did not conduct a physical examination of undercover agents and issued controlled substance prescriptions even though the agents stated they were going to party with the drugs).

were found to be drug trafficking. And it was these cases, soon after the CSA's enactment, that formed the basis for the *Rosen* factors. *See United States v. Rosen*, 582 F.2d 1032 (5th Cir. 1978). There, the Fifth Circuit compiled a list of factors that it found to coincide with drug trafficking. That listed included:

> (1) An inordinately large quantity of controlled substances was prescribed.
>
> (2) Large numbers of prescriptions were issued.
>
> (3) No physical examination was given.
>
> (4) The physician warned the patient to fill prescriptions at different drug stores.
>
> (5) The physician issued prescriptions knowing that the patient was delivering the drugs to others.
>
> (6) The physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment.
>
> (7) The physician involved used street slang rather than medical terminology for the drugs prescribed.
>
> (8) There was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing.

> (9) The physician wrote more than one prescription on occasions in order to spread them out.

Id. at 1036. The Drug Enforcement Administration ("DEA") found that list persuasive and it was added to the Federal Register. 71 Fed. Reg. 52,720 (Sept. 6, 2006) (codified 21 C.F.R. § 1306). The DEA cautioned, however, that the existence of any of the *Rosen* factors alone should not automatically lead to the conclusion that a physician acted improperly. *See Id.* "Rather, each case must be evaluated based on its own merits in view of the totality of circumstances particular to the physician and patient." *Id.*

The CSA was thus initially used to prosecute physicians whose prescribing deviated so visibly from the usual course of professional practice that it followed that their prescribing was for other than a legitimate medical purpose. The Act, in that way, lived up to its stated goal of providing physicians with sufficient notice of what constitutes unauthorized prescribing. *Moore*, 423 U.S. at 144. Over time, however, that connective tissue between prescribing outside the usual course of professional practice and other than for a legitimate medical purpose has atrophied. The government now instead prosecutes physicians based on standards of professional practice that are increasingly disconnected from prescribing for other than a legitimate medical purpose such that physicians must "read between the lines" to intuit the parameters of prescribing in the usual course of professional practice. See App., *infra*, 17a-20a ("The drug doesn't feel good. It doesn't feel, you know, you know what I'm talking

about. Okay . . . You've got to read between the lines.").[2] Physicians thus no longer have fair notice of what constitutes unauthorized prescribing.

In short, the government has moved away from prosecuting physicians who are engaged in drug trafficking, opting instead to prosecute physicians even where their prescribing was for a legitimate medical purpose. For that reason and the reasons that follow, the government's enforcement of the CSA is no longer a valid exercise of its power under the Commerce Clause. *See Gonzales v. Raich*, 545 U.S. 1, 24-26 (2005) (finding that the CSA was designed to balance the beneficial use of medications while preventing their misuse for which there is an established interstate market of illegitimate channels).

This case serves as one example of the government's misguided enforcement.

STATEMENT OF THE CASE

A. Factual Background

Petitioner, Dr. Ronald Lubetsky, was a physician who held a valid DEA registration to prescribe controlled substances and was licensed to practice medicine in Florida. See Lubetsky Br. 10.

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2. As detailed below in the Factual Background, the confidential informant in this case faulted Petitioner for failing to decipher that her statement that the prescribed opioids made her "feel good" indicated that she was abusing and diverting her prescriptions instead of signaling that the opioids provided relief from the pain that she complained.

On September 21, 2021, a grand jury indicted Petitioner on twelve counts of unlawful distribution of controlled substances under 21 U.S.C. § 841(a)(1). App., *infra*, 2a. Each of the counts involved a prescription for oxycodone and counts 11 and 12 involved both oxycodone and morphine. See Indictment, Dkt. 3 (Sept. 21, 2021). None of the prescriptions listed in the indictment were issued to genuine patients, instead each was prescribed to a confidential informant or undercover agent. Lubetsky Br. 12. The government leapfrogged the thousands of established pain patients that Petitioner treated as part of his long-standing pain practice in Florida and instead indicted him based on twelve prescriptions issued to fictitious patients. Petitioner pleaded not guilty and was tried in the Southern District of Florida.

At trial, the government's medical expert, Dr. Rubenstein, testified that each of the twelve prescriptions in the indictment were issued outside the usual course of professional practice. Lubetsky Br. 15-16. The government expert also opined that Petitioner's prescriptions had "no basis," even though the expert did not testify that the prescriptions were issued for other than a legitimate medical purpose. Lubetsky Reply 13. According to the expert, Petitioner's prescriptions were unauthorized because there was a lack of an appropriate history and physical examination to warrant the prescriptions; this, in turn, meant that: "We don't even know what body part we're talking about. There's been no history of pain, there was no exam, there was nothing about what's going on with her physically; her complaints of pain, quality, character, intensity, duration, nothing, so certainly the oxycodone has no basis in terms of being prescribed, especially at a really toxic dose of 30 milligrams." *See Id.*

The government, however, only provided its expert with undercover recordings of the confidential informant's and undercover agent's patient visits, and many of the recordings only comprised of audio.[3] The expert was not provided, nor did he review, any patient medical records, diagnostic imaging, or prescribing histories.[4] App., *infra*, 12a-16a. The government expert also applied a standard for prescribing that exceeded the requirement for prescribing in Florida, which is where both Petitioner and the expert practiced medicine. The expert, to be sure, testified that, "[w]hen you're treating someone who has a severe pain problem, severe enough to warrant opioids, some form of exam is done every visit." App., *infra*, 10a-12a. In Florida, however, "[a] complete medical history and a physical examination must be conducted *before beginning* any treatment and must be documented in the medical record." Fla. Stat. Ann. § 456.44(3)(a). That examination must be "proportionate to the diagnosis that justifies a treatment." *Id*. There is no requirement in Florida that a physical examination be performed on follow up visits. Nor is there such a requirement that is fundamental to the practice of medicine. *See Rosen*, 582 F.2d at 1036 (highlighting the absence of physical examinations altogether).

At trial, Petitioner raised that Florida only required that he administer a physical examination before beginning opioid treatment. He had his medical expert,

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3. The undercover agent testified that many times the battery would not last long enough to capture video of the patient visits with Petitioner and therefore only audio was available for the expert to review. App., *infra*, 8a-10a.

4. Even though Petitioner was indicted for prescribing to a confidential informant and undercover agent, both had prior medical histories, including diagnostic imaging and past opioid prescriptions. See Lubetsky Br. 14 n.3, 15.

