

No. 20-1410

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In The  
**Supreme Court of the United States**

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XIULU RUAN,

*Petitioner,*

v.

UNITED STATES OF AMERICA,

*Respondent.*

\_\_\_\_\_  
**On Writ of Certiorari  
to the United States Court of Appeals  
for the Eleventh Circuit**

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**BRIEF AMICUS CURIAE OF PACIFIC LEGAL  
FOUNDATION IN SUPPORT OF PETITIONER**

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## IDENTITY AND INTEREST OF AMICUS CURIAE<sup>1</sup>

Founded in 1973, Pacific Legal Foundation is a nonprofit, tax-exempt, California corporation established for the purpose of litigating matters affecting the public interest. PLF provides a voice in the courts for Americans who believe in limited constitutional government, private property rights, and individual freedom.

PLF is the most experienced public-interest legal organization defending the constitutional principle of separation of powers in the arena of administrative law. PLF's attorneys have participated as lead counsel in several cases involving the role of the Judicial Branch as an independent check on the Executive and Legislative branches under the Constitution's Separation of Powers. *See U.S. Army Corps of Eng'rs v. Hawkes Co., Inc.*, 136 S. Ct. 1807 (2016) (judicial review of agency interpretation of Clean Water Act); *Sackett v. EPA*, 566 U.S. 120 (2012) (same); *Rapanos v. United States*, 547 U.S. 715 (2006) (agency regulations defining "waters of the United States"). It also regularly participates in this Court as amici. *See, e.g., Lucia v. SEC*, 138 S. Ct. 2044 (2018)

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<sup>1</sup> After timely notice was given, counsel for all parties have consented to the filing of this brief. Pursuant to Rule 37.6, Amicus Curiae affirms that no counsel for any party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than Amicus Curiae, its members, or its counsel made a monetary contribution to its preparation or submission.



(SEC administrative-law judge is “officer of the United States” under the Appointments Clause).

This case addresses the role that an administrative agency has in creating a federal criminal offense. The decision under review allowed a prosecutorial agency to define a criminal offense, and even create criminal liability without an element of the defendant’s knowledge of wrongdoing. PLF, therefore, writes separately to explain how the result below threatens the separation of powers and defies core precepts of due process.

## **INTRODUCTION AND SUMMARY OF ARGUMENT**

Dr. Xiulu Ruan was convicted of overprescribing controlled substances outside the usual course of medical practice and was sentenced to more than 20 years in federal prison. But as the lower court held, to obtain this extraordinary prison sentence, the government never had to prove that Dr. Ruan was aware that he failed to live up to the prevailing standard of care.

That analysis botches the statutory text (as Dr. Ruan argues). But it also threatens important constitutional norms. The question dividing the courts of appeal centers not on statutory text, but on a regulation issued by the Drug Enforcement Agency, an arm of the same Department of Justice prosecuting Dr. Ruan. Through that regulation, DEA created criminal liability where there was none before, by eliminating any requirement that a physician be aware that his conduct departs from professional

practice. Congress cannot (and did not) delegate such lawmaking authority to an agency, and, even if it could, due process requires more notice to a criminal defendant before he can be imprisoned for decades. That constitutional requirement means that statutory text permits only one outcome—reading the statute to prohibit only *knowing* departures from acceptable standards of practice. A DEA regulation cannot supplant statutory text and due process.

## ARGUMENT

### I. CONGRESS PROHIBITED PRESCRIBING A CONTROLLED SUBSTANCE ONLY WHEN DONE WITH KNOWLEDGE THAT THE PRESCRIPTION WAS ISSUED OUTSIDE THE COURSE OF PROFESSIONAL PRACTICE

The Controlled Substances Act makes it unlawful “except as authorized” by the DEA, to “knowingly or intentionally” “distribute, or dispense” “a controlled substance.” 21 U.S.C. § 841(a)(1). To ensure that this prohibition encompassed the practice of medicine, Congress also provided that “no controlled substance . . . may be dispensed without the written prescription of a practitioner.” 21 U.S.C. § 829(a) (Schedule II substances). And stating the opposite, Congress said that “[p]ersons registered by the Attorney General” “to distribute, or dispense controlled substances” “are authorized” to do so, “to the extent authorized by their registration and in

conformity with the other provisions of” the CSA. 21 U.S.C. § 822(b).<sup>2</sup>

“Section 822(b) defines the scope of authorization under the Act in circular terms” though. *Moore*, 423 U.S. at 140. But, according to this Court, “the scheme of the statute, viewed against the background of the legislative history, reveals an intent to limit a registered physician’s dispensing authority to the course of his ‘professional practice.’” *Id.* Congress defined the term “practitioner,” who is forbidden to dispense controlled substances without a prescription under Section 829, to mean “a physician ... permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance *in the course of professional practice or research.*” 21 U.S.C. § 802(21) (emphasis added).

