Doctors and Pain Patients Avoid "Ruan" in the Supreme Court

Currents in Contemporary Bioethics

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Keywords: Controlled Substances Act, Criminal Prosecution, Opioids, Pain Management, Physicians

Abstract: Physicians' fear of criminal prosecution for prescribing opioid analgesics is a major reason why many chronic pain patients are having an increasingly difficult time obtaining medically appropriate pain relief. In *Ruan v. United States,* 142 S. Ct. 2370 (2022), the Supreme Court unanimously vacated two federal convictions under the Controlled Substances Act. The Court held that the government must prove that the defendant knowingly or intentionally acted in an unauthorized manner.

The opioid crisis of the last thirty years has been caused by a complex combination of social, economic, and medical factors involving both licit[1] and illicit substances. Although reckless and financially-motivated overprescribing by small numbers of physicians undoubtedly contributed to the opioid crisis,[2] it is simplistic and inaccurate to attribute responsibility for individual and societal consequences of the current opioid crisis to the excessive prescribing of opioid analgesics.[3] To take one important metric, between 2012 and 2020, the number of opioid prescriptions nationwide declined significantly from 255 million to 142 million,[4] but the number of overdose deaths soared from 41,000 to 100,000.[5] Today, opioid overdose deaths and other individual and societal drug-related harms are primarily caused by illicit synthetic opioids such as fentanyl.[6]

Notwithstanding these irrefutable data, federal and state governments, as well as many nongovernmental entities such as private hospitals and physician group practices, have adopted policies of drastically curtailing the prescribing of opioids. In many cases the changes in policy reflect the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain.[7] The Guideline, issued in 2016, took a strong stance against opioid therapy for chronic pain, recommended strict dosage and time limits for opioids, and urged tapering of current patients from opioids. Although it was expressly limited to primary care providers in outpatient settings, the Guideline has been adopted and applied more broadly by state legislatures, state medical boards, and private institutions.[8] The result has been that many patients with intractable pain, including cancer patients and those at the end of life, have been unable to get adequate pain relief.[9] According to the American Medical Association: "It is clear that the CDC guideline has harmed many patients."[10]

"[T]he guideline has achieved its greatest impact by convincing health care provider organizations that violations of the guideline by their member physicians may increase organizational liability exposure."[11] Many physicians are extremely concerned that treating patients with opioids could result in their loss of employ-

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About This Column

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The Journal of Law, Medicine & Ethics, 50 (2022): 841-847. © 2023 The Author(s)
DOI: https://doi.org/10.1017/jme.2023.25

ment or staff privileges, license revocation, civil liability, or professional discipline. These "career enders" are powerful motivators in shaping clinical practices, but the prospect of a criminal investigation, conviction, and incarceration is likely the greatest source of physicians' fears.[12]

On November 4, 2022, the CDC published a revised version of its opioid Guideline.[13] Although somewhat less restrictive than the 2016 Guideline, the 2022 Guideline also has been subject to intense criticism as unnecessarily preventing essential pain management for chronic pain patients without sufficient scientific or policy justification.[14] The Supreme Court's decision in Ruan v. United States[15] predates the revised Guideline, but the issues in the case and its implications are not affected by this modest change in CDC policy. Federal criminal prosecutions for the "unauthorized" prescribing of opioids have been brought under the Controlled Substances Act (CSA).[16] A key element of these cases is the defendant physician's *mens rea* or criminal intent. If physicians could be convicted without proof that they knew their prescribing was unauthorized under the CSA and its interpretive regulations,[17] convictions would be more likely, and the dread of physicians would increase. Such a legal standard also would cause patients suffering from severe pain to experience even more difficulty obtaining care from a primary care or specialist physician and receiving appropriate pain management.[18] Lack of access to prescription opioid analgesics to treat unremitting pain has led to tragic consequences, including unnecessary and harmful tapering of opioids,[19] overdosing on illicit substances,[20] and suicide.[21]

The gravity of the opioid crisis and the importance of these legal issues made *Ruan* one of the most closely watched drug cases in recent terms of the Supreme Court.