Dr. Sternberg, testify that in Florida "[t]he rule does not require a physical examination on every encounter. It does require physical examination prior to initiating opioid therapy." See Lubetsky Br. 34. In fact, none of the prescriptions for which Petitioner was indicted were prescribed on an initial patient visit. Instead, each prescription in the indictment was issued at a follow up patient visit. See Id. That did not matter. The government's expert held to his requirement that in Florida a physician must administer a physical examination whenever an opioid is prescribed. The expert, to this day, is committed to that opinion.[5]

Both the confidential informant and undercover agent testified at trial as well. The confidential informant testified that Petitioner did not take adequate measures to ensure she needed opioids for a legitimate medical purpose. In her view, the physical examination that Petitioner performed on her initial patient visit, the counseling that he offered her following her claims of homelessness, and the probing questions he asked to ensure that she returned to taking her opioids as prescribed were insufficient. See Lubetsky Br. 13, 18-20. Petitioner instead had to "read between the lines" and intuit that when the confidential informant stated that the prescribed opioids made her "feel good" that meant that she was using her medications recreationally and not for a legitimate medical purpose—*i.e.*, to alleviate the pain she was complaining about. App., *infra*, 17a-20a ("The drug doesn't feel good. It doesn't feel, you know,

5. For example, in *United States v. Morales*, No. 1:22-cr-20255-DPG-1 (2024), the same government expert testified that to practice in the usual course of professional practice in Florida, a physician must administer a physical examination whenever an opioid is prescribed. App., *infra*, 21a-24a.

you know what I'm talking about. Okay . . . You've got to read between the lines.").

Following the close of evidence and argument, the district court charged the jury. For the unlawful distribution counts the district court instructed that to find Petitioner guilty the government had to prove beyond a reasonable doubt that:

> 1. The Defendant dispensed a controlled substance to another person, **and**
>
> 2. The Defendant knowingly and intentionally dispensed the controlled substance *not* for a legitimate medical purpose as part of the medical treatment of a patient.

Court's Instructions to the Jury, Dkt. 54 (Nov. 3, 2022). The district court thus specifically instructed the jury that to find Petitioner guilty of unlawful distribution they had to find that he issued a controlled substance other than for a legitimate medical purpose. See Id.

Petitioner was convicted on seven of the twelve unlawful distribution counts and acquitted of the remaining five counts. App., *infra*, 2a. He was sentenced to 60 months of imprisonment for each guilty count, to be served concurrently. See Judgment, Dkt. 92 (Jan. 11, 2023).

B. The Court of Appeals' Decision

Petitioner appealed, raising that the government had failed to prove that he issued prescriptions other than for a legitimate medical purpose as instructed by

the district court. App., *infra*, 1a-4a. Petitioner argued that this Court in *Ruan* affirmed that the regulatory language to measure authorization, "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), is ambiguous and open to varying *constructions*. See Lubetsky Reply 10 n.3 (citing *Ruan,* 597 U.S. at 459). He highlighted to the court of appeals that the government medical expert applied a heightened standard for prescribing that exceeded what is required in Florida. *Id.* 7-8. He urged the court of appeals that it was not possible for the government medical expert to opine on whether prescriptions were issued other than for a legitimate medical purpose where the expert only reviewed undercover recordings—the expert did not review any patient medical records, diagnostic imaging, or prescribing histories. Lubetsky Br. 36-43. Based on all of this, Petitioner argued there was not sufficient evidence to sustain his unlawful distribution convictions. See Id.

The court of appeals rejected Petitioner's argument, invoking the prior panel precedent rule. The panel found that even though the district court had instructed that the jury had to find Petitioner prescribed other than for a legitimate medical purpose, that inquiry was irrelevant. App., *infra*, 3a-4a. Instead, under the court of appeals' holding in *United States v. Abovyan*, 988 F.3d 1288, 1305 (11th Cir. 2021), the panel found that a doctor violates § 841(a) if the 'legitimate medical purpose' or 'outside the scope of professional practice' requirement is met. App., *infra*, 3a-4a. According to the panel, *Abovyan* remains binding precedent following this Court's decision in *Ruan*. *Id.*

Petitioner sought rehearing, petitioning the court of appeals to reexamine *Abovyan* following this Court's decision in *Ruan*. He raised that the ambiguity in measuring authorization under Section 841(a)(1) leads to overdeterrence—*i.e.*, punishing conduct that lies close to, but on the permissible side of, the criminal line. Lubetsky Pet. for Reh'g 13-17. The Court in *Ruan* found that "[a] strong scienter requirement helps to diminish the risk of 'overdeterrence.'" 597 U.S. at 459. So too, Petitioner argued, does the conjunctive reading of § 1306.04(a) in measuring authorization. Lubetsky Pet. for Reh'g 13-17. To buttress his argument, Petitioner pointed to the circuit split on the disjunctive versus conjunctive reading and raised that the rule of lenity requires that the ambiguity in § 1306.04(a) be narrowly construed in favor of the defendant—*i.e.*, the conjunctive reading of the regulation as applied to 21 U.S.C. § 841(a). *Id.* At the very least, Petitioner probed the court of appeals to address in an opinion his arguments on the circuit split and rule of lenity. See *Id.* Neither of which the court of appeals has squarely addressed.

Indeed, in *United States v. Tobin*, 676 F.3d 1264 (11th Cir. 2012), *abrogated on other grounds by United States v. Davila*, 569 U.S. 597 (2013), while the court of appeals addressed the defendants' rule of lenity argument, it did so in the context of distributions and patient visits via the Internet. *Id.* at 1274-75. In that context, the court of appeals found no ambiguity to be present, and thus the defendants could not rely on the rule of lenity to escape liability under the CSA. *See Id.* The court of appeals did not, and has not, considered the rule of lenity as applied to § 1306.04(a)'s regulatory language which is "ambiguous" and "open to varying *constructions*." *See Ruan*, 597 U.S. at 459. Nor has the court of appeals reexamined the rule of

lenity following this Court's decision in *Ruan*. *See United States v. Heaton*, 59 F.4th 1226, 1239-40 (11th Cir. 2023) (disregarding the ambiguity and varying *constructions* that this Court found in *Ruan* and instead finding that the "plain language" of § 1306.04(a) resolves that the disjunctive reading is appropriate).

Rehearing was denied without comment. App., *infra*, 5a-6a.

REASONS FOR GRANTING THE PETITION

A medical doctor may be convicted under the CSA, 21 U.S.C. § 841(a)(1), if the government proves that he or she prescribed drugs "outside the usual course of professional practice." *Moore*, 423 U.S. at 124. This Court, however, has repeatedly found that phrase to be "ambiguous" and "open to varying constructions." *Ruan*, 597 U.S. at 459. That ambiguity has been the government's playground.

The government has continually moved the goal post on what constitutes the usual course of professional practice. As DEA Chief Administrative Law Judge, Hon. John J. Mulrooney, observed: "Although [ ] the Supreme Court has unambiguously clarified that the authority to set medical standards rests exclusively with the states, and is nowhere within the purview of the DEA, some recent Agency final orders have embraced the application of what the Agency has termed 'general practice standards' in ascertaining whether a practitioner has acted in the course of a professional practice."[6] *See Gonzales*, 546 U.S. at 270

6. John J. Mulrooney II and Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marq. L. Rev. 333,

(holding that the CSA manifests no intent to regulate the practice of medicine generally but instead States enjoy great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons). Such "general practice standards" include: failing to perform an appropriate physical examination; failing to utilize appropriate diagnostic testing; failing to devise and document a written treatment plan; failing to periodically reassess the effectiveness of treatment; continuing to prescribe controlled substances without pursuing alternative therapies; repeatedly and continually prescribing without referring the patient to appropriate specialists; and failing to keep and maintain records which contain adequate findings to support a diagnosis and the need to prescribe one or more medications.[7] Compare these "general practice standards" to the *Rosen* factors which the Fifth Circuit found coincided with drug trafficking. *See Rosen*, 582 F.2d at 1036. The comparison is jarring. What used to be a targeted approach aimed at preventing drug trafficking is now an exercise in restricting the way in which medicine is practiced.

