Ruan v. United States: An Important Ruling or Merely Sound and Fury?

PAUL J. LARKIN*

TABLE OF CONTENTS

Some opinions by the Supreme Court of the United States resemble the finale to Tchaikovsky's *1812 Overture*. They announce their importance not with a band but with an entire orchestra—and cannons. The Court's recent decision in *Dobbs v. Jackson Women's Health Organization* is one of those cases.[1] *Dobbs* overturned the Court's 1973 ruling in *Roe v. Wade* that the Fourteenth Amendment's Due Process Clause guarantees a woman the right to have an abortion.[2] The reverberations from *Dobbs* will be felt for a long time.[3]

By contrast, another recent Supreme Court decision—*Ruan v. United States*—will create excitement only among a particular subset of the academy and bar, those who teach or practice criminal law.[4] *Ruan* involved an interpretation of the principal federal law governing the distribution of legal and illegal drugs, the Controlled Substances Act of 1970.[5] The Court held that a licensed physician

---

* John, Barbara & Victoria Rumpel Senior Legal Research Fellow, The Heritage Foundation; M.P. P. George Washington University, 2010; J.D. Stanford Law School, 1980; B.A. Washington & Lee University, 1977. The views expressed in this Article are the authors' own and should not be construed as representing any official position of The Heritage Foundation. I am grateful to Jack Fitzhenry, John G. Malcolm, and Zack Smith for helpful comments on an earlier iteration of this Essay. Any errors are mine.

1. 142 S. Ct. 2228 (2022).

2. 410 U.S. 113 (1973).

3. *See, e.g.*, *The Fallout from Overturning* Roe, ECONOMIST (June 28, 2022), https://www.economist.com/united-states/2022/06/26/the-fallout-from-overturning-roe [https://perma.cc/4K87-UDG8].

4. 142 S. Ct. 2370 (2022).

5. The CSA was Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1242 (codified as amended at 21 U.S.C. §§ 801-904 (2018)). A "controlled substance" is "a drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V of part B of this title," except for "distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1954." 21 U.S.C. § 802(6) (2018). The CSA incorporates the definition of a "drug" from the Federal Food, Drug, and Cosmetic Act and assigns

cannot be convicted of violating the CSA for the unlawful distribution of opioids unless the government proves beyond a reasonable doubt that he or she knowingly prescribed that medication for an illegitimate purpose—viz., one that is beyond accepted medical practice. That ruling reaffirms the importance of the role of *mens rea* in distinguishing "good guys who made a mistake" from "bad guys who flouted the law." It does so by requiring the government to prove that a defendant knowingly engaged in wrongdoing. Any such ruling could greatly help defendants.

As a practical matter, however, *Ruan* might turn out to have consequences that are minimal at best. That is, *Ruan* might be of far greater interest to criminal law professors than to practitioners. The reason is that a defendant might need to testify at trial to establish his good faith, and once he does so, as a practical matter, the reasonable doubt standard exits stage right. This Article explores why the two somewhat inconsistent propositions stated above are true.

Part I will discuss the *Ruan* decision. Part II will discuss whether, practically speaking, there is a material difference between the two opinions in *Ruan*. Part III will offer some observations on whether the *Ruan* decision will make a difference in the application of the majority's opinion in cases like the particular ones that gave rise to the decision—the prosecution of physicians for the illegal distribution of controlled substances.

I. THE *RUAN* DECISION

The CSA prohibits the knowing or intentional distribution of controlled substances, such as opioids, "except as authorized."[6] Physicians are "authorized" to prescribe opioids in the practice of medicine for, among other uses, the treatment of post-surgical or end-stage cancer pain because those drugs are primo analgesics.[7] Unfortunately, opioids are also potentially addictive and can be fatal.[8]

Ruan comprised two consolidated cases involving different physicians.[9] In each case, the federal government prosecuted the physician for abusing his authority to prescribe opioids and for effectively acting as a drug trafficker. Separate juries convicted the defendants for violating the CSA, and two separate U.S. courts of appeals upheld the convictions. In both cases, the physician-defendant argued that it is a complete defense to a charge of unlawfully distributing controlled substances that he subjectively believed prescribing the drugs was in his patient's best interest.[10] In each case, the district court and court of appeals

---

drugs to one of five schedules according to their potential benefits and risks. 21 U.S.C. §§ 201(g)(1), 812, 841 (2018).

6. 21 U.S.C. § 841 (2018).

7. *See, e.g.*, JERROLD S. MEYER & LINDA F. QUENZER, PSYCHOPHARMACOLOGY: DRUGS, THE BRAIN, AND BEHAVIOR 305–06 (2d ed. 2018) ("As a class, [opioids] are the very best painkillers known to man.").

8. *See* United States v. Ruan, 966 F.3d 1101, 1122 (11th Cir. 2020), *rev'd on other grounds*, Ruan v. United States, 142 S. Ct. 2370 (2022).

9. *Ruan*, 142 S. Ct. at 2375.

10. *Id.* at 2375–76.

rejected that argument, holding that the issue of whether a physician acts in good faith is an objective one, and the juries in those cases were instructed accordingly.[11] Put differently, to those courts the issue was whether the classical "reasonable" physician would have concluded that specific prescription for opioids was beyond the scope of accepted medical practice. If not, the physician who wrote the scripts would be guilty, regardless of whether they subjectively believed that their patients would benefit from painkillers.

