

# Health Law—Prosecutorial Interpretation No Longer Enough as Subjective Standard Set for Conviction of Physicians Under the Controlled Substances Act - *United States v. Ruan*, 56 F.4th 1291 (11th Cir. 2023)

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## I. Introduction

In a decision that severed the government's overreaching efforts to criminalize medical care, the United States Court of Appeals for the Eleventh Circuit (hereinafter *Eleventh Circuit*) partially overturned a physician's conviction for violating the Controlled Substances Act (hereinafter *CSA*).<sup>1</sup> This shift in statutory interpretation emphasized the presumption of scienter in federal criminal proceedings, resulting in legal protection of physicians' imperfect medical practices when conducted in good faith.<sup>2</sup> In *United States v. Ruan*,<sup>3</sup> the Eleventh Circuit held that a properly instructed jury may not have voted to convict Ruan had they known Ruan's subjective, good faith belief in his medical practices

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<sup>1</sup> See Comprehensive Drug Abuse & Prevention & Control Act, 21 U.S.C. §§ 801–971 (1970); Frank DeVito, *Ruan is a Victory for Liberty*, THE AM. CONSERVATIVE (July 20, 2022), <https://www.theamericanconservative.com/ruan-is-a-victory-for-liberty/> [<https://perma.cc/T7VR-57FY>] (discussing reasoning for determining inadequate jury instruction based on subjective good faith standard).

<sup>2</sup> See generally *Ruan v. United States* (*Ruan II*), 142 S. Ct. 2370 (2022). The Supreme Court held that to convict a physician of illegal drug distribution, the government must prove beyond a reasonable doubt that the medical professional subjectively, knowingly, and intentionally prescribed a controlled substance with no legitimate medical purpose. *Id.* See also Kelly K. Dineen Gillespie, *Ruan v. United States: "Bad Doctors," Bad Law, and the Promise of Decriminalizing Medical Care*, CATO SUP. CT. REV. (Sept. 2022), <https://www.cato.org/sites/cato.org/files/2022-09/Supreme-Court-Review-2022-Chapter-10.pdf> [<https://perma.cc/2KUW-NQLM>] (discussing scienter requirement to exceed innovative, mistaken, and negligent prescribing); Jacklyn Wille, *Doctor "Pill Mill" Convictions Partly Undone After SCOTUS Ruling*, BLOOMBERGLAW.COM (Jan. 6, 2023), <https://news.bloomberglaw.com/health-law-and-business/doctor-pill-mill-convictions-partly-undone-after-scotus-ruling> [<https://perma.cc/V8PR-24LV>] (discussing need to convey mens rea in jury instruction). See generally *Rehaif v. U.S.*, 139 S.Ct. 2191, 2195 (2019). Scienter refers to a presumption that "criminal statutes require the degree of knowledge to make a person legally responsible for the consequences of his or her act or omission." *Id.*

<sup>3</sup> 56 F.4th 1291. Xiulu Ruan was and continues to be a co-defendant with John Patrick Couch. *Id.* When the case was argued before the United States Supreme Court on March 1, 2022, it was consolidated with *Kahn v. United States*, 989 F.3d 806 (10th Cir. 2021). *Ruan v. United States*, 142 S.Ct. 2370 (2022). For the purposes of this comment, the discussion will be limited to Xiulu Ruan.

could act as an affirmative defense.<sup>4</sup> This new statutory interpretation relies on the role of mens rea to differentiate innocent from criminal conduct within the context of health care.<sup>5</sup>

## II. Facts

In his role as a board-certified pain specialist, Dr. Xiulu Ruan served close to 8,000 patients before being indicted for unlawful distribution of controlled substances.<sup>6</sup> Dr. Ruan and his business partner issued more than 475,000 prescriptions for controlled substances over four years, allegedly without seeing the patients in some cases.<sup>7</sup> After pleading not guilty in 2017, Dr. Ruan was charged in United States District Court for the Southern District of Alabama (hereinafter *District Court*) with federal felony offenses related to his ownership and operation of two pain management clinics and a pharmacy.<sup>8</sup> Ruan was convicted by the jury after evidence was presented that he "knowingly and willfully" prescribed Schedule II and III Controlled Substances outside the "usual course of professional practice."<sup>9</sup> At the close of all evidence the court denied Ruan's motions

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<sup>4</sup> See *Supreme Court Bulletin: Ruan v. United States*, LEGAL INFO. INST. (Mar. 1, 2022), <https://www.law.cornell.edu/supct/cert/20-1410> [<https://perma.cc/G2TR-3VJX>] (discussing importance of jury instructions on good faith defense).

