

The Texas Lawbook

Free Speech, Due Process and Trial by Jury

Ruan v. United States: SCOTUS Potentially Limits CSA's Application

July 7, 2022 | BY JEFF ANSLEY & JASON SOBELMAN

On June 27, the United States Supreme Court issued a consolidated and long-anticipated opinion in *Ruan v. United States* and *Kahn v. United States*. It concerns the mens rea requirements under the Controlled Substances Act and, in particular, the availability of a good faith jury instruction to defendants charged with violating the CSA to demonstrate their lack of criminal intent. The holding finally addressed a circuit split on this issue, providing significant clarity regarding what the government must prove to convict a defendant — ordinarily a physician or other licensed medical prescriber — under the CSA.

Specifically, the court held that the government must prove beyond a reasonable doubt that a criminal defendant who is authorized to distribute or dispense controlled substances knew or intended to act in an unauthorized manner in order to support a conviction. In doing so, the court for the first time held that the subjective good faith of a defendant, and therefore a subjective good faith mistake, may be a defense under the CSA to whether that defendant sought to “knowingly or intentionally” violate the statute. This consequential decision firmly establishes the availability of a good faith defense, and good faith jury instruction when supported by sufficient evidence, to criminal defendants charged with violating the CSA.

Factual background

Petitioners Xiulu Ruan and Shakeel Kahn were doctors licensed to write medical prescriptions. The government brought criminal charges against them, alleging violations of the CSA, 21 U.S.C. § 841, through the issuance of controlled substance prescriptions to their patients. “Except as authorized,” the CSA prohibits any person from knowingly or intentionally distributing controlled substances. A prescription is considered to be authorized if it is issued for a “legitimate medical purpose.” Here, the government asserted that the prescriptions in question were issued outside the scope of the petitioners’ authority. In doing so, it contended that the charged prescriptions, when assessed under a purely objective standard, lacked the required legitimate medical purpose and were therefore illegal.

The doctors were tried and convicted for violating the CSA. Notably, the jury was not permitted to consider whether Ruan, in writing the prescriptions, genuinely believed that he was acting as a reasonable physician in providing care to his patients—in other words, the government successfully argued that Ruan’s subjective good faith in prescribing medications to his patients was wholly irrelevant to the jury’s assessment of his guilt. Accordingly, the court adopted the government’s position and refused to charge the jury with a good faith instruction. In affirming Ruan’s conviction, the Eleventh Circuit opined 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.” (emphasis added).

The Supreme Court’s holding limits the application of the CSA

The issue before the Supreme Court was whether it is “sufficient for the Government to prove that a prescription was *in fact* not authorized” or whether “the Government [must] prove that the doctor *knew* or *intended* that the prescription was unauthorized.” The petitioners asserted that their dispensation of controlled substances to their patients was lawful because they dispensed the drugs pursuant to valid prescriptions. Ultimately, the court held that “[a]fter a defendant produces evidence that he or she was authorized to dispense a controlled substance, 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.”

The court’s analysis focused on three main concepts. First, it noted that applying a “knowingly or intentionally” *mens rea* requirement to the “as authorized” clause of the CSA helps separate wrongful from innocent conduct while limiting overdeterrance. Second, the court rejected the government’s argument that the “[e]xcept as authorized” clause does not set forth an element for conviction under the CSA. Notably, the court held that 21 U.S.C. § 885 merely provides that the government does not need to plead a lack of authorization or any other exemption/exception in the criminal indictment.

The Texas Lawbook

In addition, the statutory language does not alter the government's burden of persuasion. Third, the court rejected the government's argument that only an "objectively reasonable good-faith effort" or "objective honest-effort standard"—to the exclusion of a prescriber's good faith intent—should apply to the "as authorized" clause. The court's reasoning is discussed in further detail below.

The scienter requirement in 21 U.S.C. § 841 applies to the "[e]xcept as authorized" provision.

First, the court opined that "in § 841 prosecutions, a lack of authorization is often what separates wrongfulness from innocence." Similar to other criminal offenses, a defendant's *mens rea* is a critical element in establishing a violation of the CSA. The court held that the "knowingly or intentionally" *mens rea* requirement of the CSA applies to both the act of dispensing or distributing a controlled substance and acting other than "as authorized." The scienter requirement is particularly important because "[w]e normally would not view such dispensations as inherently illegitimate; we expect, and indeed usually want, doctors to prescribe the medications their patients need." Consequently, the application of a "knowingly or intentionally" *mens rea* to the authorization provision should allow a medical professional to exercise his or her best judgment when treating a patient without having significant concerns about criminal liability.

