

‘Ruan v. United States’ Reinforces Importance of Mens Rea in Federal Criminal Law

In 1975, in a case involving food safety, the Supreme Court said that defining the outer bounds of criminal liability could be entrusted to “the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries.” *United States v. Park*, 421 U.S. 658, 669 (1975) (quoting *United States v. Dotterweich*, 320 U.S. 277, 285 (1943)). Such willingness to trust a prosecutor’s “good sense” is hardly the case now. In *McDonnell v. United States*, 579 U.S. 550, 576 (2016), to take one example, the Supreme Court declined to construe a key phrase affecting the definition of bribery expansively “on the assumption that the Government will ‘use [a criminal statute] responsibly’” (citing *United States v. Stevens*, 559 U.S. 460, 480 (2010)).

This concern with how broadly worded statutes may be used, or misused, by prosecutors was central to the Supreme Court’s decision last



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term in *Ruan v. United States*, 142 S. Ct. 2370, 2380 (2022). *Ruan* arose from a federal criminal prosecution of licensed physicians for overprescribing opioids and other addictive drugs, in violation of §841 of the Controlled Substances Act. That law prohibits distribution of controlled substances “[e]xcept as authorized.” 21 U.S.C. §841.

The Supreme Court considered whether “authorization” in that context should be based on a defendant’s subjective knowledge and beliefs or an objective standard of reasonable medical care. The court held that authorization is a subjective matter and clarified that the government bore the burden of disproving a claim of authorization when properly raised by a defendant. Declining to rely on “the good sense of prosecutors,” the court chose to construe the “[e]xcept as authorized” clause in a

manner that imposed a heavier burden on the government before treating conduct as criminal in nature.

In this article, we first analyze the majority and concurring opinions in *Ruan*. Next, we draw a parallel with the law relating to a reliance on counsel defense. We conclude by suggesting how *Ruan* might be applied in other contexts.

‘Ruan’ Prosecutions

Xiulu Ruan and Shakeel Kahn, board-certified physicians, operated pain management clinics in three states. They wrote prescriptions for various controlled substances, including oxycodone, for patients in the clinic. In separate cases filed in Alabama and Wyoming, the defendants were charged with writing prescriptions according to patients’ ability and willingness to pay, not on the basis of genuine medical need, in violation of 21 U.S.C. §841, which makes it a federal crime, “[e]xcept as authorized[,] ... for any person knowingly or intentionally ... to manufacture, distribute, or dispense ... a controlled substance” (emphasis added). Both cases went to trial.

The government contended that the defendants had committed crimes because the prescriptions they wrote for

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controlled substances were not “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice,” citing a corresponding federal regulation (21 C.F.R. §1306.04(a)). Ruan and Kahn countered that their actions were lawful because the prescriptions they wrote were legitimate and therefore “authorized” under the law.

The government and defendants agreed that the government bore the burden of proof, and that “authorization” should be judged in light of “legitimate medical purpose,” but they disagreed on the specific test to determine whether prescriptions were “authorized.” Ruan and Khan asked for an instruction that required the government to prove that the physicians subjectively knew that their conduct fell outside of the scope of legitimate prescribing authority. The government asked for an instruction that required the government to prove that the physicians did not make an objectively reasonable attempt to ascertain and act within the bounds of professional medicine.

Both trial courts rejected defendants’ proposed instructions, choosing, instead, an objective test for authorization. The courts instructed the juries that the “good faith” defense was established only if a defendant wrote prescriptions in accordance with a generally accepted (i.e., objective) standard of medical care. Ruan and Khan were convicted and sentenced to 20 and 25 years in prison, respectively. Both convictions were affirmed on appeal.

The Supreme Court consolidated the *Ruan* and *Kahn* cases for review to address a split in the circuits concerning the mens rea

requirement as to an authorization defense. In the end, both convictions were vacated, and the cases were remanded to address whether the jury instructions complied with the mens rea standard set forth in the opinion and, if not, whether the errors were harmless.

The Majority Opinion

The majority held that once evidence is presented that a defendant’s conduct was “authorized,” the government must prove beyond a reasonable doubt that the defendant knowingly and intentionally acted in an unauthorized manner.

The point of departure for the majority was the “presumption of scienter” which applies to the interpretation of criminal statutes. In Supreme Court jurisprudence, criminal statutes are presumed to require proof of a culpable mental state. The “presumption of scienter” is traceable to the common law principle that, absent specific language to the contrary, Congress intends to require that a defendant possess a culpable mental state for each element of a criminal offense. See *Rehaif v. United States*, 139 S. Ct. 2191, 2195 (2019).

Under this presumption, explicit mens rea language in a statute, such as “knowingly or intentionally,” should be applied to statutory terms that separate wrongful conduct from innocent acts. In the majority’s view, because the “[e]xcept as authorized” language plays a “crucial” role in distinguishing wrongful from innocent acts, application of the presumption is warranted. 142 S. Ct. at 2377. In a case of prescriptions written by doctors, if authorization were judged under an objective standard, then mens rea would be largely irrelevant to a jury’s determination.

