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May 24, 2022
White Collar Briefly

The U.S. Supreme Court is poised to issue what could be a monumental decision in the Court's Controlled Substances Act ("CSA") jurisprudence as applied to the nation's opioid epidemic.

At issue in *Ruan v. United States* is the requisite intent the government must prove to convict a physician under the CSA for the unlawful distribution of controlled substances.

The outcome in *Ruan* could have significant implications for prescribers, including whether their risk of criminal liability is actually higher than a narcotics trafficker distributing heroin or cocaine. More specifically, to convict

a drug trafficker, federal prosecutors must prove beyond a reasonable doubt that the trafficker *knowingly and intentionally* manufactured, transported, or distributed narcotics. If the government prevails in *Ruan*, the government would de facto have to show only that a prescribing physician was *negligent* in misprescribing opioids.

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

A Mini Survey of the CSA's Statutory Scheme

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 a Schedule II controlled substance, such as oxycodone, hydrocodone, hydromorphone, methadone, or fentanyl, in violation of the CSA.

The Government's Case Against Dr. Ruan

In 2016, a federal grand jury returned an indictment charging Dr. Xiulu Ruan, a Drug Enforcement Administration ("DEA")-registered pain management physician, with, among other things, "knowingly and unlawfully distribut[ing] and dispens[ing] . . . Schedule II Controlled Substances . . . outside the usual course of professional medical practice and not for a legitimate medical purpose, in violation of Title 21, United States Code, Section 841(a)(1)."

The government at trial presented evidence that Dr. 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 Dr. Ruan even seeing the patient. The government also presented evidence that Dr. Ruan increased prescriptions of a biopharma company's fentanyl drug a hundredfold after he and his business partner invested in it.

Dr. Ruan took the stand claiming that he, at all relevant times, honestly believed he was prescribing for a legitimate medical purpose. At the close of evidence, Dr. Ruan asked the district court to give the jury a (perhaps overly) 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. It 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."

In other words, there could be no acquittal without good faith. But the failure to prescribe the substance "both within the usual course of professional practice and for a legitimate medical purpose" alone was sufficient for a conviction.

Following a seven-week trial, Dr. Ruan was convicted of violating the CSA. He appealed, but the Eleventh Circuit affirmed. The court rejected Dr. Ruan's proffered instruction, ruling that "[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."

The Supreme Court granted Dr. Ruan's petition for a writ of certiorari—likely in part to resolve a circuit split between the Second, Fourth, Sixth, and Eleventh Circuits, on the one hand (which have articulated an objective

standard), and the First, Seventh, and Ninth Circuits, on the other (which focus on the physician's subjective intent).

The Government's Objective Standard Argument

The government contends that, to sustain a conviction for violation of the CSA, it must prove that (1) a prescribing physician knowingly or intentionally distributed or dispensed a controlled substance (a given in almost every case), (2) in a manner that was, objectively speaking, outside the usual course of professional practice or without a legitimate medical purpose.

According to the government, this standard "appropriately distinguishes between innocent and guilty minds by protecting even a physician's errors . . . so long as he undertook the *threshold step of reasonably trying to situate* himself within the medical community."

What the government is saying, then, is that a physician's *ex ante* failure to ensure adherence to legitimate medical purpose or compliance with the usual professional course of practice is the requisite "guilty mind."

Concerns Over the Government's Position

The government, in its Supreme Court briefing, notes that defense counsel were permitted to argue to the jury that "negligent misprescribing" did not constitute criminal conduct. Nevertheless, neither the tendered jury instructions nor the government's statutory text-based arguments appear to leave room for this position.

Whether it acknowledges it or not, in *Ruan*, the government embraces a utilitarian negligence standard for criminal liability. It criminalizes physicians who fail to conduct sufficiently rigorous *advanced* due diligence aimed at detecting faking or lying patients.

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., Staples 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.

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*.

The argument therefore is that, if the government believed the evidence proved Dr. Ruan to be little more than a "disguised drug dealer," then it should have prosecuted him as such. It should not have asked for a malpractice-type jury instruction. And, in any event, the government could have used the claimed objective unreasonableness of Dr. Ruan's actions as prime evidence that he did not really (subjectively) believe that his prescription practices were proper.

Conclusion

Any physician's error is unfortunate and, no doubt, adherence to medical standards must be incentivized. Those opposing the government's position in *Ruan* argue that the appropriate remedy for good-faith physician error is regulatory intervention and/or a civil malpractice action. *Amici curiae* as diverse as the Association of American Physicians and Surgeons, Professors of Health Law and Policy, the National Association of Chain Drug Stores,

and the U.S. Chamber of Commerce have written in support of this position.

The Supreme Court heard oral argument in *Ruan* on March 1, 2022, and a decision should be forthcoming soon. We look forward to unpacking and grappling with the ruling's implications in our next installment, once *Ruan* has been handed down.

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