All nine justices, spread over two separate opinions, voted to reverse the convictions. Justice Breyer wrote the majority opinion for himself and five other justices.[12] Justice Breyer concluded that a licensed physician cannot be convicted of violating the CSA for the unlawful distribution of opioids unless the government proves beyond a reasonable doubt that the physician knew that he prescribed medication for an illegitimate purpose. In a separate opinion, concurring only in the judgment, Justice Alito, joined in full by Justice Thomas and in large part by Justice Barrett, agreed with the majority that the convictions could not stand because Section 841 of the CSA incorporates a "good faith" standard that the lower courts had misapplied.[13] But Justice Alito disagreed with the majority over the proper analysis of the CSA.

Justice Breyer started by noting that the issue in *Ruan* required the Court to ask whether the CSA required proof of a certain state of mind on a physician's part. Is it sufficient for the government to prove that, by prescribing opioids, the two physician petitioners exceeded the bounds of legitimate medical practice, or must the government prove that they knowingly did so?[14] He concluded that, for multiple reasons, the CSA requires the government to prove that a physician subjectively knew that he exceeded the legitimate bounds of accepted medical practice by writing a particular prescription.[15] The courts of appeals, Justice Breyer explained, misread the statute to adopt an objective good faith standard.[16] Instead, the CSA places on a defendant the burden of raising an issue and adducing sufficient evidence that a reasonable person could decide that a physician truly believed that he was acting in the best interests of his or her patient and within accepted medical practices.[17] The Act does not require a defendant to bear

11. *Id.*

12. *Id.* at 2382.

13. *Id.* at 2383 (Alito, J., concurring in the judgment).

14. *Id.* at 2375 ("The question we face concerns § 841's exception from the general prohibition on dispensing controlled substances contained in the phrase '[e]xcept as authorized.' In particular, the question concerns the defendant's state of mind. To prove that a doctor's dispensation of drugs via prescription falls within the statute's prohibition and outside the authorization exception, is it sufficient for the Government to prove that a prescription was *in fact* not authorized, or must the Government prove that the doctor *knew* or *intended* that the prescription was unauthorized?").

15. *Id.* at 2375–76 (internal punctuation omitted).

16. *Id.* (internal punctuation omitted).

17. *Id.*; *see* 21 U.S.C. § 885(a)(1) (2018) ("It shall not be necessary for the United States to negative any exemption or exception set forth in this subchapter in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this subchapter, and the burden of

the burden of proof on that issue, he concluded. That burden remains with the government even after the defendant has validly raised it.[18]

As Justice Breyer explained, "our criminal law seeks to punish the 'vicious will,'"[19] which generally means that "wrongdoing must be conscious to be criminal."[20] When a statute requires proof of "scienter"—viz., "the degree of knowledge necessary to make a person criminally responsible for his or her acts"[21]—canons of statutory construction direct that the necessary mental state should be read to "modif[y] not only the words directly following it, but also those other statutory terms that separate wrongful from innocent acts."[22] The relevant provision of the CSA, Section 841 of Title 21, requires the government to prove that a defendant acted "knowingly or intentionally."[23] When the distribution of a controlled substance is the issue, "a lack of authorization is often what separates wrongfulness from innocence."[24] Physicians who dispense controlled substances are not engaged in an "inherently illegitimate" practice.[25] On the contrary, "we expect, and indeed usually want, doctors to prescribe the medications that their patients need."[26] Because applying the scienter requirement to the "authorization" element of Section 841 "helps to separate wrongful from innocent act," it makes sense to require the government to prove that a physician knowingly or intentionally prescribed a medication outside the bounds of a legitimate medical treatment.[27] What is more, Section 841 is not "a regulatory or public welfare offense that carries only minor penalties," nor is it a jurisdictional element of the CSA, to which there would be no presumption that a scienter element would attach.[28] The Court's precedent, Justice Breyer concluded, also supported his interpretation of Section 841.[29]

The majority was unpersuaded by the government's construction of the statute. Section 885 of Title 21 places on the accused the burden of "going forward with the evidence" to establish that an exception to the CSA applies in his case.[30] The government argued that this provision foreclosed placing on the government the even greater burden of proof that a physician knowingly exceeded the legitimate practice of medicine. Justice Breyer, however, did not read the statute as upsetting the ordinary rule that the government must bear the burden of proof under

---

going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit.").

18. *Ruan*, 142 S. Ct. at 2380–81.
19. *Id.* at 2376–77 (citation and punctuation omitted).
20. *Id.* (citation and punctuation omitted).
21. *Id.*
22. *Id.* (citation and punctuation omitted).
23. 21 U.S.C. § 841.
24. *Ruan*, 142 S. Ct. at 2377.
25. *Id.*
26. *Id.*
27. *Id.*
28. *Id.* at 2378.
29. *Id.* at 2378–79.
30. 21 U.S.C. § 885.

the reasonable doubt standard.[31] Finally, the Court declined the government's invitation to read an objective "good faith" element into the statute. Like other federal criminal laws, Section 841 uses the phrase "knowingly or intentionally," not terms such as "good faith," "objectively," or "reasonable."[32] Moreover, a "good faith" test "would turn a defendant's criminal liability on the mental state of a hypothetical 'reasonable' doctor, not on the mental state of the defendant himself or herself," which would be tantamount to using a negligence standard, inappropriate in criminal law.[33]

