

WHITE-COLLAR CRIME

License to Pill: SCOTUS Confronts Doctors' Good Faith Defense to Unlawful Distribution of Controlled Substances

When is a doctor a doctor and when is a doctor a drug dealer? In early March, the U.S. Supreme Court heard oral argument in two consolidated cases—*Ruan v. United States* and *Kahn v. United States*—to address where that line is drawn. Since the mid-1970s, doctors who prescribe controlled substances are not subject to prosecution for unlawful distribution under the Controlled Substances Act unless those prescriptions “fall outside the usual course of professional practice.” *United States v. Moore*, 423 U.S. 122, 124 (1975). If a doctor prescribing controlled substances believes, mistakenly, that he or she is acting within the usual course of professional practice, that sounds like medical malpractice, but is it also a felony? The court granted certiorari in *Ruan* and *Kahn* to

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address a circuit split on whether a physician who prescribes controlled substances may be convicted of unlawful distribution under 21 U.S.C. §841(a)(1) without regard to whether, in good faith, that physician believed the prescriptions to fall within an acceptable course of professional practice.

The issue at stake in *Ruan* and *Kahn* seems primed to fit a pattern of recent cases where the Supreme Court has addressed interpretations of criminal statutes that threaten to sweep too far. In cases like *Bond v. United States*, 572 U.S. 844 (2014), *Yates v. United States*, 574 U.S. 528 (2015), and most recently in *Van Buren v. United States*, 141 S. Ct. 1648 (2021), the Supreme Court

narrowly has interpreted broadly written criminal statutes based on a close—sometimes strained—analysis of statutory language. In these cases, the court, at times, has acknowledged the larger problem of overcriminalization via statutes susceptible of sweeping in innocent or de minimis conduct, but nevertheless anchors its decisions in the text—without express reliance on broader judicial doctrines. The parties’ arguments and the justices’ comments during oral argument in *Ruan* and *Kahn*, however, hint at the possibility that the court may break its recent pattern and delineate the boundary between medical malpractice and felony drug dealing on a more far-reaching doctrinal foundation—the bedrock criminal law principle that each statutory element distinguishing lawful from unlawful conduct must be done with mens rea.

Statutory Framework and the Good Faith Defense

The Controlled Substances Act (CSA) makes it unlawful for “any

person knowingly or intentionally ... to manufacture, distribute, or dispense” a controlled substance, “[e]xcept as authorized by this subchapter.” 21 U.S.C. §841(a)(1). Under the relevant subchapter, individuals who have registered with the Attorney General to distribute controlled substances are authorized to do so “to the extent authorized by their registration.” 21 U.S.C. 822(b). Under the CSA, the Attorney General also must accept the registration of a medical doctor or other practitioner if he is “authorized to dispense ... controlled substances under the laws of the State in which he practices.” 21 U.S.C. §823(f). Accordingly, licensed and registered physicians may lawfully prescribe controlled substances. Further, under the applicable federal regulation, 21 C.F.R. 1306.04(a) “[a] prescription is lawful ... if the prescription is ‘issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.’”

Following the Supreme Court’s ruling in *United States v. Moore*, 423 U.S. 122 (1975), lower courts have grappled with whether a doctor may raise a defense of good faith even where the doctor’s conduct “fall[s] outside the usual course of professional practice.” In response, Circuit Courts have laid out three standards. The First, Seventh, and Ninth Circuits have held that *any* sincere belief—reasonable or not—that a prescription was within the bounds of professional practice is grounds for acquittal.

In the Second Circuit, along with the Fourth and Sixth Circuits, a physician may be acquitted only if he *reasonably* believed that his prescription was within the usual course of professional practice. In *United States v. Vamos*, 797 F.2d 1146, 1152-53 (2d Cir. 1986), the Second Circuit explained that the privilege of being authorized to prescribe medications is “based on the assumption that practitioners, by reason of their expertise and training, will be guided by generally accepted professional practice, [and] carries with it greater responsibilities than those chargeable to the unlicensed person.”

