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High Court Ruling Boosts Defenses In DOJ Health Care Cases

By **Joshua Robbins, Sanjay Bhandari and Ryan Stasell**
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When health care providers try to help patients get the care they need through innovative treatments or operations, that's a good thing, to be encouraged. When they act corruptly to profit at patients' expense, that's a bad thing, and perhaps a crime.

Joshua Robbins

While the line between the two should be clear, it often is not, as complex regulatory schemes intersect with criminal law to threaten dire consequences for health care providers who stray outside of technical and sometimes arbitrary rules. Fortunately, the U.S. Supreme Court recently struck a blow for clarity and freedom to operate in heavily regulated fields like health care.

In Ruan v. U.S., the court held that a doctor who prescribes controlled substances, such as opiates, does not violate the Controlled Substances Act unless the government proves that he knew his conduct did not fall within an exception for prescriptions authorized under related regulations, which allow exercise of professional discretion. This is a welcome development for doctors who prescribe controlled substances, and for patients who need those prescriptions to relieve pain.

Sanjay Bhandari

But as Justice Samuel Alito's concurring opinion highlights, Ruan has implications far beyond the CSA, and those may include prosecutions under the federal Anti-Kickback Statute and Eliminating Kickbacks in Recovery Act.

Ruan confirms that in criminal statutes with technical exceptions that set the boundary between legal and criminal conduct, the government — not the defendant — has the burden of proving whether the defendant understood his actions fell on the wrong side of the line.

Ryan Stasell

That principle appears to apply squarely to the AKS and EKRA, which include complex safe harbors to protect health care providers from prosecution. Some courts have treated those safe harbors as affirmative defenses that the defendant must establish. Ruan appears to do away with those courts' approach, and to return proper weight to providers' reliance on regulatory assurances.

What Ruan Decided

The CSA makes it a federal crime, "[e]xcept as authorized[,] … for any person knowingly or intentionally … to manufacture, distribute, or dispense … a controlled substance."[1]

Under a federal regulation, the except-as-authorized requirement is satisfied if the prescription is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[2]

Xiulu Ruan, a doctor, was prosecuted under the CSA for running what the government called a pill mill, in which he allegedly prescribed massive volumes of opioids for patients who did not need them and often resold them to others for recreational drug use.

At trial, the doctor argued that he believed that the regulatory exception applied because the prescriptions, in his professional judgment, were medically appropriate for pain treatment. He asked that the trial court instruct the jury that unless the government proved he knowingly and intentionally failed to comply with the regulation by using proper professional judgment, he could not be convicted.

The trial court refused, and the doctor was convicted and sentenced to over 20 years in prison. The conviction was affirmed on appeal.

The Supreme Court vacated the conviction. It held that the CSA's mens rea standard — that a defendant acts knowingly or intentionally — applies not only to whether he "dispenses ... a controlled substance," but also to whether he does so as authorized.

In other words, if a doctor charged under the CSA for wrongfully prescribing a controlled substance claims that he believed certain regulations permitted him to do so, because the prescription was for a legitimate medical purpose, he can only be convicted if the government proves, beyond a reasonable doubt, that he did not subjectively believe those regulations applied.

As the court explained, its long-standing approach to criminal statutes presumes that "Congress intends to require a defendant to possess a culpable mental state," or scienter.[3] And when a statute is not clear as to which elements of a crime the scienter requirement applies to, the presumption is that it covers all elements that "separate wrongful from innocent acts."[4]

This is important because, according to the court, "the purpose of scienter" is to "help[] separate wrongful from innocent acts."[5] In the case of doctors making medical judgments, that is particularly critical because "we expect, and usually want, doctors to prescribe the medications that their patients need."[6] A law that makes a doctor a criminal if he errs in interpreting a regulation or using his clinical judgment can chill socially beneficial activity, and is simply wrong.

The court acknowledged that the CSA's exception for authorized prescriptions is not an element of the crime. The government argued that it was in fact an affirmative defense — similar to insanity or entrapment — that the defendant should have the burden of proving in order to defeat charges. But in a critical portion of the opinion, the court found that the statutory exception was "sufficiently like an element … to warrant similar legal treatment."[7]

In other words, an exception in a criminal statute that functions similarly to an element of the crime should be treated like an element, with the government, rather than the defendant, bearing the burden

of proof — including as to the mens rea requirement. In the CSA, that means requiring the government to prove the defendant knew that exception did not apply.

As Justice Alito noted in his concurring opinion, this approach can apply well beyond the CSA, and raises the question of how many other exceptions or affirmative defenses in other statutes may require the same treatment.[8] The court cited four factors as relevant to answering this question:

1. Whether the statute expressly includes a mens rea requirement;

2. Whether "authorization (or lack thereof)" plays a "crucial role" in "distinguishing morally blameworthy conduct from socially necessary conduct";

3. Whether the crime and its penalties are serious, as opposed to minor infractions or misdemeanors; and

4. Whether the exception, including any regulations it incorporates, includes "vague, highly general language."[9]

The court found that each of these factors supported treating the CSA's authorization exception as comparable to an element, and applying both the mens rea requirement and standard burden of proof accordingly. It could well have said the same about the AKS and EKRA.

Current Treatment of AKS Safe Harbors

The AKS makes it a federal crime for anyone to

> knowingly and willfully solicit[] or receive[] any remuneration (including any kickback …) directly or indirectly … for referring an individual to a person for the furnishing … of any item or service for which payment may be made in whole or in part under a Federal health care program[.][10]

But the law also says that payment is not a remuneration if it fits within a safe harbor, which is a specific exception defining "innocuous arrangements that should not be prosecuted."[11] Some safe harbors are listed in the statute itself; others have been adopted through U.S. Department of Health and Human Services regulations. If a payment falls into a safe harbor, there is no crime. If the safe harbor is not satisfied, there may be.