<sup>5</sup> See Elkan Abramowitz & Jonathan Sack, 'Ruan v. United States' Reinforces Importance of Mens Rea in Federal Criminal Law, N.Y. L. J. (Nov. 1, 2022), <https://www.maglaw.com/media/publications/articles/2022-11-01-ruan-v-united-states-reinforces-importance-of-mens-rea-in-federal-criminal-law> [<https://perma.cc/89CB-MTDH>]; see also Wille, *supra* note 2 (discussing need to convey mens rea in jury instruction to prevent impermissible low conviction standards).

<sup>6</sup> See *United States v. Ruan* (*Ruan I*), 966 F.3d 1101, 1119-21 (11th Cir. 2020) (discussing background and procedural history of case).

<sup>7</sup> See *Ruan I*, 966 F.3d 1101, 1123-1127 (11th Cir. 2020) (discussing Ruan's practicing habits including prescribing cancer medication to patients without cancer).

<sup>8</sup> See Press Release, United States Attorney's Office, S.D. Ala., Dr. Couch and Dr. Ruan Sentenced to 240 and 252 Months in Federal Prison for Running Massive Pill Mill (May 26, 2017), <https://www.justice.gov/usao-sdal/pr/dr-couch-and-dr-ruan-sentenced-240-and-252-months-federal-prison-running-massive-pill> [<https://perma.cc/PBW7-8JMC>] [hereinafter Press Release]; see also *Ruan I*, 966 F.3d 1101, 1121 (11th Cir. 2020). Between January 2011 and May 2015, Ruan and his business partner prescribed more than 475,000 doses of a specific type of opioid—more than double the number of prescriptions than any other provider in the United States. *Id.*

<sup>9</sup> See Press Release, *supra* note 8 (discussing jury's verdict and Ruan's convictions).

After seven-weeks of trial, 81 witnesses, and three days of deliberation, the jury reached the following verdicts: [Ruan] [was] convicted of (1) RICO conspiracy; (2) Conspiracy to prescribe Schedule II and III Controlled Substances outside the usual course of professional practice; (3) Conspiracy to prescribe more than 40 grams of fentanyl outside the usual course of professional practice; (4) Conspiracy to commit healthcare fraud; (5) Conspiracy to commit mail and wire fraud; (6) Conspiracy to receive illegal kickbacks from IPM/CRX related to the workers compensation dispensary; and (7) Conspiracy to receive illegal kickbacks from Insys Therapeutics in exchange for prescribing Subsys. In addition, Dr. Ruan was convicted of conspiracy and substantive money

for judgments of acquittal under Federal Rule of Criminal Procedure 29.<sup>10</sup> The court sentenced Ruan to 252 months in prison and ordered him to pay \$15,239,369.93 in restitution.<sup>11</sup>

In 2020, Ruan appealed the District Court's decision.<sup>12</sup> Among other claims, Ruan contended that the District Court erred in instructing the jury regarding "the applicable standard by which to judge a physician's conduct for violation of the Controlled Substance Act."<sup>13</sup> The District Court relied on precedent in rejecting "good faith

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laundering counts. [Ruan] was also convicted of several substantive illegal drug distribution counts related to prescriptions written to particular patients.

*Id.* See also Schedule of Controlled Substances, 21 U.S.C. 812(c) (2021), <https://www.govinfo.gov/content/pkg/USCODE-2021-title21/pdf/USCODE-2021-title21-chap13-subchapI-partB-sec812.pdf> [<https://perma.cc/6RM4-RGXE>]; DEA, *Drug Scheduling*, DRUG INFORMATION (N.D.), <https://www.dea.gov/drug-information/drug-scheduling> [<https://perma.cc/DDS8-WVA7>] (discussing drug schedule classification). Drugs and some chemical compounds are classified into 5 categories, called schedules, based on the drug's medical use and the potential of the drug to cause dependency and/or abuse. *Id.* The abuse rate of a drug is a determining factor in which schedule a drug is categorized in. *Id.* Schedule I drugs have a high potential for abuse as well as a potential to create severe psychological and/or physical dependence. *Id.* Drugs in schedule V have the lowest potential for abuse and dependence in comparison. *Id.* See also 21 C.F.R. § 1308 (codifying schedule of controlled substances); James Romoser, *The Other Supreme Court Ruling With Big Repercussions for U.S. Health Care*, SCOTUSBLOG (Oct. 24, 2022), <https://www.scotusblog.com/2022/10/the-other-supreme-court-ruling-with-big-repercussions-for-u-s-health-care/> [<https://perma.cc/2WSX-4ACW>] (discussing interpretation of dispersing "authorized" prescriptions under federal regulation).

