



The US Supreme Court in *Ruan* sided with doctors seeking a burden of proof higher than mere negligence in prosecutions for unlawful distribution of controlled substances.

The decision represents a significant win for those worried about overcriminalization and the associated risk of losing the criminal law's critical stigmatic impact, write Perkins Coie attorneys T. Markus Funk and Sean B. Solis.

The US Supreme Court issued a significant decision in its Controlled Substances Act (CSA) jurisprudence as applied to the nation's opioid epidemic. At issue in *Ruan v. United States* was the requisite intent the government must prove to convict a physician under the CSA for the unlawful distribution of controlled substances.

In a significant [win for the defense](#), specifically, and those concerned about imposing criminal liability based on mere negligence, more generally, the Supreme Court [held](#) that "[a]fter a [physician] produces evidence that he or she was authorized to dispense controlled substances" (a given in almost every case), "the Government must prove beyond a reasonable doubt that the defendant knew that he or she was acting in an unauthorized manner, or intended to do so."

In reaching this holding, the high court unanimously rejected the government's position. In its [briefing](#), the government argued that it should be allowed to convict a physician merely by showing that he or she acted "objectively unreasonably" in misprescribing opioids. In other words, under the government's requested standard, federal prosecutors would de facto only have to show that a prescribing physician acted with negligence. (Notably, this scienter requirement would be lower than the standard necessary to convict a drug trafficker for distributing heroin or cocaine—namely, "knowingly or intentionally.")

Concerns about ever-expanding prosecutorial discretion and the erosion of the criminal law's traditional "guilty mind" requirement have for good reason focused significant attention on the case.

Per the [implementing regulations](#) of [21 U.S.C. § 841\(a\)\(1\)](#), a physician may lawfully prescribe controlled substances only if they are prescribed for "a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." Even a first-time offender could face decades in prison for misprescribing opioids in violation of the CSA.

The Government's Case Against Ruan

In 2016, a federal grand jury returned an [indictment](#) charging Dr. Xiulu Ruan, a DEA-registered pain management physician, with, among other things, violating 21 U.S.C. §841(a)(1).

The government at trial presented evidence that Ruan and his business partner issued nearly 300,000 controlled substance prescriptions in a four-year period. Some of these prescriptions allegedly were signed without Ruan even seeing the patient. The government also presented evidence that he increased prescriptions of a biopharma company's fentanyl drug a hundredfold after he and his business partner invested in it.

Ruan took the stand claiming that he, at all relevant times, honestly believed he was prescribing for a legitimate medical purpose. Ruan asked the district court to give the jury a defendant-friendly jury instruction ending with this statement: "If you find that [the] 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."

The district court rejected the instruction and instead instructed the jury that a controlled substance is prescribed "lawfully if the substance is prescribed by him in good faith as part of his medical treatment of a patient in accordance with the standard of medical practice generally recognized and accepted in the United States."

Following a seven-week trial, Ruan was convicted of violating the CSA. He appealed, but the [Eleventh Circuit affirmed](#) his conviction, holding "[w]hether a defendant acts in the usual course of his professional practice must be evaluated based on an objective standard, not a subjective standard."

SCOTUS Rejects DOJ's Scienter Position

In reversing the Eleventh Circuit, the Supreme Court recognized that our system of justice, like most systems around the world, has traditionally (though not universally) operated on the proposition that a "vicious will" is necessary to establish a crime. [See, e.g., *Morissette v. United States*](#).

This approach is driven by the belief that the stigma of a criminal sanction should be reserved for only those narrow categories of conduct representing the [most significant deviations from the standard public morality](#) and deserving of moral condemnation. Thus, when interpreting criminal statutes, the high court "start[s] from a longstanding presumption...that Congress intends to require a defendant to possess a culpable mental state." [Rehaif v. United States](#).

Here, in the case of a physician registered with the DEA to lawfully prescribe controlled substances, the only element of 21 U.S.C. §841(a)(1) to which moral judgment could attach is the act of prescribing the controlled substance "[e]xcept as authorized by this subchapter" —that is, for an illegitimate medical purpose. Making negligence the mens rea standard, however, would "criminalize a broad range of apparently innocent conduct," including good faith medical prescribing error. [See Liparota v. United States](#).

In [Ruan](#), the Supreme Court applied the more robust "knowing or intentional" scienter requirement to the CSA to "diminish the risk of 'overdeterrence,' i.e., punishing acceptable and beneficial conduct that lies close to, but on the permissible side of, the criminal line." This was particularly important since the CSA "imposes severe penalties upon those who violate it, including life imprisonment and fines up to \$1 million."

[Ruan](#) represents a significant win for those worried about overcriminalization and the associated risk of losing the criminal law's critical stigmatic impact. Going forward, to sustain a conviction under the CSA, the government will be required to prove that a defendant knew or intended to prescribe controlled substances for an illegitimate medical purpose and outside the usual course of professional practice.

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