Lower Court Holdings

Ruan involved two consolidated cases, *United States v. Ruan*[22] and *United States v. Khan*.[23] In both cases, a physician was tried for violating the CSA, which makes it a federal crime, "[e]xcept as authorized[,] ... for any person knowingly or intentionally ... to manufacture, distribute, or dispense ... a controlled substance."[24] A federal regulation authorizes registered physicians to dispense controlled substances via prescription, but only if the prescription is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[25] At issue in both trials was the *mens rea* required to convict a physician for distributing controlled substances not "as authorized." The defendant physicians, Dr. Xiulu Ruan and Dr. Shakeel Khan, each contested the jury instructions pertinent to *mens rea* given at their trials, and both physicians were convicted in separate jury trials in federal district court of violating the CSA. Their convictions were separately affirmed by the Tenth and Eleventh Circuits.

The gravity of the opioid crisis and the importance of these legal issues made *Ruan v. United States* one of the most closely watched drug cases in recent terms of the Supreme Court.

United States v. Ruan

Dr. Ruan, a pain management specialist, co-owned and ran a medical clinic and pharmacy in Mobile, Alabama. Following a seven-week trial, Dr. Ruan and his partner, Dr. John Couch, were convicted by a jury of conspiring to run a medical practice constituting a racketeering enterprise in violation of several federal statutes and conspiring to violate the CSA by dispensing Schedule II and III drugs outside the usual course of professional practice and without a legitimate medical purpose. In addition, Drs. Ruan and Couch were individually convicted of multiple counts of drug distribution in violation of the CSA.

From January 2011 to May 2015, Drs. Ruan and Couch wrote nearly 300,000 prescriptions for controlled substances, over half of which were Schedule II drugs — the most powerful drugs that can be lawfully prescribed, including many pharmaceutical opioids.[26] During this same period, Dr. Couch made over $3.7 million and Dr. Ruan made over $3.9 million from the practice.

At trial, the government sought to prove that Drs. Ruan and Couch prescribed opioids and other controlled substances outside of the usual course of professional practice in violation of the CSA. To do so, the government established that the physicians prescribed millions of doses of opioids based on their financial interests, focusing especially on their frequent prescribing of a version of fentanyl called transmucosal immediate-release fentanyl (TIRF). During the relevant period, Drs. Ruan and Couch prescribed over 475,000 doses of TIRF to patients at rates often double of the next highest prescriber in the United States. Despite these high numbers of TIRF prescriptions, no more than 15 percent of their patients had cancer.[27]

Other evidence included that the physicians ordered unnecessary drug tests for patients solely because they would generate revenue, used their pharmacy inappropriately, and prescribed opioids without seeing patients, obtaining informed consent, or keeping accurate records. Further, the physicians "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," when appropriate.[28] Both physicians testified in their defense, stating that their policies and practices were within the usual course of professional practice.

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In their appeal to the Eleventh Circuit, Drs. Ruan and Couch challenged their convictions, various evidentiary rulings at trial, and the district court's jury instructions. Specifically, they asserted the jury instructions regarding the applicable standard by which to judge a physician's conduct for violations of the CSA were incorrect. They proposed a "good faith" instruction, which stated in pertinent part: "If you find that a Defendant acted in good faith in dispensing or distributing a Controlled Substance, as charged in the indictment, then you must return a not guilty verdict."[29]

The district court refused to give this instruction, finding too subjective the request to equate subjective "good faith" — acting with "good intentions and the honest exercise of professional judgment as to the patients' need" — with prescribing "for a legitimate medical purpose and within the usual course of professional practice."[30] The Eleventh Circuit agreed with the trial judge's instruction that "good faith" only acts as a defense to a CSA violation where a defendant was already acting within standard medical practice. The court noted it had repeatedly rejected good faith instructions nearly identical to the proposed instructions because they failed to include the objective standard by which to judge the physician's conduct.

United States v. Khan

In 2008, Dr. Shakeel Khan started his own private medical practice in Ft. Mohave, Arizona, and his practice increasingly shifted towards pain management. Dr. Khan regularly prescribed patients a variety of controlled substances, including oxycodone, alprazolam, and carisoprodol. However, the prescriptions he wrote aligned more with his patients' ability to pay than their medical need, evidenced by the fact that when patients were prescribed more pills, Dr. Khan charged more for his services. This shift in his practice was accompanied by a shift to a primarily "cash-only" basis, although he also accepted payment in personal property, including firearms. When patients could not afford the prescription, Dr. Khan prescribed fewer pills, or withheld a prescription entirely. The price of prescriptions also closely tracked the "street price" of the pills, which was often discussed with patients. Many of his patients sold pills so they could afford their prescriptions.