Congress stopped there, however, and left it up to the DEA to figure out exactly when, and how, medical practitioners could dispense controlled substances “in the course of professional practice.” Congress provided simply that the “Attorney General may promulgate and enforce any rules, regulations,

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<sup>2</sup> Congress also criminalized distribution or dispensing of controlled substances by a “registrant” when “not authorized by his registration” or without an appropriate order form. *See* 21 U.S.C. §§ 842(a), 843(a). These offenses came with lesser penalties than Section 841, and this Court has held that they do not displace liability under Section 841 for physicians who dispense controlled substances. *United States v. Moore*, 423 U.S. 122, 137 (1975).

and procedures which he may deem necessary and appropriate for the efficient execution of” the CSA, and the Attorney General was also authorized to “delegate any of his functions under this subchapter to any officer or employee of the Department of Justice.” 21 U.S.C. § 871(a), (b).

The DEA, acting on this delegation provision, promulgated 21 C.F.R. § 1306.04. That regulation says that either a “prescribing practitioner” or “the pharmacist who fills the prescription” “shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances” when the prescription was “issued not in the usual course of professional treatment or in legitimate and authorized research” or “issued for a legitimate medical purpose.” *Id.* at § 1306.04(a). The *regulation* is silent concerning good faith, or any mens rea concerning the course of professional practice, but instead attaches liability merely for “knowingly filling” a prescription issued outside the course of professional practice. *Id.*

As Dr. Ruan notes, the interpretation of that regulation started the Circuits down multiple, conflicting, and often internally inconsistent paths. PLF agrees with Dr. Ruan that the Eleventh Circuit’s strict-liability approach cannot be reconciled with the regulation. Indeed, Dr. Ruan was convicted based on an instruction saying that “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.” App. App’x at 139a. This says nothing about

the need for Dr. Ruan to *knowingly* depart from professional practice, and it did not consider Dr. Ruan's subjective good faith. *Id.* Yet this Court previously approved an instruction saying that a defendant "could not be convicted if he merely made 'an honest effort' to prescribe ... in compliance with an accepted standard of medical practice," so the Eleventh Circuit's approach was wrong. *See Moore*, 423 U.S. at 142 n.20.

## **II. ALLOWING CONVICTIONS FOR MERE DEPARTURES FROM PROFESSIONAL PRACTICE, REGARDLESS OF A PHYSICIAN'S INTENT, WOULD JEOPARDIZE CONSTITUTIONAL PROTECTIONS**

Aside from simply misreading the statute, the Eleventh Circuit's approach raises more fundamental problems. The lower court's holding would allow DEA to define the bounds of criminal liability in *spite* of statutory limits. That holding would have DEA define a criminal offense in a vacuum, without any Congressional oversight, and without any respect for constitutional imperatives of fair notice and the separation of powers.

### **A. The Statute Requires Knowledge of Wrongdoing**

The blame for the Eleventh Circuit's error lies squarely at the feet of DEA, as its regulation purporting to define the scope of criminal liability for physicians is anything but clear. The disagreement over "good faith" actually appears to reflect a much more basic question about what role the statutory

mens rea requirement serves, as well as what the agency meant when it said that liability arises for “knowingly” filling or issuing a prescription issued outside the course of professional practice. *See* 21 U.S.C. § 841(a)(1); 21 C.F.R. § 1306.04(a).