<sup>10</sup> See *Ruan I*, 966 F.3d 1101,1121 (11th Cir. 2020); see also Fed. R. Crim. P. 29 (providing for defendant to move for judgment of acquittal if evidence is insufficient for conviction).

<sup>11</sup> See *Ruan I*, 966 F.3d 1101, 1121 (11th Cir. 2020) (reviewing punishment imposed by the United States District Court for the Southern District of Alabama).

<sup>12</sup> See generally *Ruan I*, 966 F.3d 1101 (11th Cir. 2020).

<sup>13</sup> See *Ruan I*, 966 F.3d 1101,1165-70 (11th Cir. 2020).

The appellants' proposed [instruction] stated in pertinent part: In making a medical judgment concerning the right treatment for an individual patient, physicians have wide discretion to choose among a wide range of options. No single national standard exists. Therefore, in determining whether a Defendant acted without a legitimate medical purpose or outside the usual course of professional practice, you should examine all of a Defendant's actions and the surrounding circumstances.

*Id.* at 1165.

The district court instead instructed the jury as follows: For a controlled substance to be lawfully dispensed by a prescription, the prescription must have been issued by a practitioner both within the usual course of professional practice and for a legitimate medical purpose. If the prescription was issued either, one, not for a legitimate medical purpose or, two, outside the usual course of professional practice, then the prescription was not lawfully issued.

instructions" because they fail to include an objective standard for the jury to judge the defendant's conduct.<sup>14</sup> Ruan argued that "good faith" means acting with "good intentions and the honest exercise of professional judgment as to the patients' needs."<sup>15</sup> The Eleventh Circuit Court ruled that Ruan's interpretation was too subjective and that the jury instruction did not impair the defense, thereby affirming in part the District Court's convictions under the CSA.<sup>16</sup>

The United States Supreme Court (hereinafter *Supreme Court*) granted Ruan's petition for certiorari in 2021.<sup>17</sup> In analyzing the grammatical structure of the statute, and relying on the presumption of a culpable state of mind for criminal convictions, the Supreme Court held that a criminal conviction would require the physician to believe his actions

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A controlled substance is prescribed by a physician in the usual course of professional practice and, therefore, 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. The appellants in this case maintain at all times they acted in good faith and in accordance with standard [sic] of medical practice generally recognized and accepted in the United States in treating patients.

Thus a medical doctor has violated section 841 when the government has proved beyond a reasonable doubt that the doctor's actions were either not for a legitimate medical purpose or were outside the usual course of professional medical practice.

*Id.* at 1166.

<sup>14</sup> See *United States v. Ruan*, 966 F.3d 1101, 1167 (11th Cir. 2020); see also *United States v. Joseph*, 709 F.3d 1082, 1097 (11th Cir. 2013) (holding "usual course of professional practice" must be evaluated based on objective standard); *United States v. Merrill*, 513 F.3d 1293, 1306 (11th Cir. 2008) (holding physician should be held to objective standard when evaluating his medical practice); *United States v. Williams*, 445 F.3d 1302, 1309 (11th Cir. 2006) (holding physician's guilt is based on objective standard of medical care).

<sup>15</sup> See *Ruan I*, 966 F.3d 1101, 1166 (11th Cir. 2020); see also *United States v. Gypsum Co.*, 98 S.Ct. 2864, 2867 (1978) (holding a good faith belief could be offered as a defense); Mackenzie Bean & Erica Carbajal, *'We Can't Punish Our Way to Safer Medical Practices': 2 Experts on Criminalization of Medical Errors*, BECKER'S HOSP. REV. (Mar. 1, 2022), <https://www.beckershospitalreview.com/patient-safety-outcomes/we-can-t-punish-our-way-to-safer-medical-practices-2-experts-on-criminalization-of-medical-errors.html> [<https://perma.cc/L9RA-XVGU>] (discussing need for distinction between culpable errors and mistakes when criminally prosecuting); Lynn Webster, *'First, Do No Harm' Doesn't Mean 'No Rx Opioids'*, PAIN NEWS NETWORK (July 25, 2020), <https://www.painnewsnetwork.org/stories/2020/7/25/first-do-no-harm-doesnt-mean-no-rx-opioids> [<https://perma.cc/WZ3F-V2ZU>] (discussing ethical practice of intending to do good knowing of possible adverse effects).