In 2013, Dr. Khan started requiring patients to sign a "drug addiction statement," which stated that Dr. Khan was not a "drug dealer," the patients were not "addicts," and the patients accepted any liability of Dr. Khan, or his officers and agents, for $100,000 for any civil or criminal action brought against him, or his officers and agents, because of any action taken by the patient.

By 2012, pharmacies in the area began refusing to fill prescriptions by Dr. Khan. In 2015, Dr. Khan opened a second practice in Casper, Wyoming, but continued to travel to Arizona about once a month to see patients there. Other patients travelled to Wyoming to see Dr. Khan, where he primarily resided. While investigating Dr. Khan's prescribing practices in 2016, the government obtained a warrant to search his Arizona residence, where officers seized patient files, U.S. currency, firearms, and automobiles.

Dr. Khan was charged with violating the CSA and other related offenses. At trial, the government relied predominantly on evidence that Dr. Khan deviated from standard medical practice. An expert witness for the government opined that the required "drug addiction statement" was neither an appropriate nor acceptable way to advise a patient. The jury instructions mirrored those given in *United States v. Ruan*. The government could prove Dr. Khan did not act in "good faith" by demonstrating that he dispensed controlled substances outside the usual course of medical practice. The jury returned a verdict of guilty.

On appeal, Dr. Khan asserted that the district court erred by instructing the jury that a defendant's good faith must be reasonable, permitting the jury to convict by finding a lesser *mens rea* than the statute requires, i.e., that his actions were merely unreasonable. The Tenth Circuit rejected these assertions, holding (1) a practitioner may be convicted for prescribing controlled substances either outside the scope of professional practice or not for a legitimate medical purpose, and (2) good faith is not a defense as to *mens rea*, but rather is a defense as to the lawfulness of a prescription.[31]

The court explained that the CSA and its implementing regulations,[32] which permit a practitioner to dispense controlled substances with a prescription, require the government to prove a defendant either: (1) subjectively knew a prescription was issued not for a legitimate medical purpose; or (2) issued a prescription that was objectively not in the usual course of professional practice. The government need only prove criminal liability under one of those two prongs. Under the second prong, a prescription is valid only if it is issued in the scope of professional practice. Thus, the only relevant inquiry under that second prong is whether a defendant practitioner objectively acted within that scope, regardless of whether he believed he was doing so. The court noted that federal case law has rejected a subjective standard of good faith when referencing the usual course of professional practice. The court said that unlike other criminal statutes, good faith does not go to *mens rea* for CSA offenses involving practitioners. Rather, "good faith defines the scope of professional practice, and thus the effectiveness of the prescription exception and the lawfulness of the actus reus."[33]

Supreme Court Brief for the United States

In its brief, the government argued that dispensing drugs "without any objectively reasonable effort to actually practice medicine" violates the CSA. Specifically, the physician-registration process in which state-licensed physicians are authorized to write prescriptions in accord with general state medical practice exempts the proper prescription of controlled substances from the CSA. Thus, according to the government, "the subjective views of a physician who has not reasonably tried to practice medicine as conventionally understood do not preclude convic-

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tion" under the CSA.[34] The government also put forth a substitute *mens rea* standard, arguing that instead of "knowingly or intentionally," the statute contains an "objectively reasonable good-faith effort" or "objective honest-effort standard."[35] The government maintained that requiring it to prove that a physician knowingly or intentionally acted not "as authorized" will allow maleficent physicians to escape liability by claiming individual views about their prescribing authority that are not generally accepted by the medical community.

Supreme Court Briefs for the Physicians

In their respective briefs, the physicians argued that to obtain the conviction of a physician under the CSA, the government must prove the physician knowingly and intentionally acted outside of the usual course of professional practice. This is the proper reading because "usual course" is the element that distinguishes a guilty act from an innocent act. Failure to read the statute this way allows physicians "who intended no harm, and provided prescriptions that successfully aided their patients, to be subjected to the threat of significant criminal sanctions for failing to abide by a standard of care that is both evolving and ambiguous."[36] Additionally, Dr. Ruan argued that a subjective good faith standard is essential to the practice and progress of medicine. "Limiting criminal liability to circumstances in which physicians lack a good faith medical purpose balances the need to deter and punish drug pushing with the need for innovative medical research and effective patient care."[37] In the alternative, any "objective" good faith standard must afford physicians "breathing room for honest departures from professional norms."[38]

Amicus Curiae Briefs

The cases generated several amicus briefs in support of the physicians. The Association of American Physicians and Surgeons asserted that the "denial of the petitioner's good faith defense in prescribing medications has a chilling effect on the treatment of pain."[39]

The National Pain Advocacy Center filed an amicus brief in support of the physicians,[40] arguing that the failure of recent attempts by public health agencies to articulate a standard for treating pain contributed to confusion about opioid prescribing. Combined with fear of criminal prosecution under the CSA, physicians have been deterred from exercising good medical judgment and treating patients with chronic pain. Thus, pain patients are subjected to practices that risk their health and safety, including dangerous opioid tapering or cessation practices that greatly increase their risk of death.