In a separate opinion concurring only in the judgment, Justice Alito, joined in full by Justice Thomas and in large part by Justice Barrett, agreed with the majority that the convictions could not stand. He reasoned that Section 841 of the CSA incorporates a "good faith" standard that the lower courts had misapplied.[34] Justice Alito disagreed with the majority's interpretation of Section 841. As he saw it, the CSA should be read against the background supplied by its predecessor statute, the Harrison Narcotics Tax Act of 1918,[35] which the Court had read to allow a physician acting in "good faith" to prescribe opioids for a patient.[36] A physician's good faith would exculpate him.[37] Justice Alito, however, disagreed with the majority over the proper allocation of the burden of proof. He concluded that a defendant bears the burden of production *and* persuasion as to his good faith belief that he acted for legitimate medical reasons.[38]

---

31. *Ruan*, 142 S. Ct. at 2381.

32. *Id*.

33. *Id*. As Justice Breyer had earlier summarized: "We now hold that § 841's 'knowingly or intentionally' *mens rea* applies to the 'except as authorized' clause. This means that once a defendant meets the burden of producing evidence that his or her conduct was 'authorized,' the Government must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner." *Id*. at 2376.

34. *Id*. at 2383 (Alito, J., concurring in the judgment). Justice Alito concluded that the CSA should be read against the background supplied by its predecessor statute, the Harrison Narcotics Tax Act of 1918, ch. 1, 38 Stat. 785 (1914). In *Linder v. United States*, 268 U.S. 5, 16–17 (1925), the Court interpreted that act to provide that a physician acts "in the course of his professional practice" when he writes prescriptions "in good faith." Justice Alito believed that the CSA incorporated the *Linder* test, but that the defendant bore the burden of proof on the issue. *Ruan*, 142 S. Ct. at 2383 (Alito, J., concurring in the judgment).

35. Harrison Narcotics Tax Act, ch. 1, 38 Stat. 785 (1914).

36. *Ruan*, 142 S. Ct. at 2383, 2388–89 (Alito, J., concurring in the judgment) (discussing *Linder*, 268 U.S. at 17–18).

37. Justice Alito summarized his interpretation of the CSA as follows:

> I would thus hold that a doctor who acts in subjective good faith in prescribing drugs is entitled to invoke the CSA's authorization defense. Under the correct understanding of that defense, a doctor acts 'in the course of professional practice' in issuing a prescription under the CSA if—but only if—he or she believes in good faith that the prescription is a valid means of pursuing a medical purpose. A doctor who knows that he or she is acting for a purpose foreign to medicine—such as facilitating addiction or recreational drug abuse—is not protected by the CSA's authorization to distribute controlled substances by prescription. Such doctors may be convicted of unlawfully distributing or dispensing a controlled substance under §841(a)(1).

Id. at 2389 (Alito, J., concurring in the judgment).

38. *Id*. (Alito, J., concurring in the judgment).

II. WHAT IS THE DIFFERENCE BETWEEN THE BREYER AND ALITO OPINIONS?

The majority opinion reiterates the importance of using a scienter element to distinguish intentional wrongdoers from those who stumble into illegality through negligence or otherwise. The distinction has always been important in criminal law.[39] Since the days that the common law of crimes began to take shape in England, the criminal law has been limited to people who commit an unlawful act with a "guilty mind" or an "evil intent." Both elements have always been necessary, as seen in the adage "*Actus non facit reum nisi mens sit rea*," which (for those who were not fortunate enough to have had a Jesuit education) means that a crime consists of "a vicious will" and "an unlawful act consequent upon such vicious will."[40] The *Ruan* case is just the most recent example of a line of Supreme Court decisions reaffirming that basic point.[41]

Ruan is also noteworthy for the Supreme Court's willingness to apply a *mens rea* requirement to any and every element of an offense that separates wrongful

---

39. *See, e.g.*, John G. Malcolm, *Criminal Justice Reform at the Crossroads*, 20 TEX. REV. L. & POL. 249, 272–73 (2016) (discussing the longevity and importance of that distinction).

40. 4 WILLIAM BLACKSTONE, COMMENTARIES *21; Francis Bowes Sayre, *Mens Rea*, 45 HARV. L. REV. 974, 1023 (1932).

41. The most oft-cited case is *Morissette v. United States*, 342 U.S. 246 (1952). There, Justice Robert Jackson explained the principle as follows:

> 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. A relation between some mental element and punishment for a harmful act is almost as instinctive as the child's familiar exculpatory "But I didn't mean to," and has afforded the rational basis for a tardy and unfinished substitution of deterrence and reformation in place of retaliation and vengeance as the motivation for public prosecution. Unqualified acceptance of this doctrine by English common law in the Eighteenth Century was indicated by Blackstone's sweeping statement that to constitute any crime there must first be a 'vicious will.' Common-law commentators of the Nineteenth Century early pronounced the same principle, although a few exceptions not relevant to our present problem came to be recognized.
>
> Crime, as a compound concept, generally constituted only from concurrence of an evil-meaning mind with an evil-doing hand, was congenial to an intense individualism and took deep and early root in American soil. As the state codified the common law of crimes, even if their enactments were silent on the subject, their courts assumed that the omission did not signify disapproval of the principle but merely recognized that intent was so inherent in the idea of the offense that it required no statutory affirmation. Courts, with little hesitation or division, found an implication of the requirement as to offenses that were taken over from the common law. The unanimity with which they have adhered to the central thought that wrongdoing must be conscious to be criminal is emphasized by the variety, disparity and confusion of their definitions of the requisite but elusive mental element. However, courts of various jurisdictions, and for the purposes of different offenses, have devised working formulae, if not scientific ones, for the instruction of juries around such terms as "felonious intent," "criminal intent," "malice aforethought," "guilty knowledge," "fraudulent intent," "wilfulness," "scienter," to denote guilty knowledge, or "mens rea," to signify an evil purpose or mental culpability. By use or combination of these various tokens, they have sought to protect those who were not blameworthy in mind from conviction of infamous common-law crimes.