Yet it is not only the DEA in administrative hearings that has crafted its own standard for prescribing controlled substances. In this case, for example, the government's medical expert crafted a standard for prescribing that exceeded what was required in Florida. The government expert testified that a physician must administer a physical examination whenever an opioid is prescribed for his prescribing to fall in the usual course

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385-86 (2017), https://scholarship.law.marquette.edu/mulr/vol101/iss2/3.

7. *Id.*

of professional practice. App., *infra*, 10a-12a. In Florida, however, the requirement is that a physical examination be administered before beginning opioid treatment. See Fla. Stat. Ann. § 456.44(3)(a). This is for good reason: many patients suffer from chronic pain that does not manifest via physical infirmity or impairment. As one chronic pain patient has written: "What would help me at this point would be to have practitioners who are not only more well-versed in chronic pain, but are willing to acknowledge its disabling impacts on their patients. In other words, doctors should start believing their patients when they say they are hurting."[8] The government, however, has pitted doctors against their patients in fear of prosecution for prescribing them pain medication. Indeed, one chronic pain patient estimates that she called more than 150 doctors in search of someone to prescribe her opioids: "A lot of them are straight-up insulting." "They say things like 'We don't treat drug addicts.'"[9]

What was once the protected and confidential relationship between physician *and* patient has been supplanted by physician *versus* patient as the government forces physicians to assume the role of investigator over healer, requiring these doctors to interrogate an already stigmatized patient population of chronic pain patients.

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8. Laura Kiesel, *Chronic Pain: The "Invisible" Disability*, Harv. Health Blog, Apr. 28, 2017, https://www.health.harvard.edu/blog/chronic-pain-the-invisible-disability-2017042811360.

9. Sam Whitehead and Andy Miller, *Chronic Pain Patients Struggle to get Opioid Prescriptions Filled, Even as CDC Eases Guidelines*, CNN Health, Mar. 17, 2023, https://www.cnn.com/2023/03/17/health/opioid-chronic-pain-cdc-guidelines-khn-partner/index.html.

See e.g., App., *infra*, 17a-20a ("The drug doesn't feel good. It doesn't feel, you know, you know what I'm talking about. Okay . . . You've got to read between the lines."). "Federal prosecutors appear unfazed by that distinction."[10]

The government's enforcement of the CSA is no longer a legitimate exercise of its power. This Court found in *Gonzales* that the CSA was valid under the Commerce Clause in part because it targeted drug trafficking—*i.e.*, the illegitimate channels of controlled substances for which there was an established and lucrative interstate market. See 545 U.S. at 26. Drug trafficking, however, is separate and distinct from the practice of medicine. *Id.* at 48 (O'Connor, J., dissenting, joined by Rehnquist, C.J., and Thomas, J.) ("Both federal and state legislation—including the CSA itself, the California Compassionate Use Act, and other state medical marijuana legislation—recognize that medical and nonmedical (i.e., recreational) uses of drugs are realistically distinct and can be segregated, and regulate them differently.").

As the government's enforcement of the CSA is increasingly removed from State-specific medical and prescribing requirements, it continues to test the outer limits of its authority under the Commerce Clause. In circuits that employ the disjunctive reading to measure authorization, like the Eleventh Circuit, the government is particularly successful at spreading the outer limits of its authority. In those circuits physicians are convicted of unlawful distribution based only on whether they deviate

10. Christopher Brown, *DOJ Keeps Up Pressure on Doctors Who Prescribe Opioids Illegally*, Bloomberg Law, Jan. 24, 2020, https://perma.cc/5WN2-YD2X.

from the federal government's heightened standard for prescribing in the usual course of professional practice—regardless of how disconnected that heightened standard is from State-specific prescribing requirements or prescribing for other than a legitimate medical purpose. See App., *infra*, 3a-4a.

The Court should grant certiorari to decide exactly how far the government's authority under the Commerce Clause extends and to resolve the circuit split on the disjunctive versus conjunctive reading in unlawful distribution cases.

I. THE DECISION BELOW CONFLICTS WITH DECISIONS OF OTHER CIRCUITS AND IS DIFFFICULT TO RECONCILE WITH THE DECISIONS OF THIS COURT

Every circuit court measures authorization using 21 C.F.R. § 1306.04(a)'s requirement that for a prescription to be effective it must be "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). Some circuits, however, read that requirement in the disjunctive whereas others read the requirement in the conjunctive. Still, others oscillate between the two different readings providing some physicians the benefit of the conjunctive formulation but convicting others if they deviate from either prescribing in the usual course of professional practice *or* prescribe for other than a legitimate medical purpose.

The Eleventh Circuit has adopted the disjunctive reading. *Tobin*, 676 F.3d at 1282; *Abovyan*, 988 F.3d

at 1305. "Put simply, the regulation [§ 1306.04(a)] has two requirements for a prescription to be effective: (1) 'a legitimate medical purpose' . . . (2) by a practitioner 'acting in the usual course of his professional practice.' Conversely, a prescription for controlled substances is unlawful if it is issued (1) without a legitimate medical purpose or (2) by the physician acting outside the usual course of professional practice. Thus, both requirements must be satisfied to make a prescription authorized." *Heaton*, 59 F.4th at 1240 (citations omitted). There, the court of appeals found that even following this Court's decision in *Ruan*, its disjunctive reading "remains binding precedent." *Id.* at 1241 n.17.

The Eleventh Circuit's disjunctive reading is in sharp conflict with the conjunctive reading of many other circuit courts. As detailed below, that conflict is only growing deeper as circuit courts are encouraged to reevaluate their disjunctive reading following this Court's decision in *Ruan*. The Eleventh Circuit's decision is also difficult to square with this Court's precedent.

A. THE COURTS OF APPEALS ARE DIVIDED ON THE DISJUNCTIVE VERSUS CONJUNCTIVE READING

The First, Second, Third, and Fifth Circuits have settled on the disjunctive reading and have remained faithful to that formulation. *United States v. Simon*, 12 F.4th 1, 24 (1st Cir. 2021)[11]; *United States v. Maye*, 649

11. The only decision that the First Circuit published following *Ruan* that relates to the disjunctive versus conjunctive reading is *United States v. Doe*, 49 F.4th 589 (1st Cir. 2022). There,

Fed. Appx. 15, 16 (2d Cir. 2016); *United States v. Cristobal*, No. 23-6107, 2024 U.S. App. LEXIS 8380, at *5-7 (2d Cir. Apr. 8, 2024) (finding sufficient evidence to sustain unlawful distribution conviction where evidence that prescribing fell outside the usual course of professional practice); *United States v. Belfiore*, No. 22-20, 2024 U.S. App. LEXIS 11311, at *3 (2d Cir. May 9, 2024) (same); *United States v. Rivera*, 74 F.4th 134, 138 (3d Cir. 2023) (binding precedent confirms the disjunctive reading to measure authorization); *compare United States v. Titus*, 78 F.4th 595, 602 (3d Cir. 2023) (finding jury instructions complied with *Ruan* where they required the jury to find defendant knowingly or intentionally distributed controlled substances outside the usual course of professional practice and not for a legitimate medical purpose); *United States v. Lamartiniere*, 100 F.4th 625, 638-43 (5th Cir. 2024).