In addition, the court noted that there is a significant body of analogous case law that supports the decision to apply a general scienter clause to the "as authorized" provision. The court opined that "[a] strong scienter requirement helps 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." Further, a criminal defendant's scienter is a critical element because a violation of the CSA can result in severe penalties, including life imprisonment and fines up to \$1 million.

The "except as authorized" provision is a critical element under 21 U.S.C. § 841.

Second, the Supreme Court rejected the government's argument that the "except as authorized" clause does not set forth an element of the claim. The government improperly pointed to 21 U.S.C. § 885, which merely provides that: (1) the government is not required to plead that a defendant does not fall within the many exceptions and exemptions under the CSA; and (2) the burden of production shifts to the defendant, but it does not alter the government's burden of persuasion. Notably, "those two purposes have little or nothing to do with scienter requirements." The first component of § 885 relates to the pleading requirements for a criminal indictment. The other purpose of the statutory language addresses the burden of production, but it does not alter the burden of persuasion. Therefore, the initial burden of production is on the defendant to prove that an exception or exemption applies, but the prosecution still must prove that the defendant knew or intended that his or her conduct would

not be authorized.

The government erroneously attempted to introduce an objective standard for evaluating a defendant's mens rea under 21 U.S.C. § 841.

Third, the court was unpersuaded by the government's attempt to impose an "objectively reasonable good-faith effort" or "objective honest-effort standard," to the exclusion of a defendant's subjective good faith belief that his conduct was lawful. First, the court noted that this standard is not found anywhere in the statutory language. Moreover, the government's proposed wholly objective standard "would turn a defendant's criminal liability on the mental state of a hypothetical 'reasonable' doctor, not on the mental state of the defendant himself or herself." The court has declined to adopt this logic for other criminal offenses.

Finally, the court declined to decide whether the jury instructions complied with its new standard and so remanded both cases to allow the lower courts to consider that issue.

Key takeaways: Ruan appropriately increases the government's burden when prosecuting controlled substance prescribers under 21 U.S.C. § 841.

Ruan has significant ramifications for physicians, other authorized controlled substance prescribers, pharmacists and even corporate officers. In order to convict a defendant, the government must prove beyond a reasonable doubt that the individual knowingly dispensed or intended to dispense a controlled substance in an unauthorized manner. As a criminal charge and as found in the language of the CSA itself, this implies that a defendant may not be convicted for negligently engaging in (or, by extension, aiding and abetting or conspiring to commit the underlying offense) the conduct proscribed by the statute. Further, *Ruan* for the first time firmly establishes that a defendant may raise a good faith defense that he or she did not know or intend to dispense or distribute a controlled substance outside of the authorized limits. The availability of this good faith defense is critical for medical professionals tasked with the often difficult decision of whether and what controlled substances to prescribe for their patients— a decision that must, as found by the court, be entrusted to the sound, good faith assessment and judgment of the prescriber. Before *Ruan*, those providers could have been deterred from treating and prescribing medications to treat a patient's pain out of fear that their medical judgment would lead to criminal liability simply because it was found by "a hypothetical 'reasonable' doctor" to be objectively unreasonable. *Ruan* now assures those prescribers that exercising their good faith medical judgment appropriately protects them under the CSA.

Notwithstanding the court's holding, medical prescribers are well advised to continue to take proactive steps to ensure that their conduct falls within the authorized limits. For example, a medical professional might consider discussing with a patient the serious nature of the controlled substance and routinely monitoring a patient's symptoms and prescription dosage.

The Texas Lawbook

It would also be in a medical professional's best interest to avoid any appearance of prescribing medications for a financial benefit.

Overall, *Ruan* benefits medical prescribers because it places a significant burden on the government. Specifically, the government must prove beyond a reasonable doubt that a defendant knew or intended to act without authorization. Even with this mens rea requirement, federal, state and local governments will continue to fight the opioid epidemic through any available means. The CSA remains a very powerful tool for prosecutors that can result in serious criminal liability.

Jeff Ansley is a shareholder in the Government Investigations & White-Collar Defense group with Vedder Price's Dallas office. Ansley's practice concentrates exclusively on white-collar criminal defense, federal trials, internal investigations and regulatory and enforcement actions. He regularly defends clients against allegations of health care fraud, securities fraud, and other alleged business crimes.

Jason B. Sobelman is an associate in Vedder Price's Chicago office and a member of the firm's litigation group. Sobelman served as chief primary editor for the *Washington University Journal of Law and Policy*. During internship and externships with the U.S. Attorney's Office for the Eastern District of Missouri, he assisted federal prosecutors in the White-Collar Division and the Organized Crime Drug Enforcement Task Force by conducting evidence analysis, grand jury preparation, pretrial evidentiary motions and criminal appellate briefs.