No. 20-1410

In the Supreme Court of the United States

DR. XIULU RUAN,
Petitioner,
v.
UNITED STATES OF AMERICA,
Respondent.

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

BRIEF FOR AMICUS CURIAE DUE PROCESS INSTITUTE IN SUPPORT OF PETITIONER

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INTEREST OF AMICUS CURIAE[1]

Due Process Institute is a nonprofit bipartisan public interest organization that works to honor, preserve, and restore procedural fairness in the criminal legal system because due process is the guiding principle that underlies the Constitution's solemn promises to "establish [j]ustice" and to "secure the [b]lessings of [l]iberty." U.S. Const., preamble. Ensuring that criminal liability is not imposed on otherwise innocent conduct absent a showing of malicious intent and that individuals are provided constitutionally adequate notice of which actions are subject to criminal liability are among Due Process Institute's top priorities.

INTRODUCTION AND SUMMARY OF ARGUMENT

Physicians often confront difficult and complex choices when treating patients. But faced with increasing exposure to criminal penalties and unclear standards governing Government enforcement efforts, physicians are increasingly shifting away from treating patients out of fear. For example, a recent study found 40.7% of clinics contacted "were not willing to schedule an appointment for a new patient who was currently taking opioids for chronic pain." Pooja A. Lagisetty et al., *Access to Primary Care Clinics for Patients with Chronic Pain Receiving Opioids* 4, JAMA Network Open (2019),

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[1] No counsel for a party authored this brief in whole or in part; and no party, counsel for a party, or any person or entity other than amicus curiae and their counsel made a monetary contribution intended to fund the preparation or submission of this brief. Amicus files this brief with all parties' written consent.

https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2737896.

This Court can and should take steps to mitigate that concern. Under 21 U.S.C. § 841(a)(1) of the Controlled Substances Act ("Act" or "CSA"), "*[e]xcept as authorized by this subchapter*, it shall be unlawful for any person *knowingly or intentionally* . . . to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance." 21 U.S.C. § 841(a)(1) (emphasis added). Under the subchapter, persons who have registered with the Attorney General are authorized to distribute or dispense controlled substances "to the extent authorized by their registration." *Id.* § 822(b). To give those terms meaning, courts have looked to a regulation, 21 C.F.R. § 1306.04(a), which provides that in order for "[a] prescription for a controlled substance 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." And, in order to avoid criminalizing otherwise innocent or mere negligent conduct, several courts have correctly recognized that physicians (and pharmacists) do not violate the statute if they act in good faith when dispensing controlled substances.

But, in the decision below, the Eleventh Circuit disclaimed application of that standard and followed its prior precedent, which holds that a physician's "good faith belief that he dispensed a controlled substance in the usual course of his professional practice is *irrelevant*." *United States v. Enmon*, 686 F. App'x 769, 773 (11th Cir. 2017) (per curiam) (emphasis added). That approach is erroneous for two primary reasons.

First, this Court has long held that a showing of malicious intent is usually required to criminalize otherwise innocent conduct. And Section 841(a)(1) itself embodies this requirement by stating that a violation must occur knowingly or intentionally. What separates innocent from unlawful conduct in these cases is whether a physician dispenses controlled substances without a legitimate medical purpose in the usual course of his or her professional practice.

As a result, what a physician subjectively intended when dispensing should be determinative of criminal liability. A "medical purpose" standard—which provides that a physician who believes in good faith that his or her dispensing of a controlled substance serves a valid clinical purpose—gives full force to this Court's presumption in favor of requiring malicious intent for criminal liability, enforces the statutory requirement of knowing or intentional conduct, and safeguards the advancement of medical treatment by not penalizing physicians who have an ethical obligation to treat their patients.

Second, requiring a showing of malicious intent through the use of a subjective medical purpose standard partially obviates vagueness concerns raised by Section 841(a)(1) and 21 C.F.R. § 1306.04(a)'s ambiguous reach. "[L]egitimate medical purpose . . . in the usual course of his professional practice," 21 C.F.R. § 1306.04(a), is not defined by statute or regulation, and courts have struggled to give those phrases any concrete meaning. As a result, physicians lack sufficient notice of what conduct constitutes a criminal violation. The absence of a concrete standard leaves prosecutors with virtually unbounded discretion, which inexorably

leads to arbitrary enforcement. A good faith medical purpose standard, however, would help alleviate these concerns by tying the Government's ability to obtain a conviction under Section 841(a)(1) to proof of a culpable state of mind as opposed to the vague notion of "generally accepted medical practice."

Accordingly, this Court should make clear that a good faith medical standard is the appropriate benchmark for criminal liability for physicians under Section 841(a)(1).

ARGUMENT

I. LONGSTANDING PRINCIPLES OF CRIMINAL LAW COUNSEL IN FAVOR OF ADOPTING A GOOD FAITH MEDICAL PURPOSE STANDARD

Under 21 U.S.C. § 822, physicians registered by the Attorney General may "dispense" controlled substances. *See* 21 U.S.C. § 841(a)(1) (excluding persons from liability for conduct authorized elsewhere by the Controlled Substances Act). As to registered physicians, prescribing controlled substances[2] constitutes a criminal violation only where the prescription is not "issued for a legitimate medical purpose . . . in the usual course of his [or her] professional practice." 21 C.F.R. § 1306.04(a); *see also* 21 U.S.C. § 841(a)(1).