Id. at 250–52 (footnotes omitted). Numerous recent Supreme Court opinions make the same point. *See, e.g.*, Rehaif v. United States, 139 S. Ct. 2191, 2195–97 (2019); Elonis v. United States, 575 U.S. 723, 734 (2015); Carter v. United States, 530 U.S. 255, 269 (2000); United States v. X-Citement Video, Inc., 513 U.S. 64 (1994); Staples v. United States, 511 U.S. 600, 605 (1994).

from innocent conduct.[42] The statute in *Ruan* plainly required the government to prove that a defendant "knowingly or intentionally" delivered a controlled substance to someone else. The disputed issue was whether that scienter element also applied to the authorization element of the statute. If it did not, physicians would not be the only parties at risk of prosecution. The pharmaceutical company employees (both in the suites and on the loading dock) who "distribute" bottles of opioids to pharmacies; the truck drivers who deliver those drugs; the pharmacy employees who sell them to a customer presenting a valid prescription—all of those parties would be at risk of being charged with a violation of the CSA and forced to prove that they believed that they were authorized to act as they did if Justice Alito's approach defined the governing rule.[43] That is not a sensible way to construe the act. In the case of the loading-dock workers and truck drivers, employees are entitled to rely on the Food and Drug Administration's authorization for the pharmaceutical company to manufacture and distribute drugs to licensed pharmacies. In the case of the pharmacy employees, they are authorized to distribute opioids when they are given a facially valid prescribing physician's script. In each instance, the majority opinion in *Ruan* protects innocent parties far better than would the approach that Justice Alito proposed. So, if the point of the criminal process is to distinguish evil-minded from good-hearted individuals, the Breyer opinion is not only more faithful to the common law, but also more protective of entirely innocent conduct.

III. DOES THE *RUAN* DECISION MATTER?

Put aside the different analyses in each of the opinions in *Ruan*. Instead, think about how the majority's rule will play out in practice in courtrooms. The Breyer and Alito approaches each place on the defendant the burden of going forward with the evidence. There's no difference there. The majority opinion, however, carried the day on the location of the burden of proof, so it defines the procedure for resolving the authorization issue. The defendant must raise the issue and introduce sufficient credible evidence that would allow a jury to find that the accused was authorized to distribute controlled substances. Then, the government must prove beyond a reasonable doubt that the defendant knew that his prescriptions were not authorized by accepted medical practice.

What difference is there by allocating the burden of proof to the government rather than the defendant on the authorization issue? Does it matter who bears the risk of nonpersuasion on the issue of authorization? The short answer is this: Maybe; maybe not.

The number of prosecutions in which authorization will be an issue is likely to be limited. The drugs giving rise to this controversy are not antibiotics,

42. *Ruan*, 142 S. Ct. at 2377.

43. Numerous CSA provisions and its implementing regulations govern the lawful manufacture, transportation, and distribution of controlled substances. *See, e.g.*, 21 U.S.C. §§ 802(10), (11), (21) & (22), 822-823, 828, 829a, 831 (2018); 21 C.F.R. §§ 1306.01–1306.27 (2022).

antifungals, antivirals, antineoplastics, or anything similar. They are opioids. After all, the first few do not generate a euphoric feeling in users; narcotics do. Moreover, the category of people of concern—potential defendants—is physicians because they are the only people authorized by law to prescribe narcotics. Parties such as pharmaceutical company officials, loading dock workers, and other personnel are technically involved in the distribution of controlled substances, but only peripherally so. If physicians could not prescribe narcotics, legitimate firms would not manufacture and sell them. Moreover, the government will not target all physicians who prescribe opioids, as most comply with accepted medical guidelines and therefore do nothing wrong. But some physicians will prescribe narcotics at the same excessive rate performed by police officers ordered to hand out parking and traffic tickets at the end of the month. Prosecutors generally are big game hunters, so they will focus on those physicians.

How will those trials play out when there is an issue of authorization?[44] If the government knows that the defendant will claim that he acted legitimately in prescribing opioids, the government might introduce testimony during its case-in-chief on the subject. Once the government has rested its case-in-chief, the trial judge will turn to defense counsel and invite him or her to present the defense case. How will a defendant show that he genuinely believed he was authorized to distribute a controlled substance? What evidence satisfies his burden of production? Are there documents that bear on the question? Would a defendant offer witnesses to testify on the matter? Would he testify himself? *Must* he testify to prove to the jury his sincere belief that he was authorized to perform the acts that the government says were rancid drug trafficking rather than legitimate patient treatment? Those issues need to be answered to determine whether there is a material *practical* difference between the CSA interpretations offered by Justices Breyer and Alito.