In the Tenth and Eleventh Circuits, however, subjective good faith does not suffice as a defense. In the Tenth Circuit, a physician may be convicted “if she prescribes the substance either outside the usual course of medical practice or without a legitimate medical purpose” regardless of whether the physician acted in good faith. *United States v. Nelson*, 383 F.3d 1227, 1232 (10th Cir. 2004). In the Eleventh Circuit, “good faith [is] a defense to a Controlled Substances Act violation as long as the [doctor’s] conduct also was in accordance with the standards of medical practice generally recognized and accepted in the United States.” *United States v. Ruan*, 966 F.3d 1101, 1167 (11th Cir. 2020).

Dr. Ruan and Dr. Khan

Dr. Xiulu Ruan practiced as a board-certified interventional pain specialist, operating a pain

clinic with a partner in Mobile, Alabama. At times the pain clinic was the nation’s top prescriber of a particularly potent form of fentanyl, including one known as Abstral. Ruan purchased a large sum of stock in the manufacturer of Abstral during the same period that his clinic substantially increased prescriptions of Abstral. A grand jury charged Ruan with unlawful distribution of controlled substances in violation of 21 U.S.C. §841(a), along with a variety of other charges based largely on the distribution charge, including racketeering conspiracy, money laundering and wire fraud. At trial, the government offered the testimony of an undercover agent who had been prescribed a Schedule II pain medication without having been asked about his pain levels and spending no more than a minute with a doctor. Both the government and Ruan each offered three experts to testify about whether Ruan’s prescriptions fell outside the usual standard of care. Ruan also took the stand in his own defense. Ruan sought to offer evidence that he declined to treat patients who turned out to be undercover DEA agents, as well as testimony from patients who believed that Ruan’s treatment saved them from lives of chronic pain, but the district court excluded both categories of evidence as irrelevant. Following a hotly contested seven-week trial, the district court rejected Ruan’s requested good faith instruction, and instead instructed the jury that Ruan could be convicted

if the government proved that his “actions were either not for a legitimate medical purpose or were outside the usual course of professional medical practice.” The jury found Ruan guilty of violating §841(a)(1) and most other charges, and Ruan was later sentenced to 21 years’ imprisonment. On appeal, the Eleventh Circuit affirmed, upholding the jury instruction.

Dr. Shakeel Kahn operated pain clinics in Arizona and Wyoming. In 2015, he prescribed a high dose of oxycodone to patient who later died. Kahn was charged with conspiracy to distribute controlled substances resulting in death, along with a host of other charges based on the narcotics charge, including money laundering and operating a continuing criminal enterprise. At trial, the government called an expert who testified that Kahn’s medical records did not document sufficient monitoring of patients, indicating treatment outside the usual standard of professional practice. The government also submitted evidence that Kahn performed only a perfunctory examination—or no examination at all—before prescribing controlled substances for some patients, routinely accepted cash payments, and charged his patients higher amounts the more pills he prescribed. Following trial, a jury found Kahn guilty of, among other things, violating §841(a)(1), resulting in a sentence of 25 years’ imprisonment. On appeal, the Tenth Circuit affirmed the district court’s rejection of the Kahn’s good faith instruction,

ruling that a doctor could be convicted “issued a prescription that was objectively not in the usual course of professional practice,” regardless whether the doctor believed it was or not.

Supreme Court Argument

In their briefing, Ruan and Kahn both emphasized that “[a] meaningful good faith instruction helps ensure that convictions under the CSA are consistent with the ‘basic principle’ that ‘an injury is criminal only if inflicted knowingly.’” Ruan Br. at 29 (quoting

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Rehaif v. United States, 139 S. Ct. 2191, 2196 (2019)); see also Kahn Br. at 32 (citing *Rehaif*). Kahn, argued that because “‘outside the scope of professional practice’ is not susceptible to precise definition,” without the availability of a good faith defense, §841 should be found void for vagueness as applied to medical practitioners. Kahn Br. at 29-30.

