Nos. 20-1410 & 21-5261

In the Supreme Court of the United States

XIULU RUAN,
Petitioner,
v.
UNITED STATES,
Respondent.

SHAKEEL KAHN,
Petitioner,
v.
UNITED STATES,
Respondent.

On Writs of Certiorari to the United States Courts of Appeals for the Tenth and Eleventh Circuits

BRIEF FOR *AMICUS CURIAE* NATIONAL PAIN ADVOCACY CENTER IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*

Amicus curiae National Pain Advocacy Center (NPAC) is an organization dedicated to improving the health and protecting the rights of people living with pain.[1] NPAC is keenly interested in this case because its aims as an organization are to reduce morbidity and mortality associated with pain and to ensure that patients with pain receive appropriate access to care. Those urgent objectives are threatened by erroneous judicial interpretations of the Controlled Substances Act (CSA) that improperly lower the bar for criminally convicting physicians for prescribing pain medication, overly deter them from prescribing such medication, and keep them from exercising the best medical judgment for their patients.

SUMMARY OF ARGUMENT

Few medical decisions are more fraught than the decision of a provider to prescribe a controlled substance to his patient. At the same time, the legitimate medical use of controlled substances is a mainstay of modern medicine. While the government has an interest in preventing the diversion of controlled medications, interpretations of the CSA that undermine good medicine fail to strike the right balance, and are unfaithful to the clear language of the statute and governing regulation. Incorrect and inconsistent

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[1] All of the parties have consented to the filing of this brief. No counsel for a party authored any part of the brief, and no person or entity other than *amicus curiae* NPAC or its members or counsel made a monetary contribution toward the preparation or submission of the brief.

interpretations of Section 841(a) of the CSA have wreaked havoc on the practice of medicine in ways that endanger the health and lives of patients in medical care.

In some Circuits—including both the Tenth and Eleventh whose decisions are before the Court in this case—doctors can be found liable for the serious criminal offense of violating the CSA if they prescribe in a manner than departs from accepted norms of medical practice; that is, without the prosecution having to prove that the doctor "knew" or "intended" that his prescribing exceeds these bounds. This result contravenes the plain language of the statute and its implementing regulation, undermines the discretion this Court has recognized the Act provides to providers treating patients, *United States v. Moore*, 423 U.S. 122, 143 (1975), and chills patient care because honest providers fear being mistaken for bad actors. The practical effect of this overdeterrence is predictable, incentivizing providers to act from self-protection and even against their best medical judgment, and leading some to under-manage pain, engage in practices that increase risks to patient safety, and abandon patients from care.

The CSA makes it a crime for a person to "knowingly or intentionally" distribute a controlled substance. The Attorney General's implementing regulation provides that a registered physician may prescribe controlled substances "for a legitimate medical purpose" "in the usual course of his professional practice." The issue at the heart of this case is how to read this combination of prohibition and permission.

An authorized prescription is one that meets the requirement of being for "a legitimate medical purpose" prescribed "in the usual course" of a physician's practice. A prescription that fails this criterion is unauthorized. But the physician who writes an unauthorized prescription is only *criminally* liable if he does so "knowingly or intentionally," as the statute provides. Judicial decisions that read "knowledge" or "intent" out of the statute defy this plain meaning and effectively eviscerate the scienter requirement. The better and more straightforward statutory reading holds the physician to the same culpability standard as anyone else, appropriately distinguishing criminally culpable from criminally nonculpable actors.

To protect a significant cohort of patients who may require medical use of controlled substances—including millions with serious pain—this Court should confirm that, under the proper construction of the CSA, a medical provider may be held liable only when he knows or intends to prescribe without a legitimate medical purpose in the usual course of his professional practice.

ARGUMENT

The government has a legitimate interest in deterring diversion and misuse of controlled substances, especially amid a drug overdose crisis. But a standard for criminal liability that overly deters may cause medical professionals to act against their best medical judgment due to fear of oversight, have a chilling effect on their willingness to care for patients in pain, and even encourage them to engage in self-protective practices that risk the safety and endanger the lives of

those in their care. Each of these predictable negative outcomes is occurring in pain care today.

This Court has recognized that, in enacting the Controlled Substances Act, 84 Stat. 1242 (codified as amended at 21 U.S.C. § 801 *et seq.*) (CSA), Congress allows medical providers "reasonable discretion in treating patients and testing new theories." *Moore*, 423 U.S. at 143. Yet, as courts have also noted, "physicians are particularly easily deterred by the threat of governmental investigation and/or sanction from engaging in conduct that is entirely lawful and medically appropriate." *Conant v. Walters*, 309 F.3d 629, 640 n.2 (9th Cir. 2002) (Kozinski, J., concurring). Providers should be convicted (or rightly fear prosecution) under 21 U.S.C. § 841(a), not for testing the boundaries of treatment, nor even for negligent conduct, but when they "cease[ ] to be a physician at all," *United States v. Feingold*, 454 F.3d 1001, 1011 (9th Cir. 2006), and act instead, as this Court stated in *Moore*, as a "large-scale pusher" of drugs. 423 U.S. at 143.