The Sixth, Seventh, and Tenth Circuits have vacillated between the disjunctive and conjunctive readings. *See United States v. Bothra*, No. 2:18-cr-20800, 2022 U.S. Dist. LEXIS 84971, at *10-13 (E.D. Mich. May 11, 2022) (discussing how decades of convoluted Sixth Circuit case law has muddied the waters on the disjunctive versus conjunctive paradigm); *United States v. Oppong*, No. 21-3003, 2022 U.S. App. LEXIS 9475, at *15 (6th Cir. Apr. 8, 2022) (holding that "binding case law does not support [the conjunctive reading of the] jury-instructions.") *United*

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the First Circuit found that, under Massachusetts law, unlawful dispensing is the issuance of an invalid prescription . . . *i.e.*, one issued without a legitimate medical purpose and not in the usual course of the physician's professional practice. *Id.* at 600. There appears to be no unpublished opinions following *Ruan* on the divergent readings from the First Circuit.

States v. Bauer, 82 F.4th 522, 528 (6th Cir. 2023) (holding that registered doctors are among those authorized to prescribe controlled substances but only when issued for a legitimate medical purpose . . . acting in the usual course of his professional practice); *Jong Hi Bek*, 493 F.3d at 798; *United States v. Chube*, 538 F.3d 693, 699 (7th Cir. 2008); *compare United States v. Mikaitis*, 33 F.4th 393, 402 (7th Cir. 2022) (holding that to convict physician the government was required to prove that he knowingly distributed drugs outside the usual course of professional practice and not for a legitimate medical purpose); *United States v. Hofschulz*, No. 21-3403 & 21-3404, 2024 U.S. App. LEXIS 15366, at *13 (7th Cir. Jun. 25, 2024) (finding the conjunctive reading is an accurate statement of the law and fully compliant with *Ruan*); *United States v. Nelson*, 383 F.3d 1227, 1232-33 (10th Cir. 2004); *but see United States v. Kahn*, 58 F.4th 1308, 1316 (10th Cir. 2023) (finding that "outside the course of professional practice" is an objective measure of a physician's prescribing and that *Ruan* held the government must prove the defendant subjectively knew or intended to prescribe in an unauthorized manner).

The Eighth and Ninth Circuits appear to have settled on the conjunctive reading. *See United States v. Smith*, 573 F.3d 639, 649 (8th Cir. 2009); *Feingold*, 454 F.3d at 1012; *see also United States v. Wilson*, 850 Fed. Appx. 546, 547 (9th Cir. 2021); *United States v. Kabov*, No. 19-50083, No. 19-50089, 2023 U.S. App. LEXIS 18214, at *15 (9th Cir. Jul. 18, 2023) (finding no issue with district court's conjunctive instruction but remanding for the lower court to decide whether the instruction complied with the required *mens rea* following *Ruan* and *Rehaif*); *United States v. Motley*, No. 21-10296, 2023 U.S. App. LEXIS 34494, at *7 (9th Cir. Dec. 29, 2023) (finding no error with lower court's conjunctive jury instruction).

The Eighth Circuit, however, has hinted that it may have moved to the disjunctive reading instead. *See United States v. Elder*, 682 F.3d 1065, 1068-69 (8th Cir. 2012); *but see United States v. King*, 898 F.3d 797, 807 (8th Cir. 2018) (citing to *Smith*, 573 F.3d at 647-49 and suggesting that the conjunctive reading is appropriate).[12]

The Fourth Circuit, while seemingly adopting the disjunctive reading prior to *Ruan*, has indicated that it is now leaning toward the conjunctive reading. *United States v. Hurwitz*, 459 F.3d 463, 475 (4th Cir. 2006) (holding to convict a physician for unlawful distribution the government must prove, inter alia, that the defendant's actions were not for legitimate medical purposes in the usual course of his professional medical practice *or* were beyond the bounds of medical practice); *compare United States v. Smithers*, 92 F.4th 237, 246-47 (4th Cir. 2024) (finding that *Ruan* requires that a physician knowingly or intentionally prescribed in an unauthorized manner but that acting outside the bounds of medical practice is a purely objective standard and thus instructions phrased in the disjunctive are improper); *Id.* at 250 n.5 (directing that the panel does not reach whether a disjunctive jury instruction is an accurate statement of the law post-*Ruan*).

The Eleventh Circuit has endorsed, and continues to endorse, the disjunctive reading to measure authorization.

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12. The Eighth Circuit has not published an opinion on the disjunctive versus conjunctive reading following this Court's decision in *Ruan*. There also appears to be no unpublished opinions. The one published opinion following *Ruan* appears to be *United States v. Cardwell*, 71 F.4th 1122 (8th Cir. 2023). That opinion, however, does not address the divergent readings nor does it involve a controlled substance prescribed by a medical practitioner. *See Id.* at 1124.

Heaton, 59 F.4th at 1240. It does so despite acknowledging, like the Fourth Circuit, that the "usual course of professional practice" is a purely objective standard. *See Tobin*, 676 F.3d at 1282. There, the court of appeals dismissed concerns that its disjunctive reading would create a strict liability offense, speculating that the possibility that a practitioner will unknowingly run afoul of the CSA is extremely low because, "[i]n general, the CSA incorporates the applicable state standard of professional practice, and thus it holds practitioners to standards to which they are already bound." *Id.* at 1283 n.10. That premonition, of course, could not be further from the truth given that the government, through its experts, continues to erect its own heightened and unenumerated standard for prescribing. When confronted with that heightened standard in this case, the court of appeals resolved that issue to a footnote and omitted the issue from its analysis. See App., *infra*, 2a n.1.

Petitioner emphasized to the court of appeals that the circuits were split as to whether to apply the disjunctive versus conjunctive reading. Lubetsky Br. 32-33. He highlighted to the court of appeals that the government's medical expert applied a heightened standard for prescribing that exceeded what is required in Florida. Lubetsky Reply 7-8. He urged the court of appeals that it was not possible for the government expert to opine on whether prescriptions were issued other than for a legitimate medical purpose where the expert only reviewed undercover recordings—the expert did not review any patient medical records, diagnostic imaging, or prescribing histories. Lubetsky Br. 36-43. And he pressed the court of appeals that the rule of lenity should move it to adopt the conjunctive reading. *Id.* 32-33; *Ruan*, 597 U.S. at 459 (affirming that the regulatory

language defining authorization is ambiguous and open to varying *constructions*). The panel, in an unpublished opinion, invoked the prior panel precedent rule and in turn deferred to the court of appeals' disjunctive reading. See App., *infra*, 2a-4a. Petitioner's en banc petition was denied without comment. App., *infra*, 5a-6a.