Recall that the statute prohibits “knowing or intentional” conduct. *See* 21 U.S.C. § 841(a)(1). Several circuits, including the Eleventh, have noted that the statute and regulation, therefore, require proof that a physician *knew* the prescription was not issued in the course of professional practice. *See, e.g., United States v. Joseph*, 709 F.3d 1082, 1094 (11th Cir. 2013) (“To convict a licensed physician under section 841(a)(1), it is incumbent upon the government to prove that he dispensed controlled substances for other than legitimate medical purposes in the usual course of professional practice, and that he did so knowingly and intentionally. And to convict a licensed pharmacist under section 841(a)(1), the government must prove that the pharmacist filled a prescription knowing that a physician issued the prescription without a legitimate medical purpose or outside the usual course of professional practice.”) (citations omitted); *United States v. Guerrero*, 650 F.2d 728, 730 (5th Cir. 1981) (“To convict Dr. Guerrero, it was incumbent upon the government to prove that he dispensed controlled substances for other than legitimate medical purposes in the usual course of professional practice, and that he did so knowingly and intentionally.”). The good-faith issue arguably diverts from this more basic knowledge requirement. *See United States v. Hurwitz*, 459 F.3d 463, 475 (4th Cir. 2006) (vacating conviction on other grounds, and not reaching question of whether good

faith instruction improperly “required the jury to apply the knowledge requirement only to Hurwitz’s act of writing a prescription, and that the instructions therefore permitted the jury to convict even if it concluded that Hurwitz did not know that any given prescription was not for a legitimate medical purpose or was beyond the bounds of medical practice”).

The DEA cannot, via regulation, displace the statute’s mens rea requirement. “It is axiomatic that an administrative agency’s power to promulgate legislative regulations is limited to the authority delegated by Congress.” *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). Thus, if “Congress has directly spoken to the precise question at issue,” “that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.” *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984). And if the statute requires proof that a physician knew that he acted outside the scope of professional practice, then it also requires that he not act in good faith. After all, if a physician genuinely believed he acted in the course of professional practice, even erroneously, it’s hard to see how he “knew” his conduct was unlawful.

**B. Only Congress May Create a New  
Criminal Offense; Allowing DEA To Do  
So Violates the Non-Delegation  
Doctrine**

If the statute isn’t clear on this point, though, then much larger problems arise about DEA’s authority. The canon of constitutional avoidance

instructs that a court must “construe [a] statute to avoid [serious constitutional] problems unless such construction is plainly contrary to the intent of Congress.” *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988). This rule of construction prevails even concerning an ambiguous statute or regulation over which an agency ordinarily would be entitled to interpretive deference. *Id.* at 574–75.

Article I of the Constitution provides that “[a]ll legislative Powers herein granted shall be vested in a Congress of the United States.” U.S. Const. art. I, § 1. Moreover, “[t]he definition of the elements of a criminal offense is entrusted to the legislature, particularly in the case of federal crimes, which are solely creatures of statute.” *Liparota v. United States*, 471 U.S. 419, 424 (1985). Agencies, therefore, may not exercise Congress’s legislative power to declare “what circumstances ... should be forbidden” by criminal laws. *Panama Refining Co. v. Ryan*, 293 U.S. 388, 418–19 (1935).

It’s no secret, however, that this Court has struggled with defining the limits on the legislature’s delegation of its authority. Traditionally the Court has allowed agencies to exercise authority so long as Congress set out an “intelligible principle to which the person or body authorized to [exercise the authority] is directed to conform.” *Mistretta v. United States*, 488 U.S. 361, 372 (1989). But that test lacks clear contours. Furthermore, five members of the Court have recently expressed interest in at least exploring a reconsideration of that standard. *See Gundy v. United States*, \_\_ U.S. \_\_, 139 S. Ct. 2116, 2131–42



(2019) (Gorsuch, J., dissenting, joined by Roberts, C.J., and Thomas, J.); *id.* at 2130–31 (Alito, J., concurring in the judgment); *Paul v. United States*, \_\_\_ U.S. \_\_\_, 140 S. Ct. 342 (2019) (mem.) (Kavanaugh, J., statement respecting the denial of certiorari) (stating that the issues raised in the *Gundy* dissent “may warrant further consideration in future cases”).

Of course, even under the “intelligible principle” standard, this Court has suggested that it would present “a nondelegation question” if a statute provides an agency with “unguided” or “unchecked” authority to define a crime. *Gundy*, 139 S. Ct. at 2123 (plurality op.). While “administrative” rules implementing a statute are one thing, rules creating a new crime are quite another. *See id.* at 2129.