Settling the proper standard under Section 841(a) for criminally convicting medical professionals will reduce current and future downstream negative effects on patients and limit the imposition of conflicting ethical burdens on providers, who have a duty to care for their patients. The government's interest in preventing diversion and misuse must be balanced with sufficient latitude for medical professionals to provide appropriate care for the millions of Americans living with pain.

I. Pain is a Widespread and Consequential Public Health Problem, and Care for Patients with Pain is a Primary Duty of Healthcare Providers.

Pain is our most pervasive public health condition. One in six Americans, or 50 million, suffers from pain every day or nearly every day,[2] which is more than are affected by cancer, heart disease, diabetes, or stroke. Nearly 20 million Americans have pain severe enough that it regularly prevents them from engaging in work or in life activities.[3] Pain is also consequential: it is the primary cause of disability.[4] And pain is rising with an aging population, because older Americans more commonly experience chronic pain,[5] and during the global pandemic in which persistent pain has emerged as a key symptom in COVID long-haulers.[6]

Treatment for pain is a major reason people seek healthcare, accounting for about 115 million

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[2] James Dahlhamer et al., *Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults – United States, 2016*, 67 MORBIDITY MORTALITY WKLY. REP. 1001 (2018).

[3] *Id.* (high impact chronic pain limits life or work activities on most days or every day in the past six months).

[4] INST. FOR HEALTH METRICS & EVAL., *Findings from the Global Burden of Disease Study 2017*, at 12–13 (2018).

[5] M. Carrington Reed et al., *Management of chronic pain in older adults*, 350 BMJ 532 (2015).

[6] Kate M. Nicholson, *Another fight for Covid long-haulers: having their pain acknowledged*, STAT NEWS (Dec. 2, 2021), https://tinyurl.com/2p89rdtm.

emergency room visits each year.[7] Acute pain commonly accompanies the approximately 50 million[8] surgeries performed in the United States annually. And pain often occurs at the end of life, with some studies suggesting that 50–75% of patients die in severe pain.[9]

While providing relief from suffering is a central duty of healthcare providers,[10] pain remains poorly managed in the United States, costing over $700 billion annually (adjusted for inflation) in medical expenses, disability, and lost productivity.[11]

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[7] Omama Zubairi et al., *Acute Pain Management in the General Population*, PHARMACY TIMES (July 17, 2018), https://tinyurl.com/49v5789f.

[8] NAT'L QUALITY FORUM, NQF-ENDORSED MEASURES FOR SURGICAL PROCEDURES, 2015-2017 (2017), https://tinyurl.com/yt6u9hbk.

[9] Alfred F. Connors, Jr. et al., *A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients*, 274 JAMA 1591 (1995), https://tinyurl.com/yckmmeyp.

[10] *See* PAIN MGMT. BEST PRACS. INTERAGENCY TASK FORCE, U.S. DEP'T OF HEALTH & HUM. SERVS., PAIN MANAGEMENT BEST PRACTICES (May 9, 2019); NAT'L INSTS. OF HEALTH, NATIONAL PAIN STRATEGY: A COMPREHENSIVE POPULATION HEALTH-LEVEL STRATEGY FOR PAIN (2016); *see also infra* note 11.

[11] INST. OF MED., RELIEVING PAIN IN AMERICA: A BLUEPRINT FOR TRANSFORMING PREVENTION, CARE, EDUCATION, AND RESEARCH 1–4 (2011) (noting that the medical costs of pain care and the economic costs related to disability days and lost wages and productivity amount to at least $560–$635 billion annually in 2008 dollars).

A. There is no single standard of care for treating pain, and views on opioid prescribing are in flux.

Unlike in the treatment of conditions such as sepsis or heart attack, for example, there is no unitary standard or broadly applicable protocol for treating pain, because pain is so heterogeneous.[12] Pain ranges not only from acute to chronic but also in etiology and in severity; it may accompany or describe a multitude of conditions, including degenerative conditions like cancer, inflammatory or autoimmune conditions like lupus, or neurological conditions, like multiple sclerosis, among many others.

Although there are a variety of available modalities to treat pain, prescribed opioids[13] remain a mainstay in the management of many types of acute pain, pain from cancer or other serious diseases, and in end-of-life care.[14] All current guidelines—including that

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[12] Srinivasa N. Raja et al., *The revised International Association for the Study of Pain definition of pain: concepts, challenges, and compromises*, 161 PAIN 1976 (2020).

[13] This brief focuses on prescribed opioids, because most of the cases arise in the context of opioid prescribing, but many controlled substances have legitimate medical applications in treating conditions such as seizure disorders, anxiety, and attention deficit hyperactivity—conditions that can be concurrent with pain. The standard articulated by this Court thus stands to affect care of a substantial cohort of patients in the United States.