The majority of courts have accepted the use of a good faith standard to distinguish the *criminal* conduct contemplated by Section 841(a)(1) from innocent or negligent behaviors and many have concluded that a *subjective* good faith standard is

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[2] Under the statute, the term "dispense" encompasses "the prescribing . . . of a controlled substance." 21 U.S.C. § 802(10).

required. Three Circuits, the First, Seventh, and Ninth, utilize a "subjective" good faith standard, which focuses juries on the defendant-physician's actual malicious intent or lack thereof. *See United States v. Sabean*, 885 F.3d 27, 45-46 (1st Cir. 2018); *United States v. Kohli*, 847 F.3d 483, 490 (7th Cir. 2017); *United States v. Feingold*, 454 F.3d 1001, 1009-10 (9th Cir. 2006). Another three Circuits permit an "objective standard" of good faith, which shields from criminal liability physicians who dispense a controlled substance in accordance with what he or she reasonably believes to be proper medical practice. *United States v. Wexler*, 522 F.3d 194, 206 (2d Cir. 2008); *United States v. Hurwitz*, 459 F.3d 463, 475, 477-78 (4th Cir. 2006); *United States v. Voorhies*, 663 F.2d 30, 34 (6th Cir. 1981).

The Eleventh Circuit has departed from both of those approaches. In its view, "[t]he appropriate focus is not on the subjective intent of the doctor, but rather it rests upon whether the physician prescribes medicine 'in accordance with a standard of medical practice generally recognized and accepted in the United States.'" *United States v. Merrill*, 513 F.3d 1293, 1306 (11th Cir. 2008) (quoting *United States v. Williams*, 445 F.3d 1302, 1309 (11th Cir. 2006)). Indeed, the Circuit has deemed a physician's beliefs and intent "irrelevant." *United States v. Enmon*, 686 F. App'x 769, 773 (11th Cir. 2017) (per curiam).

The first group of Circuits, which utilize a subjective good faith standard, have more closely hewed to this Court's precedent. In order to avoid criminalization of innocent or merely medically negligent conduct and in accordance with longstanding guidance from this Court requiring a showing of malicious intent when otherwise innocent

conduct is being criminalized, the Court should hold that a physician cannot be convicted for violating Section 841(a)(1) unless he or she acts without a subjective good faith medical purpose when dispensing a controlled substance.

1. "[A] basic principle that underlies the criminal law" is "the importance of showing what Blackstone called 'a vicious will.'" *Rehaif v. United States*, 139 S. Ct. 2191, 2196 (2019) (citing 4 William Blackstone, *Commentaries on Laws of Eng.* 21 (1769)). In practice, that principle has led to "the understanding that an injury is criminal only if inflicted knowingly." *Id.*; *see also Elonis v. United States*, 575 U.S. 723, 734 (2015) ("[W]rongdoing must be conscious to be criminal." (quoting *Morissette v. United States*, 342 U.S. 246, 252 (1952))). That understanding "is as universal and persistent in mature systems of law as belief in freedom of the human will and a consequent ability and duty of the normal individual to choose between good and evil." *Morissette*, 342 U.S. at 250.

In light of that principle, this Court "start[s] from a longstanding presumption, traceable to the common law, that Congress intends to require a defendant to possess a culpable mental state regarding 'each of the statutory elements that criminalize otherwise innocent conduct.'" *Rehaif*, 139 S. Ct. at 2195 (quoting *United States v. X-Citement Video, Inc.*, 513 U.S. 64, 72 (1994)); *see also Morissette*, 342 U.S. at 256-58. Therefore, this Court "generally 'interpret[s] criminal statutes to include broadly applicable scienter requirements, even where the statute by its terms does not contain them." *Elonis*, 575 U.S. at 734 (quoting *X-Citement Video*, 513 U.S. at 70).

Take *Liparota v. United States*, where this Court evaluated a federal statute governing food stamp use,

which provided that "'whoever knowingly uses, transfers, acquires, alters, or possesses coupons or authorization cards in any manner not authorized by [the statute] or the regulations' is subject to a fine and imprisonment." 471 U.S. 419, 420 (1985) (alteration in original) (quoting 7 U.S.C. § 2024(b)(1) (1982)). The central question at issue was whether the Government was required to "prove that the defendant knew that he was acting in a manner not authorized by statute or regulations." *Id.* at 421. For its part, the Government contended that establishing a violation of the statute merely turned on whether the petitioner "knew that he acquired or possessed food stamps and if in fact that acquisition or possession was in a manner not authorized by statute or regulations." *Id.* at 423.