Professors of health law and policy also filed an amicus brief in support of the physicians.[41] They argued that conviction of practitioners should require a knowing departure from the terms of their authorization, and that eliminating the *mens rea* requirement from the CSA permits criminalization of carelessness or negligence. The professors argued that under the Eleventh Circuit's interpretation, the standard the government had to satisfy to convict Dr. Ruan of felony distribution was lower than the applicable state standard for civil malpractice liability.

Supreme Court Opinion in *Ruan v. United States*

The Supreme Court vacated the judgments of the Tenth and Eleventh Circuits and remanded the cases for further proceedings. It held that the CSA's "knowingly or intentionally" *mens rea* applies to the statute's "except as authorized" clause. Thus, 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. Accordingly, both the Tenth and Eleventh Circuits evaluated the jury instructions relating to *mens rea* under an incorrect understanding of the CSA's scienter requirements, and the separate juries were improperly instructed about the knowledge of wrongdoing required for a conviction under the CSA.

Justice Breyer's majority opinion began by explaining the fundamental idea that criminal law generally seeks to punish conscious wrongdoing. When interpreting criminal statutes, the Court starts with the presumption that Congress intended to require a defendant to possess a culpable mental state, known as scienter, and this presumption applies even when a statute does not include a scienter provision. Further, when a statute does include a general scienter provision, the presumption applies to the scope of that provision. Accordingly, the Court has held that "knowingly," modifies not only the words directly following it, but other statutory terms that "separate wrongful from innocent acts."[42]

The CSA contains such a general scienter provision — "knowingly or intentionally" — and in the context of authorized prescriptions where the regulatory language is ambiguous, "a strong scienter requirement helps reduce the risk of 'overdeterrence,' i.e., punishing conduct that lies close to, but on the permissible side of the criminal line."[43] Although the Court has held that the presumption of scienter does not apply to statutes that establish regulatory or public welfare offenses that carry only minor penalties, the statutory provisions at issue here are not of this kind.

The Court also emphasized that such a conclusion is supported by analogous precedent where the Court was tasked with interpreting statutes containing a general scienter provision ("knowingly"), and determining what mental state applied to a statutory clause that did not immediately follow the "knowingly" provision. In each case, the Court held that "knowingly" modified the statutory clause in question "because that clause played a critical role in separating a defendant's wrongful from innocent conduct."[44]

Justice Alito wrote an opinion concurring in the judgment, in which Justice Thomas joined and Justice Barrett joined in part.[45] The concurrence supported reversing the conviction of the physicians but criticized

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the framework the majority used to reach its conclusion. Justice Alito referenced the Harrison Narcotics Act of 1914, the predecessor of the CSA. The Court has interpreted the Harrison Act to hold that a physician acts "in the course of his professional practice" when the physician writes a prescription "in good faith."[46] Justice Alito would hold that this rule is still applicable under the CSA. He argued that the authorizations in the CSA that excuse acts otherwise unlawful are not elements of the offense, but rather affirmative defenses, meaning the Court's interpretation of the applicable *mens rea* is not relevant to that defense. Ultimately, Justice Alito would hold that a physician who acts in subjective good faith in prescribing is entitled to invoke the CSA's "authorization" defense.[47]

Neither the majority nor the dissent explicitly state what the practical effect of their approaches would mean on the likelihood of prosecution or conviction of physicians. It is also unclear whether, on remand, the defendants would be acquitted under the new standard, given the facts as found by the juries. Under the Supreme Court's majority view, Dr. Ruan could produce evidence that he was authorized to dispense controlled substances, and the government would then have to prove beyond a reasonable doubt that he knew that he was acting in an unauthorized manner or intended to do so.

State Laws and Other Disincentives to Prescribing Opioids

Ruan helps lessen the likelihood of successful federal criminal prosecution of physicians who prescribe opioids, but it is not known whether or by how much it will lessen the *fear* of federal prosecution. In addition, other prohibitions or disincentives to physicians prescribing opioids for chronic pain patients remain, including state criminal prosecution, tort liability for overdoses and other drug-related harms, loss of licensing or staff privileges, and parsimonious policies of hospitals and physician group practices.