<sup>16</sup> See *United States v. Ruan*, 966 F.3d 1101, 1167 (reasoning good faith only acts as defense when defendant acts within standards of medical practice).

<sup>17</sup> See *Ruan v. United States*, 142 S. Ct. 1099 (2022) (granting petition for certiorari). See generally LEGAL INFO. INST., *supra* note 4.

were illegitimate.<sup>18</sup> This standard differed from the objective standard of a hypothetical reasonable physician that the jury had used to convict Ruan.<sup>19</sup> The Supreme Court vacated the Eleventh Circuit's decision and remanded the case for further proceedings consistent with the opinion.<sup>20</sup> On remand, the Eleventh Circuit held that the jury instruction was inconsistent with the Supreme Court's holding and was not harmless beyond a reasonable doubt for Ruan's substantive drug charges.<sup>21</sup> Therefore, the Eleventh Circuit vacated the multi-indictment sentencing and remanded the case to the District Court for resentencing on the surviving counts.<sup>22</sup>

### III. History

The first comprehensive law authorizing the federal government to regulate prescription medications was the Harrison Narcotic Tax Act (hereinafter *Harrison Act*) in 1914.<sup>23</sup> As non-medical drug use and addiction were on the rise, narcotic agents from the Federal Bureau of Narcotics relied on physicians' taxation and registration of prescribed drugs to track drug use across the country.<sup>24</sup> The Harrison Act created an exception for patients possessing drugs prescribed by a "good faith physician . . . in the course of his professional practice . . . ." <sup>25</sup> The federal government attempted to override the clinical

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<sup>18</sup> See *Xiulu Ruan v. United States*, 142 S. Ct. 2370, 2375. In their interpretation of §841, the Court concluded that "knowingly" modified the words directly following it and any statutory terms that separate wrongful from criminal acts. *Id.* Specifically, that the mental state required for conviction, "knowingly," applied to the statutory clause "except as authorized," even though it did not immediately follow the scienter provision. *Id.* at 2373; see also *Liparota v. United States*, 471 U.S. 418, 422 (1985) (holding "knowingly" modified the statutory clause to prevent the criminalization of innocent behavior); *United States v. X-Citement Video, Inc.*, 513 U.S. 64, 77 (1994) (holding, despite incorrect grammatical interpretation, "knowingly" applied to all elements of the statute).

<sup>19</sup> See Abbe R. Gluck, *Subjective Intent of Wrongdoing Required to Convict Doctors Under Controlled Substances Act*, SCOTUS BLOG, (June 28, 2022, 10:15AM),

<https://www.scotusblog.com/2022/06/subjective-intent-of-wrongdoing-required-to-convict-doctors-under-controlled-substances-act/> [<https://perma.cc/C64H-KD6E>].

<sup>20</sup> See *Xiulu Ruan v. United States*, 142 S. Ct. 2370, 2382 (highlighting official decision of case).

<sup>21</sup> See 56 F.4th at 1295 (providing holding of case).

<sup>22</sup> See *id.* at 1302.

<sup>23</sup> See DEA Museum, *Opium Order Form*, THE MUSEUM COLLECTION,

<https://museum.dea.gov/museum-collection/collection-spotlight/artifact/opium-order-form> [<https://perma.cc/8W63-YGAP>] (describing history of narcotics regulation in United States).

<sup>24</sup> See *id.* (summarizing federal regulation of narcotics over last century). The Federal Bureau of Narcotics was established in 1930 and is a predecessor of the Drug Enforcement Agency. *Id.*

<sup>25</sup> See Harrison Narcotic Tax Act, Pub. L. No. 223, 38 Stat. 785 (1914) (later codified at 26 U.S.C. § 4701 et. seq.) [http://www.naabt.org/documents/Harrison\\_Narcotics\\_Tax\\_Act\\_1914.pdf](http://www.naabt.org/documents/Harrison_Narcotics_Tax_Act_1914.pdf) [<https://perma.cc/PJ54-KR7U>]; see also Gillespie, *supra* note 2; Morris Ploscowe, Interim and Final Reports of the Joint Committee of the American Bar Association and the American Medical Association on Narcotic Drugs, Appendix A, SCHAFFER LIBR. OF DRUG POL'Y (1950), <https://druglibrary.net/schaffer/Library/studies/dacd/appendixa.htm> [<https://perma.cc/WD22-QCQB>].