The National Association of Criminal Defense Lawyers (NACDL), as amicus curiae, argued that an interpretation of the CSA that omits a good faith defense would “‘criminalize a broad range of apparently innocent conduct’ by reading the ‘knowledge-of-illegality requirement’ out of the

plain statutory text enacted by Congress.” NACDL Br. at 7 (quoting *Liparota v. United States*, 471 U.S. 419, 426 (1985)). According to the NACDL, the lack of a mens rea requirement would fly in the face of established principles of criminal law, as “[t]he existence of a mens rea is the rule of, rather than the exception to, the principles of Anglo-American criminal jurisprudence.” Id. at 8 (quoting *Dennis v. United States*, 341 U.S. 494, 500 (1951)) (quotation marks omitted).

The government, for its part, argued that petitioners exaggerate the split among the Circuits. All Circuits, according to the government, recognize that *Moore* requires an objective standard for judging a physician’s conduct. The jury instructions in both *Ruan* and *Kahn*, the government asserted, sufficiently required that the doctors’ conduct went beyond malpractice and demonstrated an absence of good faith.

At oral argument, Ruan’s lawyer emphasized that the statutory element that separates legal from illegal conduct for a prescribing doctor—the phrase “except as authorized”—must have a mens rea to it. While Justices Alito and Breyer sparred over whether the phrase “knowingly and intentionally” applied to each of the statute’s terms as a matter of grammar, other Justices focused on the broader issue—that the lack of a good faith defense could criminalize otherwise innocent physicians. Justice Gorsuch’s questioning suggested a focus on a good faith defense as means

to ensure compliance with long-standing precedent requiring that the government prove mens rea for each element of a crime in order to distinguish lawful from unlawful conduct. Later, Justice Kavanaugh indicated a similar concern for the practical consequences of the government's position, noting that "legitimate medical purpose' is a very vague thing on which reasonable people can disagree... . And so, ... if you're on the wrong side of a close call about what you believed, you go to prison for 20 years?"

One often cannot predict the court's decision based on oral argument. But Justice Gorsuch's particular focus on the mens rea requirement, about which Justice Sotomayor made supportive comments, and Justices Gorsuch's and Kavanaugh's references to the practical consequences of the good faith defense, along with the sparse guidance in the statutory language on this important issue, suggest that the court's ruling might break from the mold of the court's recent criminal law jurisprudence by relying upon broad, generally applicable criminal law principles.

The Court's Approach in Recent Years

In its recent criminal cases, including a number previously addressed in this column, the Court has limited broad-reaching interpretations of criminal statutes while taking pains to maintain the veneer of a strict textualist approach. In *Bond*, 572 U.S. at 866, the court relied primarily

on textualist tools to reject an "expansive reading" of laws passed to fulfill the United States' obligations under the international Convention on Chemical Weapons absent a clear indication that the criminal provisions of the act extended to actions taken by the defendant—spreading commonly available chemicals on a mailbox and doorknobs aimed at her husband's lover. Similarly, the following term, in *Yates*, 574 U.S. at 539-40, sometimes referred to as the case of the missing fish, the court strained to use similar analytical tools to hold that the federal obstruction statute passed in the wake of the Enron scandal, which criminalized the destruction of "any tangible object" to impede a federal investigation, did not apply to the destruction of undersized fish, which would otherwise be a minor fish and wildlife violation. Finally, last year in Justice Coney Barrett's initial criminal law opinion for the court in *Van Buren*, 141 S. Ct. at 1652, 1661, the court used textual analysis to adopt a narrow construction of "exceeds authorized access" under the Computer Fraud and Abuse Act of 1986, thereby avoiding criminalizing "a breathtaking amount of commonplace computer activity." In each of these decisions trimming broad criminal statutes, apparently mindful of its deference to Congress, the court has taken special pains to root its decisions in tight textual analysis and to downplay reliance on the absurd outcomes that could result from a broader interpretation.

Conclusion

Experience suggests that it's a safer bet that, if the defendants prevail in *Ruan* and *Kahn*, the court will follow its more typical, narrow textual approach. But the parties' and some Justices' focus on the core due process principle that a criminal statute must impose a standard that "separate[s] those who understand the wrongful nature of their act from those who do not," *Rehaif v. United States*, 139 S. Ct. at 2196, offers the potential that this decision could be more far reaching. Court watchers, along with doctors who fear being treated as drug dealers because they made the wrong judgment in writing a prescription to alleviate a patient's pain symptoms, will be paying keen attention.