The first CDC Guideline on opioid prescribing was published in March 2016, and by October 2018, at least 33 states had enacted legislation drastically limiting opioid prescribing.[48] By the end of 2019, 39 states had statutes or regulations by state medical boards limiting the ability of medical professionals to prescribe pain medication.[49] The laws either limit the duration of opioid use, set maximum morphine milligram equivalents, or both.[50] Many of the laws have exceptions for chronic pain, cancer treatment, acute pain, or palliative care, but despite these provisions, the laws often have been applied indiscriminately — even as to responsible patients and those in severe medical distress. Tragically, many cancer and palliative care patients report being unable to access adequate doses of opioids to manage their pain.[51]

In addition to directly regulating prescribing opioids, every state has enacted a prescription drug monitoring law,[52] which uses an electronic database to collect records of all controlled substances prescribed and dispensed in the state. The laws have been successful in eliminating pill mills, but they also discourage well-meaning physicians from prescribing opioids because they fear state government oversight of their medical practices and possible law enforcement or regulatory action. Besides the undertreatment of pain by physicians, another unintended consequence of prescription drug monitoring laws is an increase in drug overdoses from illicit substances.[53]

Physicians willing to prescribe opioids to their patients also may be prohibited by hospitals, medical group practices, insurance companies, and other institutions with their own restrictive policies. In some cases, the policies are based on assumptions about the harms of opioid prescribing without any supporting evidence.[54]

Adding insult to injury, many hospitals and health care providers have become suspicious of the motives of patients seeking pain relief.[55] The assumption that any patient requesting pain management has opioid use disorder and is drug seeking has a negative impact on the doctor-patient relationship.[56] It is now common for physicians to condition opioid prescriptions on their patients signing "opioid contracts" and submitting to urine drug screens to confirm that the patients are taking and not selling prescribed opioids. The stigma of opioids also can extend to doctors who treat pain patients, who are viewed by some colleagues or prospective patients as running "pill mills," thereby making them reluctant to treat pain patients or prescribe opioids.

The cumulative effect of these measures is that even when state laws and regulations do not restrict access, many patients encounter insurmountable difficulties finding a doctor willing to prescribe opioids to new patients or to continue existing patients on therapeutic doses. And among those chronic pain patients able to access opioids, there has been an increase in forced tapering, which has led to a surge in overdoses and mental health crises.[57]

Conclusion

Physicians and their patients with severe pain stood to lose more than gain from the Supreme Court's decision in *Ruan*. A ruling upholding the government's position would have made it difficult for physicians facing federal criminal charges under the CSA to establish their lack of culpability. Such a result would likely have increased prosecutions and convictions. It also would have reinforced the narrative that physicians should refuse to prescribe any opioids for their patients, regardless of the medical appropriateness, because doing so risked criminal prosecution. The tragic consequence would be that millions of patients with severe pain would have an even more difficult time finding a physician to treat them, especially patients requiring ongoing treatment with opioids. On the other hand, the ruling in favor of Drs. Ruan and Khan by a unanimous Supreme Court only somewhat lessens the real or perceived risk of jeopardy for physicians who prescribe opioid analgesics. Therefore, it is unlikely that the harms to pain patients from physicians' fears of prescribing opioids will

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be eliminated or even reduced by this one decision.

Note

The authors have no conflicts of interest to declare. No external funding was used in the writing of this article.

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53. B. Kim, "Must-Access Prescription Drug Monitoring Programs and Opioid Overdose Exposure: The Unintended Consequences," *Journal of Health Economics* 75 (2021): 102408, doi.org/10.1016/j.healco.2020.102408.
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55. R.N. Jamison et al., "Attributes of Primary Care Practitioners in Managing Chronic Pain Patients Prescribed Opioids for Pain: A Prospective Longitudinal Controlled Trial," *Pain Medicine* 17, no. 1 (2016): 99-113.
56. S. Slat et al., "Opioid Policy and Chronic Pain Treatment Access Experiences: A Multi-Stakeholder Qualitative Analysis and Conceptual Model," *Journal of Pain Research* 14 (2021): 1161-1169, doi: 10.2147/JPR.S282228.
57. *See* A. Agnoli et al., *supra* note 20.

The Journal of Law, Medicine & Ethics, 50 (2022): 841-847. © 2023 The Author(s)