The physician has no way of knowing before he attempts to treat, and/or prescribe drugs to an addict, whether his activities will be condemned or

competence of physicians by setting parameters on the meaning of "the course of professional practice."<sup>26</sup> By 1925, it became apparent that physicians were abandoning patients out of fear of prosecution.<sup>27</sup>

The Harrison Act was repealed by the CSA in 1970.<sup>28</sup> Physicians have historically been prosecuted under the felony drug distribution provision of the CSA, which governs "effective prescribing."<sup>29</sup> While this act created black letter law for a layperson who distributed illegal drugs, its interpretation was less clear for those individuals to whom the "except as authorized" clause applied.<sup>30</sup> Therefore, to properly execute the "except as

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condoned. He does not have any criteria or standards to guide him in dealing with drug addicts, since what constitutes bona fide medical practice and good faith depends upon the facts and circumstances of each case.

*Id.*

<sup>26</sup> See Rufus G. King, *The Narcotics Bureau and the Harrison Act: Jailing the Healers and the Sick*, 62 YALE L.J. 5, 736, 737 (1953), [https://openyls.law.yale.edu/bitstream/handle/20.500.13051/13973/48\\_62YaleLJ736\\_April1953\\_.pdf?sequence=2](https://openyls.law.yale.edu/bitstream/handle/20.500.13051/13973/48_62YaleLJ736_April1953_.pdf?sequence=2) [<https://perma.cc/UST8-AWJZ>] (discussing criminalization of treating addicts); see also Gillespie, *supra* note 2. "[P]rescribers were left to choose between facing criminal prosecution for helping people . . . or remaining safely avoidant." *Id.* at 286; see also *Gonzales v. Oregon*, 546 U.S. 244, 264-65 (2006).

The limits on the Attorney General's authority to define medical standards for the care and treatment of patients bear also on the proper interpretation of § 871(b). This section allows the Attorney General to best determine how to execute "his functions." It is quite a different matter, however, to say that the Attorney General can define the substantive standards of medical practice as part of his authority. To find a delegation of this extent in § 871 would put that part of the statute in considerable tension with the narrowly defined delegation concerning control and registration. It would go, moreover, against the plain language of the text to treat a delegation for the "execution" of his functions as a further delegation to define other functions well beyond the statute's specific grants of authority. When Congress chooses to delegate a power of this extent, it does so not by referring back to the administrator's functions but by giving authority over the provisions of the statute he is to interpret.

*Id.*

<sup>27</sup> See Gillespie, *supra* note 2 (discussing ramifications of government regulation of medical care); see also *Linder v. United States*, 268 U.S. 5, 18 (1925) (discussing constitutional limitations on government power).

<sup>28</sup> See Gillespie, *supra* note 2, at 287; see also *A History of the Drug War*, DRUG POL'Y ALL., <https://drugpolicy.org/issues/brief-history-drug-war> [<https://perma.cc/N293-8SJT>] (discussing Nixon's declaration of "war on drugs" and increased drug control by government).

<sup>29</sup> See 21 U.S.C. § 841(a)(1) (defining legislative tool that criminalizes distribution of controlled substance); see also *United States v. Moore*, 423 U.S. 122 (1975) (arguing lawfulness of narcotic distribution by registered physician as exception authorized by CSA); see also Gillespie, *supra* note 2 (discussing precedent and standards for prosecuting § 841 prior to *Ruan*).

