What's At Stake In Doctors' Opioid Liability Case In High Court

By **Lindsay Gerdes and Madeline Pinto** (February 25, 2022)

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On March 1, the U.S. Supreme Court will hear oral arguments in Ruan v. U.S. on an issue that has appellate courts across the country deeply divided: When does a doctor's care turn criminal in the context of prescribing opioids? The court's decision will have broad implications not only for the many physicians who prescribe opioids, but also for the millions of patients who suffer from pain every day.

The circuit split on this issue has left good doctors wondering when their judgment may be called into question and has put their freedom on the line. On one side of this issue are zealous prosecutors second-guessing the decisions of doctors in the government's laudable effort to combat the opioid epidemic, and on the other are doctors trying to deliver care to patients in desperate need of pain treatment.

Doctors derive their prescribing authority from the Controlled Substances Act, which makes it unlawful "except as authorized ... for any person [to] knowingly or intentionally ... distribute ... a controlled substance."[1]

A prerequisite to authorization is registration with the U.S. Drug Enforcement Administration. DEA regulations further mandate that prescriptions "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[2] Innocent prescribing mistakes, differences of opinion on prescribing, or even negligence, should not amount to criminal liability.

In 1975, the Supreme Court held in U.S. v. Moore that doctors could be convicted under the CSA when "their activities fall outside the usual course of professional practice."[3] But in the decades since, courts have interpreted that decision differently.

Some have adopted a subjective good faith standard and hold that practitioners cannot be convicted if they sincerely and honestly believe that their prescriptions were within the usual course of professional practice.[4]

Others have adopted an objective good faith standard and hold that a practitioner cannot be convicted if they reasonably believed that their prescription was within the usual course of professional practice.[5] A minority of courts have rejected any consideration of good faith and found it irrelevant to criminal liability.[6]

Given that the statute requires the knowingly or intentionally unauthorized distribution of a controlled substance, the Supreme Court is expected to permit the good faith defense. The only question that remains is: To what extent? If a doctor honestly believed the prescription was for a legitimate medical purpose, should that absolve the conduct, or should the belief be judged on an objective standard?

Multiple advocates for the physicians filed amicus briefs with the Supreme Court arguing a subjective good faith standard is necessary because there is considerable debate within the medical community about what constitutes the usual course of professional practice when it comes to prescribing opioids.

In an amicus brief filed in connection with the pending Supreme Court case, the National Pain Advocacy Center wrote that "there is no unitary standard or broadly applicable protocol for treating pain."[7]

The nonprofit organization Compassion & Choices wrote that "Indeed, no consensus medical opinion exists even on an upper limit for opioid prescriptions, in volume or dosage."[8] As a result, advocates characterize a provider's decision to prescribe opioids as one fraught with peril.[9]

The concern among advocates is that a standard based on generally accepted practice and objective belief will lead to over-deterrence and chill the practice of pain medicine. The fear of harsh criminal penalties has already led many providers to refuse to treat patients with chronic pain and "subject patients to dangerous opioid cessation practices that may actually increase their risk of death," the National Pain Advocacy Center said.[10]

Professors of health law and policy Jennifer Oliva and Kelly Dineen predict that in the absence of a robust good faith defense, "[p]atient abandonment will grow more widespread as practitioners avoid legal scrutiny."[11]

Practitioners will "find themselves stuck in the middle between aggressive prosecutors and patients in need of pain treatment," according to the National Association of Criminal Defense Lawyers.[12]

Advocates argue exposing providers to criminal liability for nothing more than a deviation from accepted medical standards will not solve the opioid crisis. "Incarceration of physicians who treat pain does not eliminate the pain and the need to treat it," the Association of American Physicians and Surgeons wrote in its brief.[13] The association stressed that "a robust good-faith defense is essential to protect patient access to prescriptions written in good faith."[14]

In its briefs, the government argued a provider who makes no objectively reasonable attempt to comply with medical norms violates Section 841(a). The CSA "does not permit a physician to simply decide for himself that any manner or volume of drug distribution is 'medicine,'" the government wrote. Instead, the CSA requires that providers "dispense drugs in accord with accepted medical standards."

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[1] 21 U.S.C. § 841(a)(a)

[2] 21 C.F.R. § 1306.04(a)

[3] 423 U.S. 122, 124 (1975).

[4] See, e.g., United States v. Sabean, 885 F.3d 27, (1st Cir. 2018) (reasoning that "a

sincere effort to act in accordance with proper medical practice, even if flawed, could not undergird a guilty verdict so long as the defendant had acted in good faith.") (internal quotations omitted); (United States v. Feingold, 454 F.3d 1001, 1007-08 (9th Cir. 2006) (quoting United States v. Rosenberg, 515 F.2d 190 (9th Cir. 1975)) (explaining "'the jury [must] look into [a practitioner's] mind to determine whether he prescribed the pills for what he thought was a medical purpose or whether he was passing out the pills to anyone who asked for them.'"

[5] See e.g., United States v. Wexler, 522 F.3d 194, 205 (2d Cir. 2008) (explaining that good faith in the context of a §841 prosecution "means that the doctor acted in accord with what he should have reasonably believed to be proper medical practice"); (United States v. Hurwitz, 459 F.3d 463, 479 (4th Cir. 2006) (holding that in a § 841 prosecution against a doctor, "the inquiry into the doctor's good faith in treating his patients . . . must be an objective one"); United States v. Volkman, 797 F.3d 377, 387-88 (6th Cir. 2015) (explaining a physician cannot be convicted if he "dispenses a drug in good faith," where good faith "means that the defendant acted in accordance with what he reasonably believed to be proper medical practice").

[6] United States v. Enmon, 686 F. App'x 769, 773 (11th Cir. 2017) (per curiam).

[7] https://www.supremecourt.gov/DocketPDF/20/20-1410/206470/20211227110519477_National%20Pain%20Adv%20Ctr%20Amicus%20Brief.pdf.

[8] https://www.supremecourt.gov/DocketPDF/20/20-1410/205902/20211221131414908_Brief.pdf.

[9] https://www.supremecourt.gov/DocketPDF/20/20-1410/206387/20211223153256418_Ruan%20Amici%20-%20Professors%20of%20Health%20Law%20and%20Policy%20-%20Brief%20-%2012-23-2021.pdf.

[10] https://www.supremecourt.gov/DocketPDF/20/20-1410/206470/20211227110519477_National%20Pain%20Adv%20Ctr%20Amicus%20Brief.pdf.

[11] https://www.supremecourt.gov/DocketPDF/20/20-1410/178631/20210507164642254_Ruan%20Amici%20Brief%20-%20Final%20for%20Filing%20-%205-7-21.pdf.

[12] https://www.supremecourt.gov/DocketPDF/20/20-1410/206580/20211227162125599_Amicus%20Brief_NACDL_FILE.pdf.

[13] https://www.supremecourt.gov/DocketPDF/20/20-1410/206542/20211227150253495_amicus%20brief%20by%20AAPS%20and%20Dr%20Singer%20in%20Ruan%20v%20US%2020-1410.pdf.

[14] https://www.supremecourt.gov/DocketPDF/20/20-1410/206542/20211227150253495_amicus%20brief%20by%20AAPS%20and%20Dr%20Singer%20in%20Ruan%20v%20US%2020-1410.pdf.