Absent this Court's intervention, the circuit split will remain unresolved, and physicians will continue to be convicted based on shifting prescribing standards that exceed those required in the state in which the physician practices. That, in turn, restricts the types of medications that patient populations can access based on whether the physicians in their state are adjudicated on the disjunctive versus conjunctive reading.

B. THE COURT OF APPEALS' DECISION IS INCONSISTENT WITH THIS COURT'S CASE LAW

Each and every time this Court has had the opportunity it has been clear that Section 1306.04(a)'s regulatory language defining an authorized prescription is ambiguous, written in generalities, susceptible to more precise definition and open to varying *constructions*. *Ruan,* 597 U.S. at 459. There, the Court found that "[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." *Id.* A strong scienter requirement means nothing, however, if the conduct that it is applied to is a moving target, vague and incapable of a common definition. And that's exactly what "the usual course of professional practice" has devolved into under the Eleventh Circuit's disjunctive

reading. On that basis, the disjunctive reading should be set aside for the conjunctive reading of the regulatory language. See Lubetsky Br. 32.

Moreover, the conjunctive reading is required under the rule of lenity. Petitioner raised the rule of lenity to the court of appeals, arguing that the ambiguity in § 1306.04(a)'s regulatory language, as applied to 21 U.S.C. § 841(a)(1), should be construed narrowly in favor of the defendant—that is, the regulatory language should be read in the conjunctive when measuring authorization. Lubetsky Br. 33; *see Ladner v. United States*, 358 U.S. 169, 178 (1958).[13] This is doubtless given that the government has extended prosecution under § 841(a)(1) to prescribing that squarely falls within the usual course of professional practice of specific states but nonetheless exceeds the government's heightened prescribing standard. *See*

13. *See Gundy v. United States*, 139 S. Ct. 2116, 2144-45 (2019) (Gorsuch, J., dissenting, joined by Roberts, C.J., and Thomas, J.) ("To allow the nation's chief law enforcement officer to write the criminal laws he is charged with enforcing—to unit[e] the legislative and executive powers . . . in the same person—would be to mark the end of any meaningful enforcement of our separation of powers and invite the tyranny of the majority that follows when lawmaking and law enforcement responsibilities are united in the same hands."); *Whitman v. United States*, 135 S. Ct. 352, 354 (2014) (Scalia, J., respecting denial of certiorari) ("[T]he rule of lenity . . . vindicates the principle that only the legislature may define crimes and fix punishments. Congress cannot, through ambiguity, effectively leave that function to the courts—much less to the administrative bureaucracy."); *Loving v. United States*, 517 U.S. 748, 768 (1996) ("We have upheld delegations whereby the Executive or an independent agency defines by regulation what conduct will be criminal, so long as Congress makes violation of regulations a criminal offense . . . (emphasis added)).

Gonzales, 546 U.S. at 270 (holding that the structure and operation of the CSA presume and rely upon a functioning medical profession regulated under the States' police powers); *Gonzales*, 545 U.S. at 48 (O'Connor, J., dissenting, joined by Rehnquist, C.J., and Thomas, J.) (holding that the government's authority under the Commerce Clause should not extend to the medical uses of drugs which should be regulated at the state level). This Court, to be sure, has held that statutes should express the legislative intent in enacting them. *See Ladner*, 358 U.S. at 177-78.

The court of appeals was unmoved by the rule of lenity, opting instead to invoke the prior panel precedent rule in upholding its disjunctive reading. No lenity was, or will be shown, absent this Court's intervention.

II. THIS CASE IS AN IDEAL VEHICLE TO RESOLVE AN IMPORTANT ISSUE

This case is profoundly important. Clear notice to physicians of their legal liability for prescribing decisions is vital to this nation. Millions of patients currently live with chronic pain,[14] and while there is a dispute as to the appropriateness of long-term chronic opioid therapy, doctors are entitled to know when their conduct is deemed criminal. Yet, the government in crafting its own unenumerated prescribing standard has encroached on the State's authority to regulate the practice of medicine, thereby depriving physicians of notice of what constitutes unauthorized prescribing. *See Gonzales*, 546 U.S. at 270. This has turned the CSA on its head. Rather than

14. S. Michaela Rikard, et al., *Chronic Pain Among Adults—United States, 2019–2021*, CDC, Apr. 14, 2023, https://www.cdc.gov/mmwr/volumes/72/wr/mm7215a1.htm.

state governments setting the rubric for medicine and prescribing and the federal government enforcing the CSA based on that rubric, the federal government has seized the ambiguity in the "usual course of professional practice" and crafted its own restrictive and unenumerated prescribing standard, forcing physicians to heed that standard or face criminal prosecution.

The real victims, however, are the patients. Indeed, chronic pain patients have "become collateral casualties in the government's war on drugs."[15] In response, state lawmakers and attorney generals are pushing for change: For the federal government to stop forcing physicians to set aside their role as healer in favor of investigator. Shaun Boyd, *Colorado Lawmaker Introduces Bill to Provide Easier Access to Opioids for Chronic Pain Sufferers*, CBS News, Mar. 3, 2023, https://www.cbsnews.com/colorado/news/lawmaker-introduces-bill-provide-easier-access-opioids-chronic-pain-sufferers/ ("For more than a year, Ginal has worked with doctors, pharmacists, and patient advocates to draft a bill that protects providers who prescribe high-dose opioids from disciplinary action, prevents them from denying treatment based on a prescription, and prohibits them from forcibly tapering a prescription."); Letter of 30 State Attorneys General to Administrator of DEA, 151 Cong. Rec. 6974 (2005).

The Court's intervention is nonetheless needed. The government has become so comfortable in crafting its own prescribing standard that in this case, to expedite

15. Jeffrey A. Singer, *The War on Drugs is Also a War on Pain Patients*, Cato Institute, Apr. 1, 2024, https://www.cato.org/blog/war-drugs-also-war-pain-patients.

conviction, it simply had its medical expert review undercover recordings of patient visits—opting to not provide its expert with patient medical records, diagnostic imaging, or patient prescription histories. App., *infra*, 12a-16a. The government expert was thus incapable of opining on whether controlled substances were prescribed for other than a legitimate medical purpose. That did not matter to the government. It marched forward and convicted Petitioner for prescribing outside the usual course of professional practice, based on an elevated standard that required a physical examination whenever an opioid was prescribed, even though in Florida the only requirement is that a physical examination be administered before beginning opioid treatment. See Fla. Stat. Ann. § 456.44(3)(a).

This case is one of the most compelling examples of the government's errant use of the CSA. Not even the court of appeals would go so far as to hold that the government proved, based on its expert review of undercover recordings, that controlled substances were prescribed for other than a legitimate medical purpose. The court of appeals found instead that such inquiry was irrelevant under its disjunctive reading. App., *infra*, 3a-4a ("Because the evidence in this case was sufficient to prove a knowing deviation from the usual course of medical practice, it does not matter whether there was also sufficient evidence to prove a knowing lack of legitimate medical purpose.").