<sup>30</sup> See 21 U.S.C. § 841(a).

authorized" clause, Congress delegated the authority to promulgate rules and regulations, including physicians' registrations with the states to control the dispensing of controlled substances.<sup>31</sup>

#### IV. Court's Reasoning

In Ruan's first appearance before the Eleventh Circuit, the court addressed the circuit split regarding the use of a good-faith defense.<sup>32</sup> The First, Seventh, and Ninth Circuits held that a subjective good-faith defense negated the mens rea showing of knowledge or intent when the defendant believed he was prescribing in the usual course of professional practice.<sup>33</sup> The Second, Fourth, and Sixth Circuits adopted the objective

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Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or (2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

*Id.*; see also 21 CFR §1306.04(a). "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." *Id.*; see also Nora Volkow, *Rising Stimulant Deaths Show that We Face More than Just an Opioid Crisis*, NAT'L INST. ON DRUG ABUSE (Nov. 12, 2020), <https://nida.nih.gov/about-nida/noras-blog/2020/11/rising-stimulant-deaths-show-we-face-more-than-just-opioid-crisis> [<https://perma.cc/Z7DU-6L46>] (discussing need for doctor discretion with unconventional prescribing to treat illnesses with no established medication).

<sup>31</sup> See *Gonzales v. Oregon*, 546 U.S. 243, 244, 270 (2006); see also H.R.REP. NO. 93-884, at 6 (1974), as reprinted in 1974 U.S.C.C.A.N. 3029, 3034 (differentiating functions between Attorney General and Secretary of Health, Education, and Welfare in CSA).

This section preserves the distinctions found in the [CSA] between the functions of the Attorney General and the Secretary [of Health, Education, and Welfare]. All decisions of a medical nature are to be made by the Secretary [of Health, Education, and Welfare]. Law enforcement decisions respecting the security of stocks of narcotic drugs and the maintenance of records on such drugs are to be made by the Attorney General.

H.R.REP. NO. 93-884 at 3034. See also Abbe R. Gluck, *Amid Overdose Crisis, Court Will Weigh Physician Intent in "Pill Mill" Prosecutions and More Under the Controlled Substance Act*, SCOTUS Blog, (Feb. 28, 2022), <https://www.scotusblog.com/2022/02/amid-overdose-crisis-court-will-weigh-physician-intent-in-pill-mill-prosecutions-and-more-under-the-controlled-substances-act/> [<https://perma.cc/AZ5J-RNSF>] (explaining registered physicians can prescribe controlled substance according to rules Attorney General promulgated).

<sup>32</sup> See Gillespie, *supra* note 22, at 296, 300.

<sup>33</sup> See *United States v. Sabeen*, 885 F.3d 27, 45 (1st Cir. 2018); see also *United States v. Rosenberg*, 585 F.3d 355, 357 (7th Cir. 2009) (holding defendant may have had subjective good faith reasoning for prescribing with medical purpose); *United States v. Feingold*, 454 F.3d 1001, 1010 (9th Cir. 2006) (reasoning criminal conviction must constitute more than malpractice and have no semblance to legitimate treatment). "To safeguard the defendant's rights, . . . a sincere effort to act in accordance with proper medical practice, even if flawed, could not undergird a guilty

good-faith defense, requiring the defendant's belief that he was prescribing in the usual course of professional practice be objectively reasonable before a good-faith defense was available.<sup>34</sup> The Eleventh Circuit ultimately held that Ruan's subjective belief that he was meeting the needs of his patients was not a complete defense, and whether he acted in the usual course of professional practice must be evaluated based on an objective standard.<sup>35</sup>

On remand, and with the Supreme Court's guidance, the Eleventh Circuit recognized that without considering the defendant's subjective mens rea, the objective standard would inappropriately import a civil negligence standard onto a criminal prosecution.<sup>36</sup> Consistent with the basic principles of criminal law, conscious wrongdoing or vicious will is required to separate wrongful acts from innocent acts.<sup>37</sup> Legal precedent guides courts to interpret criminal statutes to include a scienter requirement when the text is silent.<sup>38</sup> Ruan's court reasoned that the jury instructions inadequately conveyed the

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verdict so long as the defendant has acted in good faith." *United States v. Sabean*, 885 F.3d 27, 45 (1st Cir. 2018).

<sup>34</sup> See *United States v. Volkman*, 797 F.3d 377, 387 (6th Cir. 2015) (reasoning physician's individual treatment methods do not objectively constitute "usual course of professional practice"); see also *United States v. Hurwitz*, 459 F.3d 463, 479 (4th Cir. 2006) (holding inquiry into doctor's good faith in treating patients considered objective).

<sup>35</sup> See *Ruan I*, 966 F.3d 1101, 1166-67 (11th Cir. 2020).

