

# STAT

## Fight over opioid prescribing — and when it turns criminal — heads to Supreme Court

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Feb. 11, 2022

Doctors have wide latitude to prescribe drugs, including potentially dangerous ones, but even they face limits. The question is, what threshold do physicians have to cross — and what sort of intent do they need to have — for their prescribing to be considered a crime?

It's an issue headed to the Supreme Court next month, in a case concerning two physicians who were convicted of unlawfully dispensing opioid painkillers.

The case is already raising alarms among advocates for pain patients and some health policy experts, who fear that a ruling could enable aggressive prosecutions of prescribers. They warn that such a decision could discourage doctors from providing opioids even when they're warranted, at a time when some pain patients are already losing access to medication or seeing their doses unsafely slashed. Advocates are asking the court to make clear that criminal punishments should be reserved for prescribers who knowingly write inappropriate prescriptions.

“What we're worried about is the downstream effect of patients being dropped from care and doctors seeing patients as liabilities,” said Kate Nicholson, the executive director of the National Pain Advocacy Center.

Oral arguments are set for March 1.

Doctors and other practitioners are free to prescribe some of the drugs that the Controlled Substances Act makes it a crime for the rest of us to distribute. After all, many common medications — not just opioids, but treatments for conditions including ADHD and anxiety — are covered by the law. Still, providers can be convicted of violating the act if they prescribe in dangerous ways. In a 1975 decision, the court found that doctors could be convicted under the CSA when “their activities fall outside the usual course of professional practice” — when they effectively act as a drug dealer.

But in the decades since, courts have landed on different interpretations of what that means. Some have found that the government needs to prove that the prescriber intentionally or knowingly violated best practices, allowing for doctors to make a “good faith” defense —

meaning they were trying to help their patients and didn't mean to prescribe in risky ways. Other courts have upheld convictions of doctors who were found guilty for prescribing in ways deemed to be outside accepted standards, without considering intent.

In recent years, courts were more likely to take the latter view, given the increased scrutiny of opioid prescribers, said Kelly Dineen, the director of Creighton University's health law program. In a brief Dineen co-wrote, she and a group of other health law and policy professors say that the Controlled Substances Act "has been weaponized against practitioners in reaction to the overdose crisis."

Starting nearly three decades ago, doctors massively overprescribed opioid painkillers, contributing to the country's ongoing and spiraling overdose emergency. Over the last 10 years, efforts to reform prescribing practices have succeeded in slashing the dispensing of the drugs.

At the same time, however, doctors have become increasingly worried about legal risks for prescribing high-dose or long-term opioids — and some have stopped providing the treatments altogether. Patients who have been on these medications for years have sometimes seen their prescriptions cut off, driving some to seek illicit supplies of opioids or to take their own lives. Experts disagree on the scale of this problem, but universally say that patients should not face sudden dosage drops or discontinuations — positions echoed by federal health authorities.

The concern among advocates about the court hearing is that if prosecutors can charge prescribers without proving they knew they were misprescribing, it could further chill doctors' willingness to treat patients in pain and exacerbate the access issues.

"Honest providers fear being mistaken for bad actors," the pain advocacy center wrote in a brief. The center cited surveys showing that many primary care providers won't take on new patients who are on opioids for chronic pain, and that those who do fear being targeted by authorities. "High prescribers may be bad actors, but they may also be good providers who appropriately care for patients with significant or complex medical needs," the brief said.

It's not that doctors who prescribe in misguided ways shouldn't be punished, Dineen told STAT, but that "we should be reserving criminal penalties for people who are knowingly engaging in criminal conduct." That way, a true "pill mill" could be prosecuted, but doctors who prescribe in negligent ways could face other ramifications. They could be sued for malpractice, the government could ban them from prescribing controlled substances, or their state medical agencies could crack down.

In its briefs, the government argued that the physicians can't just claim that prescribing any amount of controlled substances fits with legitimate medical practices.

"A doctor who makes a mistake in construing or applying those standards is not criminally liable so long as he has made an objectively reasonable good-faith effort to learn and comply with medical norms," the government wrote. "A doctor who fails to take even that modest step, however, has abandoned the medical profession altogether and cannot seek its shelter."

Advocates also argue that what constitutes “legitimate medical practice” for prescribing these kinds of drugs is not always clear-cut. Experts continue to debate whether opioids can treat long-term pain, and how widely they should be used. The Centers for Disease Control and Prevention’s 2016 opioid prescribing guidelines for chronic pain have been cited by policymakers to limit dosages, but the authors of the guidelines have stressed they’ve been misapplied, and just Thursday proposed softening them.

The patient advocates and health law experts say they’ve gotten involved in the case not to defend the two physicians, but because of the larger issues at play. Other groups that have submitted briefs in the case include the libertarian Cato Institute, which wrote that “the federal government cannot and should not criminalize good faith, legitimate medical practice.”

The two physicians whose cases are being considered are Xiulu Ruan of Alabama, who was sentenced to 21 years in prison in 2017 after being found guilty of running what the Justice Department called a pill mill, and Shakeel Kahn of Wyoming, who was sentenced to 25 years in prison in 2019 for crimes including drug distribution resulting in death. Their cases were consolidated for the Supreme Court hearing.

The doctors have argued they were acting in good faith trying to provide care for their patients, while the government has urged the court to affirm the convictions.

Ruan and Kahn “simply cloaked themselves in medical garb while acting as drug dealers, lining their own pockets by dispensing addictive, dangerous, and lethal drugs, aware all the while that their profit-seeking came at the expense of their patients’ health,” the government wrote in a brief.