[14] *See Oklahoma ex rel. Hunter v. Johnson & Johnson*, No. 118,474, 2021 WL 5191372, at *1 n.2 (Okla. Nov. 9, 2021) (citing

issued by the Centers for Disease Control and Prevention (CDC) in 2016—support the use of opioids in chronic pain that is not managed by other means.[15] Between eight million[16] and 13 million[17] Americans regularly rely on prescribed opioids to manage physical pain.

Recent attempts by public health agencies to articulate a standard of care for opioid prescribing have backfired, requiring the agencies to course correct. The CDC, for example, stated publicly that key provisions in its 2016 Guideline for Prescribing Opioids for Chronic Pain had been misapplied as one-size-fits-all mandates by policy actors in ways that risk patient harm.[18]

U.S. Food & Drug Admin., *A Guide to Safe Use of Pain Medications* 3 (Feb. 23, 2009) (URL citation omitted)) ("[T]he U.S. Food and Drug Administration ("FDA") has endorsed properly managed medical use of opioids (taken as prescribed) as safe, effective pain management, and rarely addictive.").

[15] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, 65 MORBIDITY MORTALITY WKLY. REP. 1 (2016).

[16] Kurt Kroenke et al., *Challenges with Implementing the Centers for Disease Control and Prevention Opioid Guideline: A Consensus Panel Report*, 20 PAIN MED. 724, 726 (2019).

[17] Ramin Mojtabai, *National trends in long-term use of prescription opioids*, 27 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 526 (2018).

[18] *See* Deborah Dowell et al., *No Shortcuts to Safer Opioid Prescribing*, 380 NEW ENG. J. MED. 2285, 2287 (2019) (highlighting

One of the misapplied provisions from the CDC's guideline deals with the appropriate daily dosage at which medication should be prescribed, expressed in morphine milligram equivalents or MMEs. This provision was interpreted as a mandate rather than guidance and misused by regulators—including law enforcement—as a proxy for inappropriate prescribing. As a result, providers who prescribed above the dosage threshold were subjected to scrutiny, and healthcare workers began to rapidly taper patients down to the CDC's dose threshold.[19] These actions, which risk patient safety, prompted the U.S. Food and Drug Administration (FDA) to issue a warning about the dangers of abrupt opioid cessation.[20] As recently as August

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the low evidence basis of the misapplied provisions, and their application to providers and patients which the Guideline—written as non-binding guidance for primary care providers—had specifically exempted).

[19] *See* Kate M. Nicholson & Deborah Hellman, *Opioid Prescribing and the Ethical Duty to Do No Harm*, 46 AM. J.L. & MED. 297 (2020) (tracing the history of misapplication and nexus with tapering); Stefan G. Kertesz et al., *Promoting Patient-Centeredness in Opioid Deprescribing: a Blueprint for De-implementation Science*, 35 J. GEN. INTERNAL MED. 972, 974 & nn.62–70 (2020) (describing how dosage guidance was used for oversight); Sara M. Hall et al., *INSIGHT: DOJ Opioid Warning Letters—Legitimate Law Enforcement Purpose or Prosecutorial Overreach?*, BL (Feb. 4, 2019, 4:00 AM), https://tinyurl.com/yxmazup5 (describing pattern of prosecutors sending warning letters to providers with higher doses as factor).

[20] *FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering*, U.S. FOOD & DRUG ADMIN. (Apr. 9, 2019), https://tinyurl.com/y9pda3du.

2021, the FDA has questioned validity of the MME concept when applied as a standard of care.[21]

This history reflects considerable vacillation on appropriate opioid prescribing, in which reasonable experts (include those providing expert testimony in criminal matters) may well disagree.

B. Changing views of opioid prescribing and fear of criminal prosecution under the CSA combine to deter providers from exercising good medical judgment.

The uncertainty that arises from changing philosophies on opioid prescribing, coupled with an unclear standard for prosecution under the CSA, can have a "chilling" effect on care, and lead good providers to fear that they will be taken as bad actors even when exercising their best judgment in caring for their patients. Increasingly, providers are avoiding

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[21] During meeting held by FDA, some experts testified that thresholds fail to account for known genomic differences in how people metabolize opioids. *See* Jeffrey Fudin, Individual Patient & Medication Factors that Invalidate Morphine Milligram Equivalents, Presentation at U.S. Food & Drug Admin. Virtual Public Workshop (June 7, 2021), https://tinyurl.com/yc4m943v. Other experts pointed out that variability in the formulas used to calculate average daily MMEs means that the same medication given at the same interval could have an MME that falls either above or below the CDC's threshold with significant consequences for patients and providers. *See* Nabarun Dasgupta, Inches, Centimeters, and Yards: Overlooked Definition Choices Inhibit Interpretation of Morphine Equivalence, Presentation at U.S. Food & Drug Admin. Virtual Public Workshop (June 8, 2021), https://tinyurl.com/2p9cm4c9.