The days of prosecuting "a drug dealer hiding behind a white coat," Gov't Br. 13, are no more. And there is every indication that the government will continue to chart further off course absent this Court's intervention. In 2018, for example, the then-Attorney General announced

the creation of the Department of Justice Prescription Interdiction & Litigation (PIL) Task Force with the mission of "fight[ing] the prescription opioid crisis."[16] Moreover, on June 29, 2022, two days following this Court's decision in *Ruan* on June 27, 2022, the DOJ announced the creation of its New England Prescription Opioid (NEPO) Strike Force to Focus on Illegal Opioid Prescriptions. "Th[e] NEPO Strike Force expands and sharpens the Justice Department's response to the nation's opioid epidemic."[17] According to the DOJ's latest update on October 10, 2023, the NEPO Strike Force is well on its way to prosecuting and convicting physicians. [18]

The government may be well-intentioned in its initiatives to combat an ongoing crisis with the distribution of *illegal* opioids. Nonetheless, controlled substances play a crucial role in treating and managing many

16. U.S. Dep't of Justice Office of Public Affairs, *Attorney General Sessions Announces New Prescription Interdiction & Litigation Task Force* (Feb. 27, 2018), https://www.justice.gov/opa/pr/attorney-general-sessions-announces-new-prescription-interdiction-litigation-task-force.

17. U.S. Dep't of Justice Office of Public Affairs, *Justice Department's Criminal Division Creates New England Prescription Opioid Strike Force to Focus on Illegal Opioid Prescriptions* (Jun. 29, 2022), https://www.justice.gov/opa/pr/justice-department-s-criminal-division-creates-new-england-prescription-opioid-strike-force.

18. U.S. Dep't of Justice Criminal Division, *New England Strike Force* (Oct. 10, 2023), https://www.justice.gov/criminal/new-england-strike-force#:~:text=The%20New%20England%20Strike%20Force,opioid%20prescribing%20in%20New%20England.

patients' pain. These patients and their physicians will continue to suffer at the hands of the government's errant enforcement of the CSA together with the Eleventh Circuit's disjunctive reading to measure authorization. The Court's intervention is needed to add balance to what often seem to be competing interests: The need to protect against the illegal use of opioids and the genuine need for access to opioids to treat pain.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

TABLE OF APPENDICES

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT, FILED FEBRUARY 13, 2024

IN THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 23-10142

Non-Argument Calendar

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

versus

RONALD STUART LUBETSKY,

Defendant-Appellant.

Appeal from the United States District Court
for the Southern District of Florida
D.C. Docket No. 1:21-cr-20485-DMM-1

Before LAGOA, BRASHER, and ABUDU, Circuit Judges.

PER CURIAM:

Federal law generally prohibits the distribution of controlled substances, such as oxycodone and morphine. The general prohibition is subject to some important exceptions. One such exception is that physicians are "authorized" to prescribe controlled substances to

patients, so long as those prescriptions are "issued for a legitimate medical purpose by [a physician] acting in the usual course of his professional practice." 18 U.S.C. §§ 841(a)(1), 829(a); 21 C.F.R. § 1306.04(a). The United States accused Dr. Ronald Lubetsky of carelessly and unnecessarily prescribing oxycodone and morphine. A jury agreed, finding Lubetsky guilty on seven counts of knowingly and intentionally dispensing controlled substances without authorization by law.

Lubetsky appeals on two grounds. First, he argues that the evidence produced at trial was insufficient to support the jury's guilty verdicts. Second, he contends that the jury's guilty verdicts were tainted by the prosecutor's alleged mischaracterizations of the evidence during closing arguments. Because neither argument is persuasive, we **AFFIRM**.

Lubetsky's first argument focuses on 21 C.F.R. § 1306.04(a)'s use of the phrase "issued for a legitimate medical purpose." He homes in on that phrase because there's really no disputing that the jury heard enough evidence to find that he knowingly acted outside "the usual course of his professional practice" when issuing the oxycodone and morphine prescriptions at issue here.[1]

1. Lubetsky's brief could be read as arguing the district court erred in admitting the government's expert witness and certain other pieces of evidence relating to the usual course of medical practice. Those evidentiary objections were not raised below, and Lubetsky has not established plain error in any event. *See United States v. Graham*, 981 F.3d 1254, 1260 (11th Cir. 2020). So we do not factor his evidence-admission arguments (to the extent there are any) into our analysis.

Lubetsky says that evidence is not sufficient to sustain the jury's guilty verdicts, however, because the government also had to prove that he knowingly or intentionally prescribed the oxycodone and morphine without a legitimate medical purpose. Because the government didn't prove a lack of legitimate medical purpose, the argument goes, the government did not prove the prescriptions were unauthorized.

Lubetsky's first argument is squarely foreclosed by circuit precedent. In *United States v. Abovyan*, we held that Section 841 "requires only that the jury find the doctor prescribed a drug 'not for a legitimate medical purpose' *or* not 'in the usual course of professional practice." 988 F.3d 1288, 1308 (11th Cir. 2021) (emphasis added). That is, "the test is disjunctive, and a doctor violates the law if he falls short of either requirement." *Id.* at 1305. We had also held that the "usual course of professional practice" inquiry was objective. *See United States v. Duldulao*, 87 F.4th 1239, 1250-51 (11th Cir. 2023) (collecting cases). That rule was later rejected by the Supreme Court in *Ruan v. United States*, 597 U.S. 450 (2022), where the Court clarified that Section 841's subjective "knowingly or intentionally" *mens rea* also applied to the standard of care issue. But we have since reaffirmed that "*Abovyan*'s holding—that a doctor violates § 841(a) if the 'legitimate medical purpose' or 'outside the scope of professional practice' requirement is met—remains binding precedent[.]" *United States v. Heaton*, 59 F.4th 1226, 1241 n.17 (11th Cir. 2023); *see also Duldulao*, 87 F.4th at 1259. We are bound by the prior panel precedent rule to adhere to *Abovyan*. *See Heaton*, 59 F.4th at 1241 n.17 (quoting *United States v. Archer*, 1347, 1352 (11th Cir. 2008)). Because the evidence in this case

was sufficient to prove a knowing deviation from the usual course of medical practice, it does not matter whether there was also sufficient evidence to prove a knowing lack of legitimate medical purpose.

Lubetsky's second argument is that the jury's verdicts were tainted because, during closing arguments, the prosecutor mischaracterized the expert testimony regarding Lubetsky's compliance with the medical community's standard of care. Lubetsky did not object to the prosecutor's arguments during trial. "When a defendant fails to object to the prosecutor's closing argument, relief is available to rectify only plain error that is so obvious that failure to correct it would jeopardize the fairness and integrity of the trial." *United States v. Bailey*, 123 F.3d 1381, 1400 (11th Cir. 1997). Lubetsky has not established that the prosecutor's closing arguments were improper, much less so improper as to call into question the "fairness and integrity of the trial." *Id.* Moreover, the district judge here instructed the jury that "anything the lawyers say is not evidence and isn't binding on" the jury. The district judge reemphasized that instruction immediately before closing arguments began, telling the jury that "arguments are not evidence, but [the lawyers] have an opportunity . . . to argue what the evidence and reasonable inferences that can be drawn from the evidence shows." We are satisfied that "any possible prejudice to [Lubetsky] . . . was cured by instructions from the district court." *Bailey*, 123 F.3d at 1402.