Moreover, as Justice Gorsuch recently highlighted in his dissenting opinion in *Gundy*, a delegation that “purports to endow the nation’s chief prosecutor with the power to write his own criminal code” “scrambles th[e] design” of the Constitution, which “promises that only the people’s elected representatives may adopt new federal laws restricting liberty.” 139 S. Ct. at 2131.

“[W]e know that as long as Congress makes the policy decisions when regulating private conduct, it may authorize another branch to fill up the details.” *Id.* at 2136. But the opposite is true as well—when Congress leaves policy decisions up to another branch, it unlawfully divests itself of power. *See A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 529 (1935). What constitutes a “policy decision[]” was illustrated as far back as 1825, when the Court upheld

a statute that instructed the federal courts to borrow state-court procedural rules but allowed them to make certain “alterations and additions.” *Wayman v. Southard*, 23 U.S. 1, 1 (1825). Writing for the Court, Chief Justice Marshall distinguished between those “important subjects, which must be entirely regulated by the legislature itself,” and “those of less interest, in which a general provision may be made, and power given to those who are to act ... to fill up the details.” *Id.* at 21.

The Court provided a concrete example of this distinction in *United States v. Eaton*, 144 U.S. 677 (1892). There, the Court struck down a series of federal tax regulations that purported to impose criminal liability even though Congress had not set out a penalty provision. *Id.* at 688. As there were “no common-law offenses against the United States,” it was up to Congress to provide criminal punishment for violation of a regulation. *Id.* at 687. The decision of whether to punish something as a crime could not be wholly delegated to an agency, because “[i]t would be a very dangerous principle” to allow an agency to issue regulations that, themselves, carried criminal penalties under the general rubric of being “a needful regulation” to enforce a statute. *Id.* at 688. Thus, the Court held that “[i]t is necessary that a sufficient statutory authority should exist for declaring any act or omission a criminal offense,” even if the agency could otherwise issue regulations that had, “in a proper sense, the force of law[.]” *Id.*

In more recent cases this Court has also questioned whether “something more than an ‘intelligible principle’ is required when Congress

authorizes another Branch to promulgate regulations that contemplate criminal sanctions.” *Touby v. United States*, 500 U.S. 160, 165–66 (1991). Indeed, this Court assumed so where it allowed the Attorney General to add a substance to a list of prohibited drugs temporarily if he determined that doing so was “necessary to avoid an imminent hazard to the public safety.” *Id.* at 166 (1991). But, importantly, the Court blessed the scheme under review in that case because it delegated a fact-finding role, instead of the policy question of whether something *should* be a crime. *See id.* As described by Justice Gorsuch, “In approving the statute, the Court stressed all the[] constraints on the Attorney General’s discretion and, in doing so, seemed to indicate that the statute supplied an ‘intelligible principle’ because it assigned an essentially fact-finding responsibility to the executive.” *Gundy*, 139 S. Ct. at 2141. This Court must be especially wary, however, when Congress purports to allow an agency to exercise criminal policy-making authority. *See id.*

If there truly is no conflict between Section 841(a)(1) and DEA’s regulations defining what it means to be “authorized” to prescribe controlled substances, then Congress has impermissibly allowed the Executive Branch to write criminal laws. The delegation is breathtaking—any act of prescribing controlled substances is a federal crime “except as authorized” by DEA. 21 U.S.C. § 841(a)(1). The default is criminality, abated only by the Attorney General’s good grace—the grace of the prosecutor responsible for enforcing the statute. The statute doesn’t even provide limiting principles or guidance on these questions. Moreover, if, as the court below concluded, DEA responded to this delegation by criminalizing

even unwitting departures from professional standards, then Congress's delegation allowed the prosecution to create a strict liability crime out of nothing. Surely such "unguided" or "unchecked" authority to define a crime presents "a nondelegation question." *See Gundy*, 139 S. Ct. at 2123 (plurality op.). More likely it "scrambles th[e] design" of the Constitution" *See id.* at 2131 (Gorsuch, J., dissenting).