prescribing opioids due to fear of oversight and against their best medical judgment.[22]

Just the fear of scrutiny, even absent an actual threat, is enough to change provider behavior in ways that can "substantially impair the treatment of their patients in pain."[23] Indeed, a recent qualitative study interviewing doctors in West Virginia, the so-called epicenter of the "opioid crisis," found that fear of being seen as prescribing inappropriately led to gaps in care of patients.[24] Scrutiny of prescribers has, in fact,

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[22] *See* HUM. RTS. WATCH, NOT ALLOWED TO BE COMPASSIONATE 3–4 (2018) ("[T]he atmosphere around prescribing for chronic pain had become so fraught that physicians felt they must avoid opioid analgesics even in cases when it contradicted their view of what would provide the best care for their patients.") ("HRW Report").

[23] Scott M. Fishman, *Risk of the View Through the Keyhole: There Is Much More to Physician Reactions to the DEA Than the Number of Formal Actions*, 7 PAIN MED. 360, 360 (2006); *see also* Michael C. Barnes et al., *Demanding Better: A Case for Increased Funding and Involvement of State Medical Boards in Response to America's Drug Abuse Crisis*, 106 J. MED. REGUL. 6 (2020) (investigation and prosecution of physicians has chilling effect on prescribers); Sandra H. Johnson, *Regulating Physician Behavior: Taking Doctors' "Bad Law" Claims Seriously*, 53 ST. LOUIS U. L.J. 973, 975 (2009) (providers are driven away from caring for patients in need).

[24] Cara L. Sedney et al., *"The DEA Would Come In and Destroy You": A Qualitative Study of Fear and Unintended Consequences Emerging From Restrictive Opioid Prescribing Policies in West Virginia*, RESEARCH SQUARE (Oct. 25, 2019) (preprint), https://tinyurl.com/2p8frap4 (Providers felt that taking on patients who legitimately required opioids would jeopardize their career.)

intensified in ways that an ordinary clinician may perceive as threatening.[25]

C. Overdeterrence has had predictable and significant negative downstream effects on patients.

i. Providers are refusing to treat patients with pain.

Providers are refusing to treat patients with chronic pain, even those who do not take opioids to manage it.[26] Patients who do require medical use of opioids face especially significant barriers to accessing healthcare. A survey of primary care clinics in nine states showed that 50%[27] of providers will refuse to treat a prospective patient who uses opioids to manage

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[25] The Department of Justice, for example, has issued a series of highly-publicized letters to providers who prescribe at higher levels than others. *See*, *e.g.*, Press Release, U.S. Atty's Office, W.D. Wisc., U.S. Attorneys Issue Warning to Prescribers (Feb. 5, 2019) ("Although the letters acknowledge that the prescriptions may be medically appropriate, the letters remind the practitioners that prescribing opioids without a legitimate medical purpose could subject them to enforcement action, including criminal prosecution."); Hall, *supra* note 19.

[26] George Comerci, Jr. et al., *Controlling the Swing of the Opioid Pendulum*, 378 NEW ENG. J. MED. 691, 691–93 (2018).

[27] *See* *INDUSTRY DX*, MHealthLab Blog, https://tinyurl.com/2p85msjm; Pooja Lagisetty et al., *Assessing reasons for decreased primary care access for individuals on prescribed opioids: an audit study*, 162 PAIN 1379 (2021) (study).

pain, and another study found that 81%[28] are reluctant to do so. The urgency of patient abandonment was recently acknowledged in an initiative by the California Department of Health, which described a "common problem" in which many patients on long term opioids will find themselves "suddenly stranded, without a doctor."[29]

Perversely, clinicians who *are* willing to provide care for the vulnerable group of patients—who were originally placed on opioids not by themselves but by providers and who are now facing barriers in accessing healthcare—may feel they have a target on their backs, if they are seen by government officials as a prescriber who treats a high number of patients using opioids or of patients using opioids at higher doses. High prescribers may be bad actors, but they may also be good providers who appropriately care for patients with significant or complex medical needs.

Finally, a standard that overly deters may discourage medical students from going into pain management when there are already far too few providers to meet the needs of Americans with serious pain.

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[28] Jay G. Wohlgemuth et al., *Health Trends: Drug Misuse In America 2019*, at 6, QUEST DIAGNOSTICS (Nov. 2019).

[29] Letter from Tomás J. Aragón, M.D., Dir. & State Pub. Health Officer, Cal. Dep't of Pub. Health, to Healthcare Providers (Sept. 7, 2021), https://tinyurl.com/54ya3zw7 (characterizing as "a common problem" that "many patients with long-term opioid use find themselves suddenly stranded, without a doctor, whether due to clinician retirement, state or federal action, or other cause").

ii. Patients are being subjected to practices that risk their health and safety.