The judgment of the district court is **AFFIRMED**.

APPENDIX B — DENIAL OF REHEARING OF THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT, FILED MAY 7, 2024

IN THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 23-10142

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

versus

RONALD STUART LUBETSKY,

Defendant-Appellant.

Appeal from the United States District Court
for the Southern District of Florida
D.C. Docket No. 1:21-cr-20485-DMM-1

ON PETITION(S) FOR REHEARING AND PETITION(S) FOR REHEARING EN BANC

Before LAGOA, BRASHER and ABUDU, Circuit Judges.

PER CURIAM:

The Petition for Rehearing En Banc is DENIED, no judge in regular active service on the Court having requested that the Court be polled on rehearing en banc.

Appendix B

FRAP 35. The Petition for Rehearing En Banc is also treated as a Petition for Rehearing before the panel and is DENIED. FRAP 35, IOP 2.

APPENDIX C — EXCERPTS OF TRANSCRIPT IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF FLORIDA, FILED OCTOBER 31, 2022

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
CASE NO. 21-CR-20485-MIDDLEBROOKS

UNITED STATES OF AMERICA,

vs.

RONALD STUART LUBETSKY,

Defendant.

Pages 1-174
Miami, Florida
October 31, 2022
9:00 A.M.

TRANSCRIPT OF JURY TRIAL PROCEEDINGS BEFORE THE HONORABLE DONALD M. MIDDLEBROOKS UNITED STATES DISTRICT JUDGE Volume I

Appendix C

* * *

[109]when we're paying for these informants.

Q. Now, were you her control agent, that is, the person who is watching her, monitoring her, keeping track of everything she was doing?

A. Since I was the lead on the case, I was using -- you know, she had a controlling agent, he was on our squad. But I ran my investigation, so, you know, we used her a lot together. I basically controlled her, yes.

Q. Now, when she went to see Ronald Lubetsky or just went into his pain clinic, was she always wearing at least one recording device?

A. Yes.

Q. And did you always check to make sure the recording device worked properly?

A. Yes, I did.

Q. And after she came out of the pain clinic, did she turn the recordings over to you after each meeting?

A. Yes.

Q. And have you had a chance to listen to those recordings?

A. Yes.

Q. And do they reflect that they recorded all that was going on and were working properly?

A. Usually we give other informant or our undercovers, we always give them two devices minimum; one to record audio and one to record audio video.

[110]Back then when I started the case, I had just started doing those type of investigations, we would give them recording equipment. What we didn't realize was the amount of time our informants or undercovers would spend in these doctors' offices. So we give them two devices, turn them on -- I would turn them on, give it to them, and they would go into the doctor's office.

Well, if they were in there for four or five hours, some of those devices would not record everything. They would tend to shut off because the battery wouldn't last that long. But our audio was always working. Our video pulled our battery; sometimes it shut off, sometimes it did not. Our audio always did, so we always had a device recording on them.

Q. Was it common when Yanexi Hernandez went in to see this defendant that she had to wait -- at least the first few times, that she had to wait for hours in the waiting room before she saw anyone?

A. Yes.

Q. Now, let me direct your attention to the first time she went to that office in February of 2016.

Did she meet with Ronald Lubetsky then, or did she only meet with his office staff?

A. I believe from what I remember, she met with the office staff.

Q. Okay. And now let me direct your attention to April 6th of 2016.

On that occasion did she go in again, and that time meet

* * *

[150]terms of if you're talking about a disc bulge or a disc herniation evident on an MRI, correct, highly unlikely that it's of significance if their neurologic exam is completely normal.

Q. What is the appropriate use of MRIs in diagnosing pain problems in people complaining of pain in their neck or shoulder or back?

A. Most appropriately it's an extension of the history and physical examination that we perform to help further clarify the diagnosis.

For example, if a patient I feel has a torn rotator cuff and I can determine by my physical exam that they're the four muscles that rotate the shoulder and clinically I suspect that, if I'm concerned that they may need to see a surgeon for repair, I may want to do an injection because I'm concerned about inflammation, I'll want to obtain an imaging study to correlate.

If there is a neurologic deficit, for example, in someone who has back pain, I will usually order an MRI to look at the spinal cord and the nerve roots. If the patient's neurologically intact, it's unlikely that I need an MRI based on my own physical exam and the patient's history.

Q. Did an MRI provide a complete story to a doctor of what's wrong with a patient who has neck or back pain?

A. Not at all. What I teach when I teach students and residents is that 80 percent of the diagnosis actually comes from the history. If you ask the patient the right questions, they'll tell[151]you what's wrong. They may not say: I have a herniated disc or I have a fine spinal cord tumor, but they'll give you enough clues in their history that we can narrow what we call the different diagnoses or differential to say what it is. Then we do the physical exam, and we get to about 95 percent certainty of what's wrong with the patient between the history and the physical. You add the diagnostic studies, like the X rays, CT scans, MRI studies, to get to about 99 percent certainty.

So that MRI is an extension of the history and physical. If you're going to use it to effect treatment, you don't need to prescribe medications, but it might mean a surgical consultation, it might mean an injection, it might mean some procedure that may need to be done that would effect treatment and help improve the patient.

Q. Would all of those studies be incumbent on a physician who wanted to practice medicine in accordance with the professional standards of medical care?

A. In terms of proper and judicious use -- the appropriate use of those studies, yes.

Q. Now, if a patient has been getting treatment for pain with opioids over a period of months, how often should the doctor do another physical -- a thorough physical exam to see how things are coming along?

Like, would one examination at the beginning be enough, or does he have an obligation to do follow ups?

[152]A. When you're treating someone who has a severe pain problem, severe enough to warrant opioids, some form of exam is done every visit. It doesn't have to be the same complete exam.

But, for example, if a patient has a back problem, at every visit I'm going to at least assess gait, strength, reflexes, make sure that there is no progressive change if I know that there's lesion, for example, in the spinal cord.

If you don't monitor the patient, you can't tell if they're getting better or getting worse, and that's why we do that. We take a detailed interim history and we perform a physical exam. Not in as much detail as we do at the initial visit, but serial exams to compare for sure on each visit.

Q. Is it adequate to simply ask the patient how the patient is doing and the patient says: The pills are working great. I'm doing fine?

A. Not for treatment of chronic nonmalignant pain, no. No.

Q. Now, in working on this case and preparing for today's appearance, have you had time to review the audio or video recordings of 13 visits in which Yanexi Hernandez or Alex Vega went to see Ronald Lubetsky and complained about pain?

A. I did.

Q. And have you formed opinions about each of those 13 visits as to whether the prescription for narcotic drugs given at that meeting was appropriate?

A. I did.

* * *

[168]Q. And January 31, 2018?