Make no mistake—DEA's creation of a professional practice offense is an exercise in pure Congressional policymaking. Defining a criminal offense, such as how one is guilty of federal drug offenses, is something that "is entrusted to the legislature." *See Liparota*, 471 U.S. at 424. DEA has no authority to create a crime, much less exercise the power to arbitrarily withhold criminal punishment except where it sees fit.

### **C. Due Process Forbids Criminalizing Good Faith Efforts To Comply With the CSA**

Yet another vital constitutional principle dooms DEA's attempt to create a crime lacking any culpable state of mind. Basics of fair notice would likely prevent *Congress* from writing a statute criminalizing good faith mistakes by medical professionals. DEA certainly cannot escape that same limit.

"The contention that an injury can amount to a crime only when inflicted by intention is no provincial or transient notion. It 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 v. United States*, 342 U.S. 246, 250 (1952). Thus, “mere omission from [a statute] of any mention of intent will not be construed as eliminating that element from the crimes denounced.” *Id.* at 263. “This rule of construction reflects the basic principle that wrongdoing must be conscious to be criminal.” *Elonis v. United States*, 575 U.S. 723, 734 (2015) (citation omitted).

Thus, strict liability here might violate due process. “Engrained in our concept of due process is the requirement of notice. Notice is sometimes essential so that the citizen has the chance to defend charges.” *Lambert v. People of the State of California*, 355 U.S. 225, 228 (1957). If a person is not aware that his conduct is forbidden, and has no ability to learn so, due process bars “the imposition of heavy criminal penalties.” *Id.* at 230 “Were it otherwise, the evil would be as great as it is when the law is written in print too fine to read or in a language foreign to the community.” *Id.*

The need for a presumption of mens rea also maintains the separation of powers, which are critical to ensuring liberty. “The spirit of the doctrine which denies to the federal judiciary power to create crimes forthrightly admonishes that we should not enlarge the reach of enacted crimes by constituting them from anything less than the incriminating components contemplated by the words used in the statute.” *Morissette*, 342 U.S. at 263.

To be sure, this Court has noted that a “limited class” of strict liability “offenses against [] statutory regulations” might comport with constitutional limits. *Id.* at 258. But it has also stressed that this exception applies only when such offenses “were punishable only by fine moderate in amount,” and “in sustaining the power so to fine unintended violations we are not to be understood as sustaining to a like length the power to imprison.” *Id.* at 257–58 (quoting *People ex rel. Price v. Sheffield Farms-Slawson-Decker Co.*, 225 N.Y. 25, 32–33 (1918)). Thus, in a case where a regulatory offense also came with the possibility of a penalty of up to three years’ imprisonment, this Court refused to expose “a good-faith error of judgment” to criminal punishment. *United States v. U.S. Gypsum Co.*, 438 U.S. 422, 442 (1978). Otherwise, the “criminal sanctions would be used, not to punish conscious and calculated wrongdoing at odds with statutory proscriptions, but instead simply to *regulate* business practices regardless of the intent with which they were undertaken.” *Id.* (emphasis in original).

The lower court’s interpretation of the statute threatens these constitutional protections. Dr. Ruan faced prosecution regardless of his subjective good faith, based only on an objective standard of whether he departed, even unwittingly, from professional practice. Such an objective standard is “inconsistent with the conventional requirement for criminal conduct—awareness of some wrongdoing.” See *Elonis*, 575 U.S. at 738 (citation omitted). Liability based on an abstract notion of the correct standard of care—“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.* (citations omitted). How could Dr. Ruan have fair notice of his offense if he lacked any opportunity to “choose between good and evil?” *See Morissette*, 342 U.S. at 250. Moreover, allowing DEA to “enlarge the reach of [the] enacted crimes” in Section 841(a)(1) in such a way, doubly frustrates the guarantees protected by the separation of powers. *See id.* at 263.

It is also no excuse for DEA to claim that this is a “regulatory” offense. Dr. Ruan was sentenced to more than 20 years in federal prison for violating Section 841(a)(1), which is the main authority for all types of drug federal prosecutions. Dr. Ruan clearly did not suffer a “fine moderate in amount,” for his offense. *See id.* at 257–58. Nor was he prosecuted under a limited regulatory regime. *See id.* If the regulation omits a knowledge requirement, then the harsh punishments set out by the CSA would simply regulate the medical profession through the threat of arbitrary punishment. *See U.S. Gypsum Co.*, 438 U.S. at 442.