This Court soundly rejected the Government's argument, holding that the statute "requires a showing that the defendant knew his conduct to be unauthorized by statute or regulations." *Id.* at 425. That construction was driven in large part because, "to interpret the statute otherwise[,] would . . . criminalize a broad range of apparently innocent conduct." *Id.* at 426. As the Court noted, the statute provides that coupons "shall be used . . . to purchase food in retail food stores which have been approved for participation in the food stamp program at prices prevailing in such stores." *Id.* (emphasis omitted) (quoting 7 U.S.C. § 2016(b) (1982)). Under the view urged by the Government—"[a] strict reading of the statute with no knowledge-of-illegality requirement"—an individual would be rendered a criminal where he or she "used stamps to purchase food from a store that, unknown to him, charged higher than normal prices to food stamp program

participants." *Id.* That result ran counter to the fundamental principles of criminal law, namely the requirement that a violator have malicious intent.

The Court further refined those principles in *Elonis*, where it evaluated a statute that provided "[a]n individual who 'transmits in interstate or foreign commerce any communication containing any threat to kidnap any person or any threat to injure the person of another' is guilty of a felony." 575 U.S. at 732 (quoting 18 U.S.C. § 875(c)). In that case, the Government contended that the statute did not require a showing of any particular mindset as to the act of communicating a threat. *Id.* at 733.

The Court rejected that approach. Both parties agreed as a foundational point that a defendant must know he was transmitting a communication for criminal liability to attach. *Id.* at 737. As this Court put it, however, "communicating *something* is not what makes the conduct 'wrongful," rather "'the crucial element separating legal innocence from wrongful conduct' is the threatening nature of the communication." *Id.* (quoting *X-Citement Video*, 513 U.S. at 73). As a result, "[t]he mental state requirement must therefore apply to the fact that the communication contains a threat." *Id.*

Based on that conclusion, the Court reversed because the defendant's conviction "was premised solely on how his posts would be understood by a reasonable person." *Id.* at 737. The Court decried the carrying over of a "reasonable person" standard from tort law, observing that it "is inconsistent with 'the conventional requirement for criminal conduct—*awareness* of some wrongdoing.'" *Id.* at 737-38 (quoting *Staples v. United States*, 511 U.S. 600, 606-07 (1994)). Indeed, the Court observed that reliance

on a reasonable person standard, "regardless of what the defendant thinks[,] 'reduces culpability on the all-important element of the crime to negligence,' and we 'have long been reluctant to infer that a negligence standard was intended in criminal statutes.'" *Id.* at 738 (first quoting *United States v. Jeffries*, 692 F.3d 473, 484 (6th Cir. 2012) (Sutton, J., dubitante); and then quoting *Rogers v. United States*, 422 U.S. 35, 47 (1975) (Marshall, J., concurring)).

And, although the Government attempted to reframe its standard as something more than mere negligence, the Court was not persuaded. The Government "emphasiz[ed] that its approach would require proof that a defendant 'comprehended [the] contents and context' of the communication." *Id.* at 738 (alteration in original) (quoting *Elonis* United States Br. 29, 2014 WL 4895283). The Court observed that was nothing more than a negligence standard, which was insufficient to establish federal criminal liability: [The defendant] can be convicted, the Government contends, if he himself knew the contents and context of his posts, and a reasonable person would have recognized that the posts would be read as genuine threats. That is a negligence standard." *Id.* at 739. That reliance on a negligence standard was insufficient in the Court's view to impose *criminal* liability.

2. These bedrock principles of criminal law point to a clear answer in this case—a defendant-physician violates Section 841(a)(1) only when he or she dispenses a controlled substance without a subjective good faith medical purpose. Under *Liparota* and *Elonis*, where otherwise innocent conduct is at issue, a court should focus on the mens rea as to the element or act that separates *innocent* conduct from *criminal*

conduct. *See Liparota*, 471 U.S. at 425-26; *Elonis*, 575 U.S. at 737. And, as to that element or act, a mens rea of negligence is not sufficient to impose criminal liability. *Elonis*, 575 U.S. at 737-38.

The statute at issue here provides: "Except as authorized by this subchapter, it shall be unlawful for any person *knowingly or intentionally* . . . to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance." 21 U.S.C. § 841(a)(1) (emphasis added). Under the subchapter, persons who have registered with the Attorney General are authorized to dispense controlled substances "to the extent authorized by their registration." *Id.* § 822(b). To define that offense as to physicians who routinely dispense controlled substances as part of their professional duties, courts have looked to 21 C.F.R. § 1306.04(a), which provides that, for "[a] prescription for a controlled substance 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." The phrase "legitimate medical purpose . . . in the usual course of his professional practice" has no statutory or regulatory definition. *See United States v. Birbragher*, 603 F.3d 478, 485 (6th Cir. 2010) (citation omitted).

Under Section 841(a)(1), what separates otherwise innocent conduct from "'wrongful conduct' is the" knowing or intentional dispensing of a controlled substance without a "legitimate medical purpose." *See Elonis*, 575 U.S. at 737 (citation omitted). As a result, a defendant-physician's mens rea *as to legitimate medical purpose* is determinative of criminal liability.