To raise an authorization defense, defense counsel can introduce certified copies of the defendant's state license to practice medicine and his Drug Enforcement Administration registration certificate showing that he is authorized to prescribe controlled substances.[45] No witnesses need testify because government documents prove their authenticity on their face, and they are admissible under an exception to the hearsay rule for government records.[46] That suffices to establish the defendant's legal authority to prescribe a controlled substance.

---

44. For an example of how a trial might go, see *United States v. Ruan*, 966 F.3d 1101, 1120 (11th Cir. 2020) ("The government called more than 50 witnesses, including 15 of their former patients or their relatives; 12 of their former staff members, including nurse practitioners with whom they had worked closely; four pharmaceutical company employees; seven representatives from various medical insurance companies; three medical experts; the director of the Alabama Department of Public Health; and 12 law enforcement agents and analysts. The government also introduced numerous charts from insurers and the Drug Enforcement Administration ('DEA') reflecting the volume and cost to insurers of prescriptions for controlled substances that Ruan and Couch had written, compared to other physicians in Alabama and nationally. Both Ruan and Couch testified in their defense, and they also called five former patients, 11 additional former employees, and three medical experts of their own.").

45. *See, e.g.*, 21 U.S.C. § 829 (2018); 21 C.F.R. § 1306.03 (2022).

46. *See* FED. R. EVID. 803(8) (public records).

But counsel cannot rest at that point because that is only half of the defense burden. The defense must also satisfactorily show that *the defendant* believed that the particular distributions alleged to be unlawful were within the boundaries of reasonable medical practice. Of course, that burden might force the defense to show that the physician-defendant's prescriptions were objectively reasonable. Pharmacology texts can establish the general reasonableness of prescribing opioids for severe pain as well as the recommended number of milligrams for particular analgesics. But that might not be sufficient. General prescription practices might not show that the particular scripts written by the physician on trial fell within the proper treatment guidelines for the individual patients he treated. As a result, the defense likely will need to establish that point through the medical records of the patients at issue[47] and the testimony of at least one expert witness. That witness would likely be another treating physician who also has prescribed narcotics to treat pain, such as an oncologist, a trauma specialist, or an orthopedic surgeon. Such a witness would likely testify that he or she would have written the same or similar prescriptions for their own patients.[48]

Yet, there is one particular witness whom the jury will expect to testify: the defendant. The average person accused of an illegal or wrongful act is likely to deny having done it, sometimes most vigorously. That is the rationale for the concept that silence in the face of an accusation is ordinarily a tacit admission of guilt.[49] A physician-defendant might also feel compelled to testify to show the jury that he acted in good faith. Nonetheless, the Fifth Amendment Self-Incrimination Privilege entitles a defendant to remain silent at trial and also bars the court or prosecutor from arguing that the jury should treat his silence as evidence of guilt.[50] We don't know for certain whether juries follow those instructions. Defense counsel hold different opinions on the plusses and minuses of having the defendant give his side of the story on the stand.[51] So, it is by no means

47. They would be admissible under the exception to the hearsay rule for medical records. *See* FED. R. EVID. 803(4).

48. *See Ruan*, 966 F.3d at 1120.

49. *See, e.g.*, MCCORMICK ON EVIDENCE § 161 (Robert P. Mosteller gen'l ed., 8th ed. 2020) ("Under the general rules regarding admissions, the prosecution is generally permitted in a criminal case to prove that an accusatory statement was made in the hearing of the defendant and that the defendant's response was such as to justify the inference that he agreed with or 'adopted' the statement.") (footnote omitted).

50. Griffin v. California, 380 U.S. 609 (1965) (so ruling); *see* Carter v. Kentucky, 450 U.S. 288 (1981) (ruling that a defendant who declines to testify has a right to have the trial judge instruct the jury that no one may draw an adverse inference against the defendant for his decision); *cf.* Lakeside v. Oregon, 435 U.S. 333, 342 (1978) (Stevens, J., dissenting) ("Experience teaches us that most people formally charged with crime are guilty; yet we presume innocence until the trial is over. Experience also justifies the inference that most people who remain silent in the face of serious accusation have something to hide and are therefore probably guilty; yet we forbid trial judges or juries to draw that inference."). For a trenchant criticism of the *Griffin* decision, *see* Donald B. Ayer, *The Fifth Amendment and the Inference of Guilt from Silence:* Griffin v. California *After Fifteen Years*, 78 MICH. L. REV. 841 (1980).

51. *See* Wade Davis, *Should the Defendant Testify? Is There Any Research?*, TENN. BAR ASS'N L. BLOG (Mar. 1, 2018), https://www.tba.org/?pg=LawBlog&blAction=showEntry&blogEntry=30260 [https://perma.cc/STV3-SMPH] ("Some good lawyers feel strongly that the jury wants to hear from the

clear that a physician-defendant will testify in every such case.[52] Some physician-defendants will testify, but others will rely on their patients' medical records and the expert opinions of other doctors.

Yet, what is certain to happen if a physician-defendant—or any other defendant for that matter—testifies is this: as a practical matter, the prosecution's obligation to prove the defendant's guilt beyond a reasonable doubt goes out the window. Regardless of what they are told about the government's burden, the jury will decide whether the defendant is telling the truth by a preponderance of the evidence, and once the jury makes that decision, the verdict of "Guilty" or "Not guilty" follows ineluctably. Defendants dislike that phenomenon, but it is a fact of life in criminal cases, and it is not a constitutional defect in the trial process. Different rules govern the judge's decision whether to admit evidence and the jury's decision whether to convict.[53] The upshot is this: A defendant has a right to testify or not at his trial,[54] but if he does, the benefits of the reasonable doubt standard largely disappear.