<sup>36</sup> See 56 F.4th at 1296; see also *United States v. Vamos*, 797 F.2d 1146, 1153 (2d Cir. 1986). "To permit a practitioner to substitute his or her views of what is good medical practice for standards generally recognized and accepted in the United States would be to weaken the enforcement of our drug laws in a critical area." *United States v. Vamos*, 797 F.2d 1146, 1153 (2d Cir. 1986).

<sup>37</sup> See *Rehaif v. United States*, 139 S.Ct. 2191, 2193 (2019) (discussing importance of culpable state of mind for criminal convictions); see also *United States v. X-Citement Video, Inc.*, 513 U.S. 64, 72 (1994). "[T]he presumption in favor of a scienter requirement should apply to each of the statutory elements that criminalize otherwise innocent conduct." *United States*, 513 U.S. at 72; see also Trevor Burrus et al., *Ruan v. United States*, CATO INST. (Dec. 27, 2021), <https://www.cato.org/legal-briefs/ruan-v-united-states> [<https://perma.cc/4UG3-8QJW>] (stating proper venue for negligent malpractice is civil court); Eric Moran, *Will the Supreme Court's Latest Decision on Mens Rea Leave Medical Professional Prosecutions Ruan-ing on Empty?*, EPSTEIN BECKER & GREEN, P.C., <https://www.commerciallitigationupdate.com/will-the-supreme-courts-latest-decision-on-mens-rea-leave-medical-professional-prosecutions-ruan-ing-on-empty> [<https://perma.cc/W5GF-9G3U>].

<sup>38</sup> See *Staples v. United States*, 511 U.S. 600, 605 (1994) (stating statutory silence does not suggest Congress intended to dispense of mens rea element). See also *United States v. U.S. Gypsum Co.*, 438 U.S. 422, 436 (1978). "[T]he existence of a mens rea is the rule of, rather than the exception to, the principles of . . . criminal jurisprudence." *Id.*

The contention that an injury can amount to a crime only when inflicted by intention is no provincial or transient notion. It is as universal and persistent in mature systems of law as belief in freedom of the human will and a consequent ability and duty of the normal individual to choose between good and evil. A relation between some mental element and punishment for a harmful act is almost as instinctive as the child's familiar exculpatory "But I didn't mean to," and has afforded the rational basis for a tardy and unfinished substitution of deterrence and reformation in place of retaliation and vengeance as the



required mens rea to convict, so the jury convicted on the notion that a reasonable doctor, under an objective standard, would not have believed the defendant acted within medical standards—despite Ruan's subjective belief that he properly acted according to his patients' needs.<sup>39</sup>

## V. Analysis

As Justice Alito's concurrence in *Ruan* discusses, the majority holding is consistent with the precedent that a registered physician acts "in the course of his professional practice" when writing prescriptions "in good faith."<sup>40</sup> In the absence of any

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motivation for public prosecution. Unqualified acceptance of this doctrine by English common law in the Eighteenth Century was indicated by Blackstone's sweeping statement that to constitute any crime there must first be a "vicious will."

*Morrisette v. United States*, 342 U.S. 246, 250-51 (1952); *see also* Nick Oberheiden, *U.S. Supreme Court Overturns Doctors' Opioid Convictions in Ruan v. United States, Paving the Way for Additional Appeals*, JDSUPRA (Jan. 24, 2023), <https://www.jdsupra.com/legalnews/u-s-supreme-court-overturns-doctors-6915994/> [<https://perma.cc/9EN4-M4FV>]; Dan Schweitzer, *Opinion: Ruan v. United States, 20-1410*, NAT'L ASS'N OF ATT'YS GEN. (Jul. 7, 2022), <https://www.naag.org/attorney-general-journal/opinion-ruan-v-united-states-20-1410/> [<https://perma.cc/R64X-2U4T>].

<sup>39</sup> *See* *United States v. Ruan*, 54 F.4th 1291, 1298 (11th Cir. 2023); *see also* Jolie Apicella, *Impact of 'Ruan v. United States: Taking Stock of the Legal and Compliance Implications for Criminal Law and Health Care Practice*, N.Y. L. J. (Dec. 2, 2022), <https://www.law.com/newyorklawjournal/2022/12/02/impact-of-ruan-v-united-states-taking-stock-of-the-legal-and-compliance-implications-for-criminal-law-and-health-care-practice/?slreturn=20231006213330> [<https://perma.cc/88CW-9WZQ>] (discussing need for criminal defendant to possess culpable mental state for conviction under CSA); *see also* *United States v. Williams*, 445 F.3d 1302, 1307-08 (11th Cir. 2006) (arguing jury instruction caused confusion about applicable standard of care used for conviction).