And, in accordance with this Court's holding in *Elonis*, a negligence standard, *i.e.* a reasonable person standard (or reasonable physician standard), should not be considered sufficient to establish criminal liability. Yet, punishing a physician for violating "generally accepted medical practice" does just that—by punishing mere medical negligence.[3] In contrast, a standard that provides a physician cannot be convicted under Section 841(a)(1) unless he or she acts without a subjective good faith medical purpose properly focuses the inquiry on a physician's criminal intent and fully accords with the Court's treatment of Section 2024(b)(1) in *Liparota* and Section 875(c) in *Elonis*.[4]

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[3] Of course, physicians may be held liable in civil proceedings, where a showing of negligence can be sufficient for liability. Additionally, State bodies possess the authority to regulate medical practice under their reserved police powers. *See* Br. of Amici Curiae Professors of Health Law & Policy in Supp. of Pet'r 15-25, *Ruan v. United States*, No. 20-1410 (May 7, 2021).

[4] To the extent this Court concludes that the statute or regulation is ambiguous as to the mens rea required for the "legitimate medical purpose . . . acting in the usual course of his professional practice" element because the regulation does not include a mens rea requirement, it should apply the rule of lenity and construe the statute and regulation in favor of petitioner-physicians. Any "ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity." *Liparota*, 471 U.S. at 427 (quoting *Rewis v. United States*, 401 U.S. 808, 812 (1971)). In cases where physicians face decades of imprisonment for dispensing prescriptions (a routine part of a physician's obligation as a medical professional and part of their ethical obligations to alleviate suffering, described *infra* at 13-15), the rule of lenity counsels in favor of requiring a showing of malicious intent to avoid criminalizing innocent or merely negligent conduct. And the statute, to the extent it is ambiguous

Courts that have accepted a subjective good faith standard recognize the wisdom of this approach. Echoing this Court's admonition in *Liparota* that a defendant must act intentionally as to the element that separates otherwise innocent conduct from criminal conduct, the Ninth Circuit has held "that a practitioner who acts outside the usual course of professional practice may be convicted under [Section] 841(a) only if he does so intentionally." *Feingold*, 454 F.3d at 1007-08. Because "a practitioner's distribution of controlled substances becomes illegal only by virtue of the fact that his actions are 'outside the usual course of professional practice,' it follows that the practitioner must have deliberately acted in this fashion in order for him to be convicted of a crime." *Id.* (quoting *United States v. Moore*, 423 U.S. 122, 124 (1975)); *see also United States v. Rosenberg*, 515 F.2d 190, 197 (9th Cir. 1975) (holding "the jury [must] look into [a practitioner's] mind to determine whether he prescribed the pills for what he thought was a medical purpose or whether he was passing out the pills to anyone who asked for them").

The First Circuit has recognized that a subjective good faith standard is similarly necessary to distinguish medical negligence from malicious intent. *See Sabean*, 885 F.3d at 45 ("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

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as applied to physicians, clearly points in favor of requiring a knowing and intentional violation for criminal liability to attach. 21 U.S.C. § 841(a)(1).

the two standards.'" (quoting *United States v. Smith*, 573 F.3d 639, 650 (8th Cir. 2009))); *see also Kohli*, 847 F.3d at 490 ("In other words, the evidence must how that the physician not only intentionally distributed drugs, but that he intentionally 'act[ed] as a pusher rather than a medical professional.'" (quoting *United States v. Chube*, 538 F.3d 693, 698 (7th Cir. 2008))).

In contrast, under the Eleventh Circuit's approach, "whether the [physician] had a good faith belief that he dispensed a controlled substance in the usual course of his professional practice *is irrelevant*." *Enmon*, 686 F. App'x at 773, 779 (emphasis added) (affirming conviction where jury instruction quoted was used). Under that formulation, a physician who believes he or she is acting in accordance with generally accepted medical principles, however those are defined, could nonetheless be subject to criminal liability and lengthy imprisonment. That approach runs headlong into this Court's decision in *Elonis*. In the context of a criminal statute, the *intent* and *subjective beliefs* of the defendant are precisely what matter.

3. The issue of subjective belief is even more important in light of physicians' ethical duties and the ever-advancing nature of medicine. As this Court has made clear, "[t]he statute and our case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally." *Gonzalez v. Oregon*, 546 U.S. 243, 269-70 (2006).

A standard that is bound to "generally accepted practice" and objective belief punishes physicians who may act outside of that practice to serve the best interests of their patients (as they are ethically bound to do). American Medical Association ("AMA"), Patient-Physician Relationships: Code of Medical Ethics Opinion 1.1.1., https://www.ama-assn.org/delivering-care/ethics/patient-physician-relationships (last visited Dec. 23, 2021). The physician-patient relationship *requires* physicians to "place patients' welfare above the physician's own self-interest or obligations to others" and "to advocate for their patients' welfare." *Id.*

Physicians' ethical duties to patients include alleviating suffering and providing pain relief where appropriate. *Id.*; *see also* Kate M. Nicholson & Deborah Hellman, *Opioid Prescribing and the Ethical Duty to* Do No Harm, 46 Am. J. L. & Med. 297, 299 (2020) ("Relief from suffering is a central duty of physicians, and by all measures, pain remains undertreated."). According to estimates, "50 million Americans suffer from persistent, daily, or near daily pain; 40 million report severe pain, and nearly 20 million have pain that is effectively disabling." *Id.* Physicians are under an obligation to provide treatment to those individuals and, arguably, *cannot* in accordance with their ethical duties to patients refuse to prescribe controlled substances to patients suffering from debilitating pain.