Accordingly, the disagreement between Justice Breyer and Justice Alito over who bears the burden of proof on the authorization issue might essentially be *macht nichts* in many cases. Defendants who choose not to testify in favor of using their patients' medical records and expert witnesses will benefit from the government bearing the burden of proving beyond a reasonable doubt that a prescription exceeded reasonable medical practice and therefore was not authorized. But non-testifying physician-defendants will not have the opportunity to look the jurors in their eyes, say "I tried to alleviate my patients' suffering," and thereby communicate with the jurors at a very human, personal level.

If so, if that issue essentially doesn't matter, what is the *Ruan* case all about? That is where the problem might get interesting. Why? The federal government and the medical profession have gone back and forth on the proper use of opioids to treat chronic pain, and the people for whom the CSA authorization element might be most relevant are physicians who prescribe opioids slightly or somewhat above the dosages recommended by the U.S. Centers for Disease Control and Prevention.

Beginning in the 1990s, physicians increased their prescription of opioids for the treatment of chronic pain in response to social pressure to treat pain as the fifth vital sign (atop temperature, heart rate, respiration rate, and blood pressure) and insurers' demands that physicians increase the number of their patients,

---

accused and that the defendant should testify whenever defense counsel can ethically put the client on the stand. Other lawyers concentrate more on what can go wrong when a defendant testifies.").

52. Defendants with a criminal record might not testify because they do not want to have their prior exploits laid before the jury during the prosecutor's cross-examination. That factor should not often be a factor for a physician-defendant to consider.

53. That is why defense counsel in *Lego v. Twomey*, 404 U.S. 477 (1971), argued that the prosecution should be required to establish the admissibility of a confession under the reasonable doubt standard. Otherwise, once the confession was admitted, there was nothing the accused could do to contest his guilt. The Supreme Court was not persuaded. *Id.* at 482–89.

54. *See* Rock v. Arkansas, 483 U.S. 44, 49-53 (1987) (so ruling).

which could be done by regularly prescribing analgesics to manage chronic pain.[55] Sadly, but perhaps predictably, "[o]ver the last decade, America has witnessed an increase in drug overdose deaths in numbers partaking of Biblical proportions"[56] due principally to overuse of opioids, whether legal or illegal.[57] In response, the CDC recommended lesser use of opioids to address chronic pain.[58] The medical profession listened and throttled back its willingness to prescribe powerful analgesics such as oxycontin for that problem.[59]

Sadly, but perhaps predictably yet again, that shift in gears created a different problem. Some patients could not obtain prescription opioids in the amount necessary to alleviate their suffering even if they were not supplementing their medication with additional opioids or other black-market drugs, like heroin. The profession's new attitude toward chronic pain and long-term opioid use made it more burdensome for physicians to prescribe high doses of opioids for patients suffering from chronic pain, leaving them in misery and driving some to commit

---

55. *See, e.g.*, ANNA LEMBKE, DRUG DEALER, MD: HOW DOCTORS WERE DUPED, PATIENTS GOT HOOKED, AND WHY IT'S SO HARD TO STOP (2016).

56. Paul J. Larkin, Jr. & Bertha K. Madras, *Opioids, Overdoses, and Cannabis: Is Marijuana an Effective Therapeutic Response to the Opioid Abuse Epidemic?*, 17 GEO. J. L. & PUB. POL'Y 555, 557 (2019). As one physician described it, "The proliferation of opioid use in the United States is called an epidemic, but it more resembles metastatic cancer." David Brown, *Opioids and Paternalism*, AM. SCHOLAR 22–23 (Sept. 5, 2017), https://theamericanscholar.org/opioids-and-paternalism/ [https://perma.cc/KV7Z-VTNY].

57. *See, e.g.*, Larkin & Madras, *supra* note 56, at 561–62, 588 (describing the three "waves" of the opioid epidemic). Numerous studies, books, and articles discuss the provenance and extent of that epidemic. *See, e.g.*, *Understanding the Epidemic*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 19, 2018), https://www.cdc.gov/drugoverdose/epidemic/index.html [https://perma.cc/SFQ6-RLKF]; BARRY MEIER, PAIN KILLER: AN EMPIRE OF DECEIT AND THE ORIGIN OF AMERICA'S OPIOID EPIDEMIC (2018); SAM QUINONES, DREAMLAND: THE TRUE TALE OF AMERICA'S OPIATE EPIDEMIC (2016).

58. *See, e.g.*, Ctrs. for Disease Control & Prevention, *CDC Guidelines for Prescribing Opioids for Chronic Pain—United States, 2016*, 65 RECOMMENDATIONS & REPS. 1 (Mar. 15, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm [https://perma.cc/EGZ7-96KC], *revised by an errata at* https://www.cdc.gov/mmwr/volumes/65/wr/mm6511a6.htm?s_cid=mm6511a6_w.htm [https://perma.cc/9TU9-EXDE].