The EKRA, a newer statute, is modeled on the AKS and similarly includes exceptions like, and sometimes incorporating, its predecessor's safe harbors.

Some courts have held that the AKS safe harbors are "affirmative defense[s] which the defendant must prove."[12]

Like the lower courts in Ruan, these courts held that the AKS safe harbors do not "serve as an additional element of the criminal offense."[13]

Thus, even when an AKS defendant claims that he believed that a safe harbor applied to his conduct, some courts have required him to prove to the jury that the safe harbor did, in fact, apply.

In those cases, the government has not been required to prove — beyond a reasonable doubt or otherwise — that the defendant knew the safe harbor was not actually met.

As a result, under those courts' approach, one could argue that a jury could convict a doctor or other health care profession of a criminal kickback violation even without proof that he understood that a safe harbor he was relying on did not actually apply.

Applying Ruan to the AKS Context

Ruan calls into question those earlier courts' approach to the AKS, and, presumably, EKRA, safe harbors.

Under the Supreme Court's reasoning, if the safe harbors — like the statutory exception in Ruan — are sufficiently like an element of the crime, then if an AKS or EKRA defendant claims he believed a safe harbor applied, the government must prove beyond a reasonable doubt that he did not have that belief — that is, that his failure to fall within the safe harbor was knowing and willful, the AKS and EKRA mens rea standard.[14]

Each of the Ruan factors seems to support treating AKS and EKRA safe harbors like elements for this purpose.

First, both AKS and EKRA include a mens rea standard: The government must prove the defendant acted knowingly and willfully. This is an even higher level of scienter than in the CSA, and requires an awareness that one is acting against the law.

Second, the AKS and EKRA safe harbors "play a 'crucial' role in separating innocent conduct ... from wrongful conduct." If a person makes or receives a payment that would otherwise be deemed an illegal kickback, but meets the technical requirements of the safe harbor, she has committed no crime. The line between full innocence and criminal conviction runs directly through the terms of the safe harbor.

Third, the AKS and EKRA are serious criminal statutes with imposing penalties: 10 years in prison per violation, with a fine of up to $100,000 under the AKS and $200,000 under EKRA.

Fourth, the AKS and EKRA safe harbors are is "written in generalit[ies], susceptible to more precise definition and open to varying constructions." Many of them are riddled with broad criteria that are often difficult to implement precisely.[15]

Thus, safe harbors make it difficult to distinguish between conduct prohibited by such language and "the gray zone of socially acceptable … conduct," as the Supreme Court stated in U.S. v. U.S. Gypsym Co. in 1978.[16]

Arguably, the AKS and EKRA safe harbors are even more like an element than the CSA exception at issue in Ruan.

A safe harbor determines whether a payment is remuneration for purposes of the AKS, and remuneration is a key element of the offense that the government must both plead in an indictment and prove at trial.

The EKRA states that its general prohibition shall not apply to cases covered by one of its exceptions. By contrast, in Ruan, the court acknowledged that the CSA exception did not define any of the elements of the offense that the government was ordinarily required to plead and prove.

Takeaway

Regulatory crimes involving highly technical rules and exceptions, turning on complex questions of intent and medical judgment, and threatening life-altering consequences for anyone who gets it wrong have long plagued doctors and other health care providers.

The Supreme Court has now sent a reminder that the criminal law is a blunt and heavy weapon that must be wielded with great caution when policing those who provide valuable public services, lest they be intimidated from using judgment and innovation to help those in need. That message should — and likely will — resound in cases outside Ruan's immediate context.

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[1] 21 U.S.C. §841.

[2] 21 CFR §1306.04(a).

[3] Id. at 5 (citing Rehaif v. United States, 588 U. S. ___, ___ (2019) (slip op., at 3)).

[4] Id. at 6 (citing Rehaif at 6).

[5] Id.

[6] Id.

[7] Id. at 12.

[8] Id., Alito, J. concurring, at 3.

[9] Id. at 12.

[10] 42 U.S.C. § 1320a-7b.

[11] 56 Fed. Reg. at 35957 (introducing HHS safe harbors).

[12] United States v. Turner, 561 F. App'x 312, 319 (5th Cir. 2014). See also, e.g., United States v. Ekwebelem, 669 F. App'x 868 (9th Cir. 2016) (unpublished), cert. denied, 137 S. Ct. 2230 (2017) ("The trial court did not err in holding that the 'bona fide employment relationship' safe harbor … is an affirmative defense."); United States v. Rogan, 459 F. Supp. 2d 692, 716 (N.D. Ill. 2006) ("Once the United States has demonstrated proof of each element of a violation of the Anti–Kickback and/or Stark Statutes, the burden shifts to the defendant to establish that his conduct was protected by a safe harbor or exception[.]")

[13] United States v. Shaw, 106 F. Supp. 2d 103, 122 (D. Mass. 2000); United States v. Rogan, 459 F.

Supp. 2d 692, 716 (N.D. Ill. 2006) ("[T]he United States need not prove, as an element of its case, that defendant's conduct does not fit within a safe harbor or exception.")

[14] Xiulu Ruan v. United States.

[15] See 42 C.F.R. § 1001.952((b) and (c) Space rental/Equipment rental safe harbors – "aggregate space/equipment rented does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental"; (d) Personal services and management contracts safe harbor – "compensation … is consistent with fair market value in arm's length transactions"; ((e) Sale of practice safe harbor – "entity must diligently and in good faith engage in commercially reasonable recruitment activities").

[16] United States v. United States Gypsum Co., 438 U.S. 422, 441 (1978).