In some cases, physicians may need to go outside of "generally accepted medical practice" in order to fulfill their ethical obligations to provide treatment and alleviate suffering. That is not a practice this society should discourage. Physicians should not be forced to choose between their ethical obligations to

their patients and the risk of imprisonment where they harbor a good faith belief that their dispensing is for a legitimate medical purpose.[5]

Criminalizing physicians who have transgressed the "generally accepted" bounds of practice while acting in their patients' best interests also risks impeding the advancement of medical treatment. Developments in medicine have often been driven by those on the vanguard of practice. As Amici Curiae Professors of Health Law and Policy discussed at the certiorari stage, "[t]he dark side of standard of care as a proxy in criminal prescribing cases is that fear of scrutiny pushes practitioners solidly to the 'safe middle,' at least for the practitioner, where adoption of new practices dies." Br. of Amici Curiae Professors of Health Law & Policy in Supp. of Pet'r 12, *Ruan v. United States*, No. 20-1410 (May 7, 2021). By criminalizing physicians who dare to stray from the middle-of-the-pack, the Government's urged approach risks stymieing future medical advances. That runs counter to this Court's precedent, which has long recognized that criminal law should not be interpreted so as to discourage beneficial conduct and create socially undesirable results. *Cf. United States v. U.S. Gypsum Co.*, 438 U.S. 422, 441 (1978) (expressing concern in the antitrust context that

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[5] Of course, in our Federalist system, States have a legitimate interest in regulating the practice of medicine within their borders and may impose limitations on particular treatments pursuant to those interests. *See Whalen v. Roe*, 429 U.S. 589, 603 n.30 (1977) (noting it is "well settled that the State has broad police powers in regulating the administration of drugs by the health professions"). Federal criminal law, however, is not the appropriate mechanism to impose such limitations.

criminalization could raise the "distinct possibility of overdeterrence; salutary and procompetitive conduct lying close to the borderline of impermissible conduct might be shunned by businessmen who chose to be excessively cautious in the face of uncertainty regarding possible exposure to criminal punishment for even a good-faith error of judgment"); *United States v. Feola*, 420 U.S. 671, 678-79 & n.14 (1975) ("Were knowledge not required in obstruction of justice offenses described by these terms, wholly innocent (or even socially desirable) behavior could be transformed into a felony by the wholly fortuitous circumstance of the concealed identity of the person resisted." (quoting *United States v. Fernandez*, 497 F.2d 730, 744 (9th Cir. 1974) (Hufstedler, J., concurring))).

4. Notwithstanding this Court's longstanding requirement that malicious intent be shown for criminal liability to attach and the wisdom of that approach when criminalizing conduct that is an everyday part of physicians' professional and ethical duties, the Government may argue that Section 841(a)(1) is nonetheless akin to a strict liability statute. Although a small range of offenses are exempt from the broad principle that malicious intent is required (so-called "public welfare offenses" or "regulatory offenses"), this Court should not expand that category to encompass Section 841(a)(1) as applied to physicians because (1) Congress has provided a general mens rea requirement and (2) the penalties for violation of the Controlled Substances Act are severe.

In a small subset of cases, this Court has "understood Congress to impose a form of strict criminal liability through statutes that do not require

the defendant to know the facts that make his conduct illegal." *Staples v. United States*, 511 U.S. 600, 606 (1994). But importantly, the statutes there were *silent* on mens rea. *Id.* at 606-07. By contrast here, the statute evinces an intent by Congress to require knowing or intentional conduct. 21 U.S.C. § 841(a)(1). Given that Congress was not wholly silent on the mens rea required, this Court should avoid construing a violation as a public welfare offense.

In any event, the severity of the penalties under the Act counsels against construing this as a public welfare offense and in favor of requiring a showing of malicious intent. Convictions under Section 841(a)(1) are felonies and carry lengthy terms of imprisonment. *See* 21 U.S.C. § 841(b). The convictions at issue here, concerning the dispensing of Schedule II and Schedule III narcotics, carry terms of potential imprisonment of up to 20 and 15 years, respectively. *Id.* That potential sentence accrues for each act of dispensing, which a physician may do hundreds of times a year. Those harsh penalties further buttress the need for this Court to weigh in and conclude that the statute requires more than negligent medical conduct by a doctor to permit conviction. *See U.S. Gypsum Co.*, 438 U.S. at 442 n.18 (imprisonment of up to three years counsels against construing statute as a strict-liability crime); *see also Rehaif*, 139 S. Ct. at 2197 (potential penalty of 10 years' imprisonment weighs against discarding the presumption requiring a showing of malicious intent); *United States v. Wulff*, 758 F.2d 1121, 1125 (6th Cir. 1985) (imprisonment of up to two years advises against construing statute as strict liability).