59. *See, e.g.*, Stefan G. Kertesz et al., *Promoting Patient-Centeredness in Opioid Deprescribing: A Blueprint for De-Implementation Science*, 35 J. GEN. INTERNAL MED. S972, S972 (2020) ("A downward trend in opioid prescribing between 2011 and 2018 has brought per-capita opioid prescriptions below the levels of 2006, the earliest year for which the Centers for Disease Control and Prevention has published data."). Given the uproar over the opioid epidemic, the medical profession was concerned not only about their patients' health, but also about being investigated by state licensing boards and law enforcement authorities. *See* Sally Satel & Kate M. Nicholson, *How Rochelle Walensky Can Improve the CDC's Pain Guidelines*, WASHINGTON MONTHLY (Mar. 24, 2022), https://washingtonmonthly.com/2022/03/24/how-rochelle-walensky-can-improve-the-cdcs-pain-guidelines/ [https://perma.cc/63TX-7FB5] ("Another problem with the new draft guideline is that the updated text instructs clinicians to 'pause and carefully reassess' . . . if they are raising a dose above 50 MME per day. While not bad advice in theory, specifying a dosage threshold is a set-up for clinicians and policy makers to adopt it as a ceiling and not a suggestion. [¶] This is precisely what happened when the 2016 guideline asked clinicians to justify prescribing more than 90 MME a day. Instead of explaining their decisions, nervous clinicians, fearful of law enforcement or lawsuits, seized on the 90 MME dosage as a decree to reduce all amounts below that threshold. A hard limit of 50 MME in the updated guidance threatens to create an even worse outcome.") (emphasis omitted).

suicide.[60] Some physicians argued that the medical profession overcorrected by declining to prescribe necessary quantities of analgesics for chronic-pain sufferers, particularly when there was no reason to believe that a patient was abusing his or her medication or supplementing it with illegal narcotics.[61] The issue was whether society should lighten up on the new brakes because of patients' ongoing legitimate needs for opioids.

How, then, will the *Ruan* decision affect doctors' prescription practices? There are at least three categories of physicians to consider. The first one includes physicians who remain within the CDC's opioid prescription guidelines. They are likely shielded from prosecution, as their prescription practices are within the guardrails set by the CDC, the federal agency responsible for making public health policy.[62] The second category consists of physicians who operate a "pill mill."[63] These are the physicians who prescribe a truckload of high-dose opioids for a minor injury, like a bruise, and who might not even physically examine their

60. *See, e.g.*, Kertesz et al., *supra* note 59, at S972 ("By 2019, there was widespread recognition that reductions in prescribing had not been implemented in ways that consistently protected patients. Patients, media, government agencies, and professional literature acknowledged instances of worsening pain, loss of access to care, and death by suicide, even as others described successes in patient-centered voluntary dose reduction and post-operative pain management.") (footnotes omitted); Jan Hoffman & Abby Goldsmith, *Good News: Opioid Prescribing Fell. The Bad?: Patients Suffer, Doctors Say*, N.Y. TIMES, Mar. 7, 2019, at A16; Elizabeth Llorente, *As Doctors Taper or End Opioid Prescriptions, Many Patients Driven to Despair, Suicide*, FOX NEWS (Dec. 10, 2018, 11:29 AM), https://www.foxnews.com/health/as-opioids-become-taboo-doctors-taper-down-or-abandon-pain-patients-driving-many-to-suicide [https://perma.cc/7ZS2-BRYE].

61. *See, e.g.*, Letter from Health Professionals for Patients in Pain (HP3) to the CDC (Mar. 6, 2019), https://healthprofessionalsforpatientsinpain.org/the-letter-1 [https://perma.cc/FGM9-SV86] ("1. We urge the CDC to follow through with its commitment to evaluate impact by consulting directly with a wide range of patients and caregivers, and by engaging epidemiologic experts to investigate reported suicides, increases in illicit opioid use and, to the extent possible, expressions of suicidal ideation following involuntary opioid taper or discontinuation. [¶] 2. We urge the CDC to issue a bold clarification about the 2016 Guideline—what it says and what it does not say, particularly on the matters of opioid taper and discontinuation."); Kertesz et al., *supra* note 59, at S972 ("By 2019, the CDC avowed that its guidance had been misapplied. Just as opioid prescribing once had rocketed ahead of the supporting science, opioid deprescribing was often mandated and carried out in ways that lacked evidentiary support.") (footnotes omitted); Satel & Nicholson, *supra* note 59 ("The CDC's 2016 'Guideline for Prescribing Opioids for Chronic Pain' wrought havoc. Regulators, insurers, pharmacies, clinicians, and law enforcement misinterpreted the document as a government mandate that limited doctors' use of opioid painkillers for pain or directed them to stop prescribing opioids completely. While the guideline, written amid the opioid crisis, did recommend limits on prescribed painkillers, it was issued only as *guidance*, and not the near ban many interpreted it as being. Yet the result was (and still is) that tens of thousands of Americans who were in agony because of medical conditions could not get essential pain medication or treatment. [¶] Patients who had functioned well for years became couch bound because they could not get the necessary medication. Others suffered withdrawal from abrupt opioid discontinuation, sometimes turning to street drugs for pain relief. Many 'pain refugees,' as the media called them, searched desperately for care when their doctors abandoned them. Some even died by suicide.").

62. *See* United States v. Penn. Indus. Chem. Corp., 411 U.S. 655, 670–75 (1973) (ruling that a defendant cannot be convicted if it reasonably relied on an agency's official regulatory guidance).