A. I believe so. I've reviewed all of those.

Q. Both for Alex Vega, as well as Yanexi Hernandez?

A. Correct, sir.

Q. And for No. 9, No. 10, April 9, 2018, you reviewed that?

A. Yes, sir.

Q. And June 11, 2018; correct?

A. If you have those encounters, I reviewed them, yes.

Q. And August 20th, 2018?

A. The same answer. If you have a record of that encounter, I have reviewed it, yes.

Q. On the first visit --

Now, did you look at the medical record itself, the file?

A. No.

Q. No?

A. That was not provided.

Q. So you didn't look at the medical record at all?

A. Correct. Well, I reviewed prescriptions from the file that were provided to me.

Q. Okay. So you did not review the documents that were provided by Ms. Hernandez and Mr. Vega that was part of their medical history?

A. I don't recall same, because I don't believe that they sent me the files.

They sent me audio and audio-visual recordings to review.

[169]Q. Okay. And so you made your decision based upon the audio and video solely?

A. Correct, and the prescription review I had of the prescriptions that were forwarded to me for review.

Q. Okay. Now, going to Ms. Hernandez's first visit on January -- on April 6, 2016, did you hear Ms. Hernandez essentially begging Dr. Lubetsky to take her on as a patient because she had a criminal history?

A. Not because she had a criminal history; but to still take her on as a patient, despite her criminal history.

Q. Right. Despite her criminal history?

A. Yes, sir.

Q. And that would be something that doctors should screen for is if a person has a medical history, particularly one involving abuse of drugs or anything like that?

A. Any history of substance abuse, correct.

Q. But her history wasn't of substance abuse though; right?

A. I don't recall.

Q. Okay.

A. But any criminal history, as the doctor identified, that their staff -- he had trained his staff to do that research, and they had identified that. That's something you pursue.

Q. And so essentially the staff was going to reject her; correct?

A. That's the -- my understanding from the discussion that was held and the transcript that you have and you have reviewed.

* * * *

APPENDIX D — EXCERPTS OF TRANSCRIPT IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF FLORIDA, FILED NOVEMBER 1, 2022

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
CASE NO. 21-CR-20485-MIDDLEBROOKS

UNITED STATES OF AMERICA,

vs.

RONALD STUART LUBETSKY,

Defendant.

Pages 1-114
Miami, Florida
November 1, 2022
9:00 A.M.

TRANSCRIPT OF JURY TRIAL PROCEEDINGS BEFORE THE HONORABLE DONALD M. MIDDLEBROOKS UNITED STATES DISTRICT JUDGE Volume II

* * *

[89]for the DEA and I want to know if you're doing illegal activities in here? I can't do that.

Q. The DEA could have done that though; couldn't they?

A. You'd have to DEA.

Q. Yeah, I'd have to ask the DEA.

Page 4: The drug doesn't feel good, it doesn't feel, you know, you know what I'm talking about.

He's talking about the long-acting medication. That's not true, because you're not taking them; right?

A. The drug doesn't feel good. It doesn't feel, you know, you know what I'm talking about. Okay.

What? What's the question?

Q. So when you say: The drug doesn't feel good, it doesn't feel, you know what I'm talking about, you're not telling the truth because you're not taking the drug; right?

A. I'm not taking the drug, no.

Q. Page 6: He asks: Or do you mean the oxycodone 30?

Sure, that's what makes me feel better.

That's not the truth, because you don't take it; right?

A. Yeah, we've established that I don't take it.

Q. The thing is, you know, people mess up every now and then, we are human, but you know how it is. It's real life out there. It's just -- if you get, I -- I don't know. You

got a certain amount of medication, who wants to cut down to half when you don't even have enough with what you got.

[90]That's not true. You didn't take any medication; correct?

A. I wasn't talking about taking medication.

Q. Were you talking about treating for pain?

A. No. I was talking about getting medication. Imagine if you get 90 pills or 120 pills and they take half, well how are you going to make any money off of that?

Q. Did you say: How are you going to make any money off of it?

A. You've got to read between the lines, just like when he told me: I need you to have a dirty urine because I have to put something in here. You know, it's just -- you've got to read between the lines.

I'm talking about we're all messed up, you know, we're human. What am I going to be talking about? Pain?

Q. He's talking about pain, yes.

A. Okay. All right.

Q. Okay. Page 10.

MR. TAMEN: Which exhibit?

Appendix D

MR. CASSIDY: This is the same exhibit. One moment.

BY MR. CASSIDY:

Q. The transcript as I printed came out a little different, so.

Page 9, you seem like a really nice doctor. You seem like a really good guy, you really do.

You said that to him; right?

A. I did.

Q. Okay. And that was a lie?

* * * *

APPENDIX E — TRANSCRIPT OF EXCERPT, TESTIMONY OF DR. MARK RUBENSTEIN IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF FLORIDA, MIAMI DIVISION, FILED JANUARY 9, 2024

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

CASE NO. 22-20255-cr-GAYLES(COHN)

UNITED STATES OF AMERICA,

Plaintiff,

vs.

OSMIN MORALES,

Defendant.

January 9, 2024

TRANSCRIPT OF EXCERPT
TESTIMONY OF DR. MARK RUBENSTEIN
BEFORE THE HONORABLE JAMES I. COHN
UNITED STATES DISTRICT JUDGE

* * *

[23] the procedure I may be doing, it's appropriate for me to issue that with the proper history and physical documented.

Appendix E

Medical recordkeeping being the standard that we've talked about.

Q. I think you just described the sufficient physical examination aspect of your review. Right?

A. Yes, sir.

Q. Okay. Now, that's for the initial patient visit; right?

A. A comprehensive history and physical is required for the initial prescriptions and visit.

Q. Okay. And you agree that a physical examination is not required for follow-up visits, after that initial, before you can issue a controlled substance prescription?

A. It is the standard that a physical -- a limited physical exam, as I said yesterday, germane to the patient's diagnosis be performed. That's the standard of care in this field, but that doesn't mean it's required.

It's the standard, and that's what the reasonable physician and the reasonable community would do, but it's not required that a complete physical exam be done at each visit.

Q. So for a patient that's already had a complete physical examination, and you're going to consider issuing a prescription on a later date, are you saying that it's

required or not required under minimum standards of care to give that patient a physical examination?

[24] A. Under the statute, which changed relatively recently, the previous statutes, in fact, in play at the time back in 2018 and 2019 required a visit. But the more recent statutes don't require a visit. It's still the standard of care, however, to do a focused exam.

Q. Okay. So within your practice, when you issue prescriptions for controlled substances to your patients, okay, do you sometimes, on one visit at your office, give a patient three prescriptions? In other words, prescriptions to cover three months?

A. Yes.

Q. So that means, for instance, if you saw a patient today, and you handed her three prescriptions, you would not see her the next month for a physical examination?

MR. TAMEN: I am going to object unless we can specify what kind of prescriptions we're talking about.

THE COURT: Sustained.

MR. MELTZ: Sure.

BY MR. MELTZ:

Q. Pain medication.

Appendix E

A. What you're referring to are the issuance of prescriptions for controlled substances. Controlled substances, specifically the Schedule II controlled substances, cannot be renewed. But if a patient is stable and doesn't require, for example, that physical exam each month and, for example, we have been

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