Fear of oversight is also leading providers to subject patients to dangerous opioid cessation practices that may actually *increase* their risk of death in addition to destabilizing their health, mental health, and lives.[30]

It is risky for a patient who has been stable on opioids to have them suddenly stopped,[31] and even gradual stoppage may increase patient risks.[32] Nevertheless, tapering is on the rise and it often happens far more abruptly than is medically recommended. *See*, *e.g.*, Tami L. Mark & Wm. Parish, *Opioid medication discontinuation and risk of adverse opioid-related health care events*, 103 J. SUBSTANCE ABUSE TREATMENT 58 (2019) (in Medicaid patients discontinuation often happened within 24 hours with almost half such cases resulting in related hospitalization or an emergency room visit); Hannah T. Neprash et al., *Abrupt*

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[30] *See* HRW Report, *supra* note 22.

[31] Anyone who has taken opioids long-term is likely to develop physical dependence, requiring that opioids be tapered slowly to avoid side effects. Dependence is distinct from addiction because it lacks the behavioral component that characterizes a use disorder. *See*, *e.g.*, *Media Guide: The Science of Drug Use and Addiction* 3, NAT'L INST. ON DRUG ABUSE (2018), https://perma.cc/35D7-8BTZ.

[32] *See* Jason M. Glanz et al., *Association Between Opioid Dose Variability and Opioid Overdose Among Adults Prescribed Long-term Opioid Therapy*, 2 JAMA NETWORK OPEN e192613 (2019) (just destabilizing a patient's dose results in a three-fold increased risk of death).

Discontinuation of Long-term Opioid Therapy Among Medicare Beneficiaries, *2012–2017*, 36 J. GEN. INTERNAL MED. 1576 (2021) (mounting pressure to reduce opioids increased abrupt tapering in Medicare patients); Joshua J. Fenton et al., *Trends and Rapidity of Dose Tapering Among Patients Prescribed Long-term Opioid Therapy, 2008–2017*, 2 JAMA NETWORK OPEN e1916271 (2019) (tapering occurred more often in women and people of color); Joshua J. Fenton et al., *Longitudinal Dose Trajectory Among Patients Tapering Long-Term Opioids*, 22 PAIN MED. 1660 (2021) (among insured and Medicare Advantage patients likelihood of being tapered increased over time).

Numerous studies now show that tapering increases the risk of patient mortality. *See* Jocelyn R. James et al., *Mortality After Discontinuation of Primary Care-Based Chronic Opioid Therapy for Pain: a Retrospective Cohort Study*, 34 J. GEN. INTERNAL MED. 2749 (2019) (tapering results in an increased risk of death in patients in primary care settings); Elizabeth M. Oliva et al., *Associations between stopping prescriptions for opioids, length of opioid treatment, and overdose or suicide deaths in US veterans: observational evaluation*, 368 BMJ m283 (2020) (tapering is associated with an increased risk of death in Veterans); Alicia Agnoli et al., *Association of Dose Tapering With Overdose or Mental Health Crisis Among Patients Prescribed Long-term Opioids*, 326 JAMA 411 (2021) (tapering is associated with a significant increased risk of death and mental health crises).

Tapering is also associated with the breakdown of

healthcare relationships.[33]

Scholars have argued that court cases interpreting 21 U.S.C. § 841(a) essentially hold providers liable, not for criminal activity, but for negligence, for which other remedies exist in the statute and in common law.[34] Some have argued for standards that do not force providers to choose between their ethical duties to their patients and the threat of criminal sanction.[35]

Because of the importance of properly interpreting the CSA to separate good actors from bad, we proceed to the merits of the questions before this Court.

II. To Obtain a Conviction Under Section 841(a), the Government Must Prove That a Physician Knowingly or Intentionally Acted Without a Legitimate Medical Purpose in the Usual Course of His Own Practice.

In "determining the mental state required for

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[33] *See* Hector R. Perez et al., *Opioid Taper Is Associated with Subsequent Termination of Care: a Retrospective Cohort Study*, 35 J. GEN. INTERNAL MED. 36 (2020).

[34] *See*, *e.g.*, Diane E. Hoffman, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 ST. LOUIS U. J. HEALTH L. & POL'Y 231 (2008); Kelly K. Dineen & James M. DuBois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42 AM. J.L. & MED. 1, 21 (2016).