II. THE VAGUENESS OF SECTION 841(A)(1) AND 21 C.F.R. § 1306.04(A) PROVIDE ADDITIONAL SUPPORT FOR REQUIRING A GOOD FAITH MEDICAL PURPOSE STANDARD

Applying a subjective good faith medical purpose standard would also help alleviate vagueness concerns.

"The Fifth Amendment provides that '[n]o person shall . . . be deprived of life, liberty, or property, without due process of law." *Johnson v. United States*, 576 U.S. 591, 595 (2015) (alterations in original) (quoting U.S. Const. amend. V). This Court's "cases establish that the Government violates this guarantee by taking away someone's life, liberty, or property under a criminal law so vague that it fails to give ordinary people fair notice of the conduct it punishes, or so standardless it invites arbitrary enforcement." *Id.*; *see also Skilling v. United States*, 561 U.S. 358, 412 (2010) ("[T]he void-for-vagueness doctrine addresses concerns about (1) fair notice and (2) arbitrary and discriminatory prosecutions."); *City of Chicago v. Morales*, 527 U.S. 41, 56 (1999) ("Vagueness may invalidate a criminal law for either of two independent reasons.').

Under the Eleventh Circuit's construction of the statute and regulation, both of those concerns are present in spades. As this Court has previously recognized, to avoid "the due process concerns underlying the vagueness doctrine," the Court may draw limitations not explicitly found in a criminal statute. *See Skilling*, 561 U.S. at 408-09; *id.* at 406 ("It has long been our practice, however, before striking a federal statute as impermissibly vague, to

consider whether the prescription is amenable to a limiting construction."). To the extent the Court concludes that a good faith medical purpose standard is not provided for explicitly, it should interpret any ambiguities to authorize one in light of the statute's and regulation's vague natures.

A. The Statute And Regulation's Lack Of Clear Guidelines Presents Grave Notice Concerns

"Perhaps the most basic of due process's customary protections is the demand of fair notice." *Sessions v. Dimaya*, 138 S. Ct. 1204, 1225 (2018) (Gorsuch, J., concurring in part and concurring in the judgment). "[T]he purpose of the fair notice requirement is to enable the ordinary citizen to conform his or her conduct to the law." *City of Chicago*, 527 U.S. at 58. The statutory and regulatory scheme as interpreted by the Eleventh Circuit fails to provide that clear guidance.

As mentioned *supra* at 10, the phrase "legitimate medical purpose . . . in the usual course of his professional practice" has no statutory or regulatory definition (in fact, it is not mentioned in the statutory provision at all). *See United States v. Birbragher*, 603 F.3d 478, 485 (6th Cir. 2010). Courts have regularly acknowledged the lack of substance in those terms. *See, e.g.*, *United States v. Singh*, 54 F.3d 1182, 1187 (4th Cir. 1995) ("[T]here are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice." (quoting *United States v. August*, 984 F.2d 705, 713 (6th Cir. 1992)); *Sabean*, 885 F.3d at 46 ("There is no pat formula describing what proof is required to ground a finding that a

defendant acted outside the usual course of professional practice."). The Eleventh Circuit, however, has essentially distilled the inquiry into whether a physician's prescription is consistent with "medical practice generally recognized and accepted." *United States v. Merrill*, 513 F.3d 1293, 1306 (11th Cir. 2008) (quoting *United States v. Williams*, 445 F.3d 1302, 1309 (11th Cir. 2006)). That approach results in significant fair notice problems for physicians.

1. Specifically, "medical practice generally recognized and accepted" is not susceptible to a precise definition, depriving physicians of adequate advance notice of what types of dispensing conduct will be deemed criminal.

There is no consensus within the medical field over what constitutes appropriate treatment. The recent divergence between recent federal recommendations and the American Medical Association's ("AMA") views exemplifies that point. In 2016, the Centers for Disease Control and Prevention ("CDC") issued its first national guidelines that concerned opioid prescriptions and addressed: (1) "when to initiate or continue opioids for chronic pain"; (2) "opioid selection, dosage, duration, follow-up, and discontinuation"; and (3) "assessing risk and . . . harms of opioid use." Deborah Dowell, Tamara M. Haegerich, & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity and Mortality Weekly Report (Mar. 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

Those guidelines were disputed by the very organization, the AMA, on which courts sometimes rely for the applicable medical standard in

Section 841(a)(1) cases involving physicians.[6] Specifically, in November 2018, the AMA criticized the CDC guidelines, particularly the guidelines regarding the maximum recommended opioid dose. *See* Julia B. MacDonald, *"Do No Harm or Injustice to Them": Indicting and Convicting Physicians for Controlled Substance Distribution in the Age of the Opioid Crisis*, 72 Me. L. Rev. 197, 221 (2020), https://digitalcommons.mainelaw.maine.edu/cgi/viewcontent.cgi?article=1730&context=mlr (noting that "[t]he AMA resolved that 'some patients with acute or chronic pain can benefit from taking opioids at greater dosages than recommended by the CDC Guidelines for Prescribing Opioids for chronic pain and that such care may be medically necessary and appropriate" (citation omitted)). The AMA also stated that the CDC guidelines should not be utilized "as anything more than guidance, and physicians should not be subject to professional discipline, . . . criminal prosecution, civil liability, or other penalties . . . solely for prescribing opioids at a quantitative level above the MME thresholds found in the CDC Guidelines." *Id.* (citation omitted).