In that case, the defendant would surely have “knowingly and intentionally” dispensed controlled substances, and the only question left would be the “reasonableness” of the defendant’s conduct. As a practical matter, mens rea would be out of the case, and guilt would turn almost entirely on the reasonableness of the defendants’ behavior. That outcome was rejected.

The majority supported its conclusion by relying on a prior finding that the regulatory definition of “authorization” is “ambiguous” and “open to varying constructions.” *Id.* (quoting *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006)). This ambiguity was of particular concern, in the majority’s view, when a statute, like the one at issue, carries severe penalties. Severe penalties combined with ambiguous language could have the effect of producing excessive caution and deterring beneficial courses of treatment.

The majority wrote that because the authorization clause is “sufficiently like an element,” the government should have the burden of disproving a showing that the conduct at issue was authorized. Because authorization goes to the heart of distinguishing criminal from innocent conduct, it should not be an affirmative defense, as to which the defendant carries the burden of production and persuasion. In sum, under *Ruan*, once a defendant produces evidence that her conduct was “authorized,” the government must prove beyond a reasonable doubt that the defendant knowingly and intentionally acted in an unauthorized manner.

Concurring Opinion

The concurring opinion, authored by Justice Alito and joined by Justice

Thomas and Justice Coney Barrett (in part), agreed that authorization turned on a defendant's mental state but, unlike the majority and circuit courts that had considered the issue, would not have put the burden of proof on the government. The concurring justices disagreed with the majority's "sufficiently like an element" formulation and would have treated authorization as an affirmative defense.

The concurring Justices disagreed with the majority's application of the "presumption of scienter." In their view, that presumption should be reserved for elements of an offense, and "authorization" was not an element as §841 of the Controlled Substances Act was written. Rather, the Act is written in a manner that makes the authorization clause an affirmative defense—with the burden of production and persuasion remaining with the defendant.

Justice Alito relies on §885 of the Controlled Substances Act for his interpretation of the statute. §885 states that the government need not refute "any exemption or exception ... in any trial" and that the "the burden of going forward with the evidence with respect to any ... exemption or exception shall be upon the person claiming its benefit." Justice Alito reads this provision to relieve the government of negating any exceptions to criminal liability under the Act, including an "authorization" defense, so that the burden of proof as well as production rests with the defendant. The majority had a different view, writing that this provision refers only to a defendant's burden of production, and not to the government's burden of proof. In Justice Alito's view, the majority's "element-

like" treatment of this affirmative defense of authorization may cause "confusion and disruption" in criminal law.

Reliance on Counsel

Case law relating to "reliance on counsel," often an issue of importance in white-collar prosecutions, has wrestled with the issue that divided the majority and concurring opinions in *Ruan*. Some courts have viewed reliance on counsel as an affirmative defense; other courts have held that, once a defendant made a showing of such reliance, the government had the burden of disproving reliance on counsel as part of its burden of proving mens rea beyond a reasonable doubt.

In the Second Circuit, the issue was decided in *United States v. Scully*, 877 F.3d 464 (2d Cir. 2017), which held that reliance on counsel relates to the mens rea of a crime and therefore should not be treated as an affirmative defense. Once a defendant offers sufficient evidence of reliance on counsel, the trial court must instruct the jury that at all times the government has the burden of proving unlawful intent.

Scully clarified the proper treatment of the reliance on counsel defense in the Second Circuit, but a minority of courts continue to treat reliance on counsel as an affirmative defense as to which defendant has a burden of proof. See, e.g., *United States v. Narang*, 2021 WL 3484683, at *8 (4th Cir. Aug. 9, 2021); *U.S. v. Vernon*, 723 F.3d 1234, at 1269 (11th Cir. 2013).

Conclusion

White-collar criminal cases often boil down to contests over mental state: what did the defendant know and intend? Statutes commonly specify the mens rea associated with

criminal conduct—but not always, and not always clearly, as suggested by the *Ruan* decision.

A recent petition for certiorari may illustrate future efforts to extend the majority's view in *Ruan* by clarifying the government's burden to prove mens rea. See *Pfizer v. U.S. Department of Health and Human Services Office*, petition for cert. pending, No. 22-339 (filed Oct. 7, 2022). In that case, Pfizer is challenging a regulatory advisory opinion that a co-pay assistance program for high-cost treatment would violate the federal Anti-Kickback Statute (AKS), which criminalizes offering "remuneration ... to induce" the purchase of federally reimbursed health care. See *Pfizer v. U.S. Department of Health and Human Services Office*, 42 F.4th 67 (2d Cir. 2022). At issue is the mental state relating to the word "induce." Relying on *Ruan*, Pfizer argues that the term "induce" requires proof of corrupt intent because, otherwise, the AKS would be construed and applied so broadly that it would deter lawful and beneficial behavior—a consideration central to the *Ruan* majority. Whether the petition will be granted is unclear.

In health care and other areas of the law where the line between legal and illegal conduct can be unclear, the *Ruan* decision, and the majority's emphasis on mens rea, may prove to be very important. The *Ruan* decision underscores the significance of mens rea as both a factual and legal matter in federal prosecutions.