[35] *See* Deborah Hellman, *Prosecuting Doctors for Trusting Patients*, 16 GEO. MASON L. REV. 701 (2009) (hereinafter, "Hellman, *Prosecuting Doctors*").

commission of a federal crime" the "starting place in our inquiry" is "[t]he language of the statute." *Staples v. United States*, 511 U.S. 600, 605 (1994). The CSA, a criminal statute, contains "an express mens rea requirement." *United States v. Jeffries*, 958 F.3d 517, 522 (6th Cir. 2020), *cert denied*, 141 S. Ct. 931 (2020).[36] It is "unlawful for any person *knowingly or intentionally* … to manufacture, distribute, or dispense … a controlled substance." 21 U.S.C. § 841(a)(1) (emphasis added). Because of this *mens rea* requirement, a conviction under Section 841(a) cannot be obtained based on mere negligence or recklessness. "To convict a defendant of a § 841(a) offense, the government must prove that the defendant committed the criminal act 'knowingly or intentionally,' as opposed to negligently or recklessly, for example." *United States v. Dado*, 759 F.3d 550, 570 (6th Cir. 2014).

Another CSA provision authorizes the Attorney General "to promulgate rules and regulations … relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances." 21 U.S.C. § 821. One such regulation is 21 C.F.R. § 1306.03(a)—captioned "Persons entitled to issue prescriptions"—which states: "A prescription for a controlled substance may be issued … by an individual practitioner." Such a practitioner must be "(1) [a]uthorized to prescribe controlled substances by the jurisdiction in which he

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[36] *See also United States v. Ali*, 735 F.3d 176, 186 (4th Cir. 2013) ("The *mens rea* of [21 U.S.C.] § 841(a) is articulated explicitly in the statute.").

is licensed to practice his profession" and "(2) [e]ither registered or exempted from registration pursuant to §§ 1301.22(c) and 1301.23 of this chapter." *Id*. The word "practitioner" includes, *inter alios*, a physician. *See* 21 U.S.C. § 802(21).

A. The statutory and regulatory text mandate that violations be knowing or intentional, and accord with the presumption of scienter.

The regulation at the heart of this case, 21 C.F.R. § 1306.04(a), provides: "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." Thus, if a physician issues a prescription for a "legitimate medical purpose" "in the usual course of his professional practice" he has not committed a crime under Section 841(a). Conversely, if the prescription is *not* for a "legitimate medical purpose" in the "usual course" of the physician's own ("his") practice, the regulation does not shield the physician and so writing the prescription is a crime under the statute.

Importantly, the required *mens rea* for writing a prescription without a legitimate medical purpose is the *mens rea* set forth in Section 841(a). The physician must "knowingly or intentionally" issue a prescription that is not for a legitimate medical purpose in the usual course of his own practice.

This Court has held that the "knowingly or intentionally" requirement in Section 841(a) applies to

more than the verbs in the statute; it also applies to the objects therein. The best reading of the statute requires the Government to prove that the prescribing physician subjectively knew that the prescription was not for a legitimate medical purpose in the usual course of his practice. *See McFadden v. United States*, 576 U.S. 186, 191 (2015) ("Under the most natural reading of this provision, the word 'knowingly' applies not just to the statute's verbs but also to the object of those verbs …"); *accord id.* at 198 (Roberts, C.J., concurring in part and concurring in the judgment).

"As a matter of ordinary English grammar, it seems natural to read the statute's word 'knowingly' as applying to all the subsequently listed elements of the crime." *Flores-Figueroa v. United States*, 556 U.S. 646, 650 (2009) (construing 18 U.S.C. § 1028A(a)(1)); *accord Rehaif v. United States*, 139 S. Ct. 2191, 2195 (2019) (applying this same "presumption in favor of scienter" in construing 18 U.S.C. § 922(g) and 18 U.S.C. § 924(a)(2)). Indeed, "courts ordinarily read a phrase in a criminal statute that introduces the elements of a crime with the word 'knowingly' as applying that word to each element." *Flores-Figueroa*, 556 U.S. at 652; *see id.* at 657 (Scalia, J., joined by Thomas, J., concurring in part and concurring in the judgment) ("'Knowingly' is not limited to the statute's verbs"). "Thus, unless the text of the statute dictates a different result, the term 'knowingly' … requires proof of knowledge of the facts that constitute the offense." *Bryan v. United States*, 524 U.S. 184, 193 (1998) (footnote omitted); *accord Dixon v. United States*, 548 U.S. 1, 5 (2006).

In this case, as in *Rehaif*, there is "no convincing reason to depart from the ordinary presumption in favor of scienter." *Rehaif*, 139 S. Ct. at 2195. The best reading of Section 841(a) and Section 1306.04(a) is that they combine to make a physician criminally liable for *knowingly or intentionally* acting without a legitimate medical purpose in the usual course of his own practice. *Cf. Rehaif*, 139 S. Ct. at 2195–96 (holding that the word "knowingly" in 18 U.S.C. § 924(a) applies to a prosecution based on the combination of § 924(a) and 18 U.S.C. § 922(g)).