Further complicating matters, the norms of medical practice are ever-shifting and ever-evolving. *See* Diane E. Hoffman, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance*

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[6] The Government has been permitted to call experts to testify as to the standard of care for physicians, including those outlined in the AMA's guidelines. *See United States v. Hoffman,* No. 06-CR-66-P-S, 2006 WL 3691487, at *3 (D. Me. Dec. 12, 2006)*; see also* Order on Def.'s Mot. in Limine to Exclude Certain Testimony of Gary Hatfield, M.D. 2-3*, United States v. Sabean*, No. 2:15-cr-00175-GZS (D. Me. Oct. 18, 2016), ECF No. 94 (permitting witness to testify as to the AMA Ethical Guidelines).

in our Drug Control Laws and Policies, 1 St. Louis U.. J. Health Care L. & Pol'y 231, 274, 291 (2008), https://www.slu.edu/law/academics/journals/health-law-policy/pdfs/issues/v1-i2/hoffmann_article.pdf (noting that courts have struggled with these undefined concepts and that the standard today is arguably vaguer than it was thirty years ago given the current state of medicine); MacDonald, *supra*, at 222 ("Given the debate within the medical community as to the standard of care for opioid prescriptions, the without a legitimate medical purpose element seems nearly impossible to define, much less to disprove.").[7] Given the lack of consensus and ever-changing norms, physicians are left without adequate guidance when "medical practice generally recognized and accepted" is used as the benchmark.

2. Indeed, even the United States Drug Enforcement Administration ("DEA"), the agency charged with enforcing the CSA and that promulgated the regulation at 21 C.F.R. § 1306.04(a), cannot articulate any clear meaning of the phrase "legitimate medical purpose . . . in the usual course of his practice." *See* 71 Fed. Reg. 52,716, 52,717 (Sept. 6, 2006) ("Federal courts have long recognized that it is not possible to expand on the phrase 'legitimate medical purpose in the usual course of professional practice,' in a way that will provide definitive

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[7] One commenter has observed that "[t]hese vague standards are particularly harmful for older or rural physicians, who are often overburdened with patients and not up to speed on the latest in medical ethics and best practices," noting that "[o]f the 378 physicians charged with controlled substance distribution under federal law or equivalent state laws between 2006 and 2016, over forty percent were over the age of sixty." MacDonald, *supra*, at 223.

guidelines that address all the varied situations physicians might encounter."). For example, in one adjudication applying 21 C.F.R. § 1306.04(a), the agency, through its expert, first purported to rely on a number of medical guidelines but then characterized the standard of care as "what the community does based on all the doctors and how they work together." 86 Fed. Reg. 33,748, 33,755 (June 25, 2021) (alterations in original). The agency's expert also acknowledged that the standard of care is imprecise, explaining "there's an art to medicine" that goes beyond any guidelines. *Id.* By its own admission then, the standard could be based on a potentially indeterminate number of sources as well as a vague consensus of "what . . . physicians are doing in the marketplace." *Id.* That hodgepodge is no standard at all—and certainly not the substance of which criminal violations are made.

The agency has likewise failed through guidance to piece together a coherent and concrete interpretation of the phrase "legitimate medical purpose . . . in the usual course of his practice" to guide physicians' conduct. In August 2004, the agency issued a guidance document that answered frequently asked questions from physicians. *See DEA's Flip-Flop on Prescribing Fuels Concern*, Drug Topics (Oct. 10, 2005), https://www.drugtopics.com/view/deas-flip-flop-prescribing-fuels-concern (last visited Dec. 20, 2021). That document addressed the use of pain medications and drugs like Ritalin used to treat attention deficit hyperactivity disorder. *Id.* But within a few weeks, DEA had pulled the document without warning—a move that "[m]any health professionals believe[d] . . . came in response to the drug trafficking trial of a Virginia physician, William

Hurwitz, whose attorneys tried to introduce the [document] into evidence." *Id.* In a subsequently issued guidance, DEA stated that the August 2004 contained "misstatements." 69 Fed. Reg. 67,170, 67,170-71 (Nov. 16, 2004).

Absent clear guidelines, physicians are left without adequate notice of what conduct may conceivably subject them to decades of imprisonment. Our Constitution does not countenance such treatment.

B. The Statute And Regulation's Imprecision Invites Arbitrary Enforcement

The vague nature of Section 841(a)(1) and 21 C.F.R. § 1306.04(a) gifts prosecutors almost unfettered discretion. Faced with prosecutorial overcharging, many physicians choose to plead guilty rather than take the massive risk of proceeding to trial.