63. *See* United States v. Ruan, 966 F.3d 1101, 1120 (11th Cir. 2020) ("The Superseding Indictment alleged that Ruan and Couch's medical clinic was essentially a 'pill mill,' which prescribed controlled substances for no legitimate medical purpose or outside the usual course of professional practice.").

patients, assuming that they see their patients at all.[64] Those doctors certainly are at risk of being charged with violations of the CSA. Many, however, might not go to trial. They face a lengthy term of imprisonment on each count of conviction—as much as 20 years.[65] Accordingly, many seek plea bargains to reduce their potential exposure. For them, *Ruan* would not come into play, except perhaps as a factor in the plea bargaining calculus.[66] The third category encompasses physicians who exceeded the CDC's guidelines by a relatively small amount and who believe that they can persuade the jurors they acted in good faith.[67] One vote for acquittal defeats a conviction. But the number of such defendants might well be small.

The third category of physicians—the doctors who exceeded the CDC's recommended treatment protocols, but not by a mile—is the group most likely to go to trial. Some will do so to alleviate their patients' suffering; others because prescribing a larger dose of painkillers allows them to avoid critical patient reviews; still others for the money that follows from having additional patients. Whatever the reason, that third category of physicians might be the principal ones affected by the *Ruan* case. Of course, that assumes they do not testify and that juries follow a judge's instructions not to hold against them their decision not to take the

64. *See, e.g.*, *id.* at 1123 (referring to the defendant's practice of prescribing transmucosal immediate-release fentanyl, or TIRF, an FDA-approved drug used "to treat 'breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy'": "From January 2011 to May 2015, Ruan and Couch prescribed more than 475,000 doses of TIRFs to over 1,000 patients. From 2012 to 2014, they sharply increased both the number of patients receiving TIRF prescriptions and the dosages prescribed. This practice placed the appellants among the top TIRF prescribers nationwide: they often surpassed the next highest prescriber by more than double. Despite these high numbers of TIRF prescriptions, no more than 15% of PPSA patients had cancer."); *id.* at 1126–27 ("Another way that the government sought to establish that PPSA operated outside the usual course of professional practice was to show that Ruan and Couch prescribed powerful opioids without actually seeing patients. The government's medical experts testified that before prescribing controlled substances, a doctor should see the patient, take a medical history, and do an exam. A doctor who conducts a thorough evaluation of each patient can normally see 20 to 25 patients per day, but PPSA routinely processed 150 to 200 patients daily, often quadruple-booking patients for the same time. This worked because many PPSA patients never saw Couch and rarely saw Ruan. In fact, one patient for whom Couch signed multiple prescriptions and another patient's wife who came to half of her husband's appointments could not identify Couch in court because they had never met him. Others said they had met him only once, despite multiple PPSA visits during which he signed prescriptions for them. Instead, patients were seen by nurse practitioners who were not doctors."); *id.* at 1130 ("Evidence was presented that Ruan and Couch rapidly increased patients' opioid dosages beyond the minimum necessary for pain control and failed to refer patients for mental-health treatment, surgery, or physical therapy that their records indicated would have been appropriate. They prescribed powerful opioids to people displaying red flags for diversion and abuse, like criminal records, inconsistent drug screens, and drug-seeking behavior. Some patients testified that they were overmedicated on opioids, making their lives worse.").

65. *See* 21 U.S.C. 841(b)(1)(C).

66. For example, a defendant (Xiulu Ruan) in one of the cases consolidated in the Supreme Court chose to go to trial, and he was convicted. The presentence report calculated his potential term of incarceration at 3,000 months (or 250 years), and the district court sentenced him to 252 months' (or 21 years') imprisonment. *Ruan*, 966 F.3d at 1133, 1136.

67. One vote for acquittal defeats a conviction. *See* Ramos v. Louisiana, 140 S. Ct. 1390 (2020) (ruling that a jury must vote unanimously to convict a defendant of a serious offense).

stand.[68] But *Ruan* will affect only those cases that go to trial, and there might not be many of them. As a result, *Ruan* might be of interest only to law professors, not criminal defense lawyers or their clients.

CONCLUSION

The Supreme Court's *Ruan* decision reaffirmed the importance of a *mens rea* element to limit criminal liability to those who willfully flout the law. In that regard, the lower federal courts should deem important the Supreme Court's directive always to interpret criminal statutes with that goal in mind.[69] Law professors also will enjoy using the decision in a class on *mens rea* as a way of inviting students to consider how that decision might be applied to a host of different statutes. But practitioners are unlikely to find that *Ruan* does much to assist in the defense of their clients. As a practical matter, physician-defendants charged with excessively prescribing opioids might believe that they must testify at trial to persuade the jury that they acted in good faith. As a practical matter, the jury will decide whether it finds the defendant credible by a mere preponderance of the evidence, which then will dictate the verdict that the jury returns. If true, the *Ruan* decision, like Macbeth's description of the consequences of his own life, will be no more than "a tale, told by an idiot, full of sound and fury, signifying nothing."[70]

68. *See supra* note 50.

69. *See Ruan*, 142 S. Ct. at 2377 ("[W]hen we interpret criminal statutes, we normally start from a longstanding presumption, traceable to the common law, that Congress intends to require a defendant to possess a culpable mental state.") (citation and punctuation omitted).

70. WILLIAM SHAKESPEARE, MACBETH act 5, sc. 5, l. 29–31 (The Folger Shakespeare).