In one of the decisions below, the Tenth Circuit held that "§ 841(a)(1) and § 1306.04(a) require the government to prove that a practitioner-defendant either: (1) subjectively knew a prescription was issued not for a legitimate medical purpose; or (2) issued a prescription that was objectively not in the usual course of professional practice." Pet. App. 30a–31a. The *Kahn* court got things partially right and partially wrong.

For starters, the Tenth Circuit was wrong to say that the government can convict under *either* the "legitimate medical purpose" language *or* the "usual course" of practice language. The operative text of the regulation is unitary: "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." 21 C.F.R. § 1306.04(a). Whether a physician is acting for a legitimate medical purpose in the usual course of his professional practice is a single test, not two tests. A conviction may not be

obtained by showing that the physician's action is not for a legitimate medical purpose *or* else not in the usual course of his practice. The text of the regulation does not support such a disjunctive reading. The government has only one route to conviction, contrary to the Tenth Circuit's reading of the statute and regulation.

The Tenth Circuit's opinion was correct, however, in one important respect. In addressing the legitimate medical purpose language in the regulation, the Tenth Circuit rightly held that the government must prove that the physician "*subjectively knew* a prescription was issued not for a legitimate medical purpose." Pet. App. 30a–31a (emphasis added). This is so because the *mens rea* requirement in Section 841(a) applies to the *actus reus* in Section 1306.04(a). "Thus, the only relevant inquiry … is why a defendant-practitioner subjectively issued that prescription, regardless of whether other practitioners would have done the same." *Id.* at 31a. *See* Hellman, *Prosecuting Doctors*, 16 GEO. MASON L. REV. at 710 ("A subjective approach would criminalize only the conduct of the doctor who himself believes that what is he is doing is not within the scope of medical practice …").

But the Tenth Circuit was wrong to say a physician may be convicted if he wrote a prescription that was "*objectively* not in the usual course of professional practice." Pet. App. 31a (emphasis added). The subjective *mens rea* requirement in Section 841(a)—"knowingly or intentionally"—applies to *all* of Section 1306.04(a), not just the legitimate medical purpose language. This is bolstered by the fact that the text of

the regulation is phrased in personal terms: It speaks of "an *individual* practitioner acting in the usual course of *his* professional practice." 21 C.F.R. § 1306.04(a) (emphases added). That is the language of subjectivity, not objectivity. Accordingly, to obtain a conviction, it is necessary (but not sufficient) for the government to prove that the physician *knowingly or intentionally* acted outside of the usual course of *his own* medical practice in writing a prescription for a controlled substance.

This reading of the statute is not only the most faithful to the text grammatically, it is also the only reading that comports with the text in holding the physician to the same standard of culpability as the ordinary person. *Moore* clarifies that doctors are not exempt simply by their status, but neither does the CSA hold providers to a higher standard than that of a non-physician or ordinary person who distributes controlled substances. 432 U.S. at 140.

The ordinary person is criminally liable under the Act only when he distributes drugs *knowingly or intentionally*. Because distributing drugs is what the physician practicing medicine *does* ordinarily and non-culpably, the mental state elements cannot be satisfied by the writing of the prescription itself. That reading would negate the mental state element of the offense and thus the culpable state of mind that the statute clearly requires. To hold the physician to the same standards of culpability as the non-physician, the best reading of the statute requires that the physician knowingly or intentionally writes *an unauthorized prescription*. In other words, the physician must

know or intend that the prescription is not "for a legitimate medical purpose" issued "in the usual course of his professional practice." This interpretation would hold the physician who sells his prescriptions for money criminally liable because this physician intends to write an unauthorized prescription. It also would hold culpable the physician who knowingly writes a prescription for nonmedical purposes because this physician knows that prescription is unauthorized. What it excludes is the physician who neither intends nor knows that his prescribing is not in accord with current medical standards. While this physician may be negligent, he does not act criminally.

B. The objective elements of the regulations should be read as consistent with the subjective *mens rea* requirement, so that together they separate good actors from bad actors.

Some objectivity is built into the regulation. To be convicted, the physician must subjectively know that his prescription was not for a legitimate medical purpose. But the legitimacy of a medical purpose is assessed objectively. A physician cannot successfully defend by saying that he wrote a prescription for what he subjectively believed was a legitimate medical purpose but which he knows departs from what is a legitimate medical purpose as an objective matter. *See* BLACK'S LAW DICTIONARY (11th ed. 2019) (defining "legitimate" as lawful; genuine; valid). Similarly, the phrase "the usual course of his professional practice" has a subjective element ("his") and an objective one ("usual"). The doctor is criminally liable only if he

knows or intends that his conduct exceeds these boundaries.

What work, then, do the objective elements in the regulation perform? They separate two types of criminal actors from two types of non-criminal actors. The objective elements separate (a) the practitioner who is simply a drug dealer, not a doctor, and (b) the practitioner who knows his goals in prescribing are not among medicine's traditional aims from (c) the physician who acts with a good intent but makes an honest mistake and (d) the physician who experiments with new treatments in an evolving field of medicine. In other words, the objective elements separate the Drug Pusher and the Aberrant Physician from the Out-of-Date Physician and the Potential Pioneer.