#### **D. The Rule of Lenity Was Designed To Prevent These Constitutional Problems**

This Court has long used a tool of statutory construction to avoid the precise constitutional problems discussed above—the rule of lenity. It should use that rule again now and reject DEA’s effort to create a new strict liability offense in the absence of Congressional direction.

“[R]equiring *mens rea* is in keeping with our longstanding recognition of the principle that ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity.” *Liparota*, 471 U.S. at 427 (citation omitted). The rule of lenity is a tool of construction “perhaps not much less old than construction itself.” *United States v. Wiltberger*, 18 U.S. (1 Wheat.) 76, 95 (1820). In simple terms, “lenity requires ambiguous criminal laws to be interpreted in favor of the defendants subjected to them.” *United States v. Santos*, 553 U.S. 507, 514 (2008). Three “core values of the Republic” underlie the rule of lenity: (1) due process; (2) the separation of governmental powers; and (3) “our nation’s strong preference for liberty.” *United States v. Nasir*, 17 F.4th 459, 473 (3d Cir. 2021) (en banc) (Bibas, J., concurring).

Due process requires that “a fair warning should be given to the world in language that the common world will understand, of what the law intends to do if a certain line is passed. To make the warning fair, so far as possible the line should be clear.” *McBoyle v. United States*, 283 U.S. 25, 27 (1931). By construing ambiguities in the defendant’s favor, lenity prohibits criminal consequences when Congress did not provide a fair warning through clear statutory language. *Id.*

Lenity also protects the freedoms protected by the separation of powers: the legislature criminalizes conduct and sets statutory penalties, the executive prosecutes crimes, and the judiciary interprets the law’s reach. *United States v. Bass*, 404 U.S. 336, 348 (1971). Lenity “strikes the appropriate balance between the legislature, the prosecutor, and the court



in defining criminal liability.” *Liparota*, 471 U.S. at 427.

Finally, and “perhaps most importantly,” lenity “embodies ‘the instinctive distaste against men languishing in prison unless the lawmaker has clearly said they should.’” *Nasir*, 17 F.4th at 472 (Bibas, J., concurring) (quoting *Bass*, 404 U.S. at 347). By promoting liberty, lenity “fits with one of the core purposes of our Constitution, to ‘secure the Blessings of Liberty’ for all[.]” *Id.* (quoting U.S. Const. pmb1.).

The rule of lenity is simply the mechanism this Court must employ to avoid the constitutional errors intrinsic to the Eleventh Circuit’s decision. Congress did not criminalize accidental departures from the standards of professional practice by prescribing physicians. It did not intend for doctors to languish in federal prison for decades based on good faith mistakes. But if there was some question about Congressional choice, then this Court must come down on the only side that respects due process and the separate roles that it, Congress, and the prosecution play. This Court should therefore require proof of a physician’s *knowledge* that he has departed from professional practice, knowledge that can be negated by his *subjective* good faith efforts to comply with prevailing standards.<sup>3</sup>

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<sup>3</sup> The Eleventh Circuit did not address the possibility that the government’s reading of the relevant regulation warranted interpretive deference. But that was because interpretive “deference does not apply in criminal cases,” because it is “defeat[ed]” by the “rule of lenity.” *United States v. Phifer*, 909 F.3d 372, 384–85 (11th Cir. 2018); *see also Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 140 S. Ct. 789, 790

## CONCLUSION

Dr. Ruan’s prosecution irrespective of his subjective good faith efforts to comply with the law is constitutionally untenable. Congress did not impose criminal liability in such instances. But a regulatory agency, particularly a prosecutorial one, cannot decide, on its own, that such conduct should be unlawful. Fair notice, the separation of powers, and our constitution’s essential desire to maximize liberty must not be so casually cast aside.

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Respectfully submitted,

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(2020) (Gorsuch, J., statement regarding denial of certiorari) (“[W]hen liberty is at stake,” deference “has no role to play.”); *Abramski v. United States*, 573 U.S. 169, 191 (2014) (“The critical point is that criminal laws are for courts, not for the Government, to construe.”); *United States v. Apel*, 571 U.S. 359, 369 (2014) (“[W]e have never held that the Government’s reading of a criminal statute is entitled to any deference.”).