1. As this Court has noted, "[a]lthough the [vagueness] doctrine focuses both on actual notice to citizens and arbitrary enforcement, we have recognized recently that the more important aspect of the vagueness doctrine 'is . . . the requirement that a legislature establish minimal guidelines to govern law enforcement.'" *Kolender v. Lawson*, 461 U.S. 352, 357-58 (1983) (quoting *Smith v. Goguen*, 415 U.S. 566, 574 (1974)). "Where the legislature fails to provide such minimal guidelines, a criminal statute may permit 'a standardless sweep [that] allows policemen, prosecutors, and juries to pursue their personal predilections.'" *Kolender*, 461 U.S. at 358 (alteration in original) (quoting *Goguen*, 415 U.S. at 575). "Vague laws also threaten to transfer legislative power to police and prosecutors, leaving to them the job of

shaping a vague statute's contours through their enforcement decisions." *Dimaya*, 138 S. Ct. at 1228 (Gorsuch, J., concurring in part and concurring in the judgment).

2. The threat of arbitrary enforcement looms large in the context of Section 841(a)(1) absent a subjective good faith medical purpose standard.

Without any meaningful guideposts concerning what is lawful for physicians under Section 841(a)(1), prosecutors are left to develop their own standards, without advance notice to physicians, regarding what type of dispensing is unlawful. That issue is compounded by the fact that in some Circuits, including the Eleventh, it is trivially easy to obtain an indictment because those Circuits have concluded that the Government need not even allege that a practitioner is acting in a manner unauthorized by the CSA. *See, e.g.*, *United States v. Steele*, 147 F.3d 1316, 1318 (11th Cir. 1998) ("[A]n indictment charging a violation of § 841(a) need not negate the course of professional practice exception . . . ."); *United States v. Polan*, 970 F.2d 1280, 1282 (3d Cir. 1992); *cf. United States v. Seelig*, 622 F.2d 207, 211 (6th Cir. 1980); *United States v. Roya*, 574 F.2d 386, 390–91 (7th Cir. 1978). That effectively allows the Government to charge any physician solely based on the fact that the physician has dispensed controlled substances. The Eleventh Circuit's only answer to that concern is that "busy government prosecutors would [not] want to indict any case that they are certain to lose when it goes to trial." *Steele*, 147 F.3d at 1319. But in our current plea-bargaining heavy system, that reasoning is cold comfort to physicians facing decades of imprisonment for doing their jobs.

In reality, for many physicians, the prosecutor's decision to charge and the resulting indictment is the final say on guilt or innocence. "Out of roughly 268 doctors investigated by the DEA and ultimately found guilty of either . . . federal or state crimes between 2003 and 2017, 222 pled guilty or no contest, while only 46 were convicted by a jury." MacDonald, *supra*, at 218. That is unsurprising given the charging decisions that many prosecutors make, including the choice to overcharge in order to obtain a more favorable position during plea bargain negotiation. *See* Stephanos Bibas, *Transparency and Participation in Criminal Procedure*, 81 N.Y.U. L. Rev. 911, 934 (2006), https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=1080&context=faculty_scholarship (last visited Dec. 20, 2021) (noting prosecutors "may file multiple initial charges to given themselves plea-bargaining chips").

As one scholar in the area noted, "[p]hysicians who are targeted by the DEA and their state-enforcement counterparts find it very difficult to defend against the alleged charges. In these cases, the physicians are often charged with hundreds of counts of criminal wrongdoing." Hoffman, *supra*, at 278. Each prescription for a controlled substance "can be a separate crime." *Id.* The heavy penalties associated with such charges and the massive risk associated with hundreds of counts of wrongdoing undoubtedly influence defendants to plead guilty, notwithstanding their actual intent when dispensing.

Given the potential for arbitrary enforcement unique to Section 841(a)(1), a good faith medical purpose standard is particularly appropriate. That standard would, at least, give defendant-physicians who acted with a good faith belief a greater chance of

successfully contesting the charges against them. In contrast, the Eleventh Circuit's approach here (rejecting a good faith medical purpose standard and even denying an objective good faith defense) strips defendant-physicians of the central defense in a case under Section 841(a)(1).

* * *

This Court's decision will have a wide-ranging impact. Both physicians and pharmacists are subject to 21 C.F.R. 1306.04(a)'s terms. Section 841(a)(1)'s reach is even broader. A number of actors, including manufacturers and distributors, are subject to its prohibition. By defining the contours of liability for physicians, under 21 C.F.R. § 1306.04(a) and Section 841(a)(1), this Court will also help make clear that its precedent equally applies to Section 841(a)(1) and that those actors' conduct cannot be criminalized absent a showing of malicious intent.

CONCLUSION

For the foregoing reasons, the Court should hold that a physician does not violate Section 841(a)(1) unless he or she dispenses a controlled substance without a good faith medical purpose.

Respectfully submitted,

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December 27, 2021