Consider these examples:

The Drug Pusher: The physician who neither intends to practice medicine, nor believes that what he is doing constitutes the practice of medicine, is criminally liable under the statute. The doctor who sells prescriptions fits this description.

The Aberrant Physician: The physician who prescribes controlled substances for aims other than to promote healing or alleviate suffering is no longer practicing medicine. He is criminally liable when he knows that his prescribing departs from legitimate medical purposes, objectively defined.

The Out-of-Date Physician: The physician who intends to alleviate the suffering of patients in pain but is not up-to-date regarding fast moving standards of pain treatment is not liable under the statute. He

neither intends to prescribe without a legitimate medical purpose, nor knows that his prescribing no longer accords with accepted norms.

The Potential Pioneer: The physician who intends to alleviate the suffering of patients in pain and adopts a new method of treatment that is not (or not yet) accepted by the profession is not liable under the statute. He neither intends to prescribe without a legitimate medical purpose, nor knows that his prescribing exceeds the usual course of *his* professional practice.

C. Jury instructions must clearly require the subjective mental states of knowledge or intention.

Turning now to the other decision below. In *United States v. Ruan*, 966 F.3d 1101 (11th Cir. 2020), *cert. granted*, 142 S. Ct. 457 (2021), the Eleventh Circuit erred by affirming jury instructions that omitted the statutory *mens rea* requirement entirely: "Thus a medical doctor has violated Section 841 when the government has proved beyond a reasonable doubt that the doctor's actions were either not for a legitimate medical purpose or were outside the usual course of professional medical practice." Pet. App. 139a. The instructions should have instructed the jury to convict only if the physician *knew* or *intended* that his actions were not for a legitimate medical purpose in the usual course of *his* own professional practice.

The Eleventh Circuit held in *Ruan* that "[w]hether a defendant acts in the usual course of his professional

practice must be evaluated based on an objective standard, not a subjective standard." Pet. App. 105a (internal quotation marks omitted). That is incorrect; whether "an *individual* practitioner" intends or knows he is "acting in the usual course of *his* professional practice," is a subjective standard. 21 C.F.R. § 1306.04(a) (emphases added). *See* Hellman, *Prosecuting Doctors*, 16 GEO. MASON L. REV. at 707–08 ("[T]he use of the possessive 'his' in front of 'professional' suggests that the doctor acts permissibly so long as he exercises his own professional judgment in prescribing drugs, even if this manner of practice departs from a generally accepted standard.").

Petitioner Ruan properly faults the district court for not giving his proposed "good faith" instruction and the Eleventh Circuit for affirming that call. Good faith is best understood as another way to describe the *mens rea* element. If a physician acted for a good purpose, he acted in good faith. If he did not know that his conduct departs from accepted medical practice, he acted in good faith. It is important precisely because the statute refers to the standards of medical practice and thus could, mistakenly, be taken to imply that a doctor who departs from these standards is *criminally* liable.

Negligent conduct is not made criminal by this statute, however, as the statute clearly requires a *mens rea* of knowledge or intent. "[E]ven a negligent physician is inoculated against criminal liability under Section 841(a) as long as he acts in good faith." *United States v. Sabean*, 885 F.3d 27, 44 (1st Cir. 2018). "Because good faith is a defense to criminal

charges under Section 841(a) but not to civil liability for medical malpractice, 'inclusion of a good faith instruction is … a plainspoken method of explaining to the jury a critical difference between the two standards.'" *Id.* at 45 (quoting *United States v. Smith*, 573 F.3d 639, 650 (8th Cir. 2009)).

It must be acknowledged, however, that the words "good faith" do not appear in Section 841(a) or Section 1306.04(a). If proper jury instructions consistent with the "knowingly or intentionally" *mens rea* requirement in the statute are given, there may well be no need for a judge-made "good faith" defense. In the decisions below, however, proper jury instructions were not given. Thus, the *Kahn* and *Ruan* decisions cannot stand.

* * *

Proper interpretation of the CSA is vital to the tens of millions of Americans who must contend every day with severe and chronic pain. The appropriate standard for criminal intent under Section 841(a) must protect providers who are good actors and the patients in their care, and not create incentives for patient abandonment or neglect. Correctly construed, the CSA's *mens rea* requirement avoids overdeterrence of physicians while permitting prosecution of bad actors. The plain text of Section 841(a) controls here: The "knowingly or intentionally" *mens rea* requirement enacted by Congress in Section 841(a) applies in a prosecution of a physician under Section 1306.04(a).

CONCLUSION

For the foregoing reasons, the judgments of the Courts of Appeals should be vacated, and the cases should be remanded for further proceedings.

Respectfully submitted,

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