A district court's failure to give a requested jury instruction is an abuse of discretion if the requested instruction (1) was correct, (2) was not substantially covered by the charge actually given, and (3) dealt with some point in the trial so important that the failure to give the requested instruction seriously impaired the defendant's ability to conduct his defense.

*United States v. Jockisch*, 857 F.3d 1122, 1126 (11th Cir. 2017); *see also* *United States v. Cochran*, 683 F.3d 1314, 1319 (11th Cir. 2012) (holding misstated law prejudiced defendant); *Neder v. United States*, 527 U.S. 1, 15-16 (1999) (holding omission of element validates reversal unless error was harmless beyond reasonable doubt).

<sup>40</sup> *See* *Ruan v. United States*, 142 S. Ct. 2370, 2382-89 (Alito, J., concurring); *see also* *Linder v. United States*, 268 U.S. 5, 17-18 (1925) (discussing medical practice legitimacy determined by attending circumstances and prescribing without conscious illegality is lawful); Harrison Narcotic Tax Act, Pub. L. 223, 38 Stat. 785 (1914) (containing explicit exemption for medical practice). "Nothing contained in this section shall apply . . . [t]o the dispensing or distribution of any of the aforesaid drugs to a patient by a physician, dentist, or veterinary surgeon registered under this Act

indication of conventionally understood trafficking and drug dealing, the CSA limits the power of the federal government to exercise authority over the practice of medicine.<sup>41</sup> Without allowing physicians to use a good faith defense, the CSA transcends constitutional boundaries by interfering with the states' police powers to regulate the medical profession.<sup>42</sup> The Eleventh Circuit failed to acknowledge this separation of power, explicitly provided by the "except as authorized" clause, and erred in interpreting that the CSA criminalizes good-faith prescriptions of controlled substances.<sup>43</sup>

While unconventional prescribing may be negligent or fall outside of the standard of care as a potential malpractice issue, it is not automatically criminal.<sup>44</sup> Negligence and good-faith efforts are not high enough standards for criminal convictions because they lack the culpable mental state required.<sup>45</sup> Once a physician proves they fall within the

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in the course of his professional practice only . . . ." Harrison Narcotic Tax Act, Pub. L. 223, 38 Stat. 785 (1914).).

<sup>41</sup> See 21 U.S.C. § 823(g)(2)(H)(i). "Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided." See *id.*; see also *United States v. Moore*, 423 U.S. 122, 135-43 (1975). "Conventionally understood" drug dealing and trafficking means "selling drugs, 'primarily for the profits to be derived therefrom' and acting so far outside the usual course of professional practice that their behavior is akin to that of a 'large-scale [drug] pusher, not as a physician.'" 432 U.S. 122, 135-43 (citations omitted); see also *Gonzales v. Oregon*, 546 U.S. 243, 269 (2006). "[W]hen Congress wants to regulate medical practice in the given scheme, it does so by explicit language in the statute." *Id.* at 272.

<sup>42</sup> *Id.* at 267-70 (holding CSA lacks intent to regulate practice of medicine beyond illicit drug dealing and trafficking); see also 21 U.S.C. § 801 (preserving delegation of power between federal government and states). The *Gonzales* Court held the structure limitations of federalism allow states to regulate the medical profession and allowing federal prosecutors to act like a national medical board would preempt the state medical board efforts. See *Gonzales v. Oregon*, 546 U.S. 243, 267-70 (2006). The Court added that the CSA does not grant the federal government power in regulating prescription-writing practice beyond situations where physicians engage in illicit drug dealing and trafficking. *Id.*; see also LEGAL INFO. INST., *supra* note 4 (suggesting denial of good faith defense causes CSA to absorb state malpractice law).

<sup>43</sup> See 21 U.S.C. § 841(a); see also *Ruan I*, 966 F.3d 1101, 1119 (11th Cir. 2020).

<sup>44</sup> See Schweitzer, *Opinion: Ruan v. United States, 20-1410*, NAT'L ASS'N OF ATT'YS GEN. (Jul. 7, 2022), <https://www.naag.org/attorney-general-journal/opinion-ruan-v-united-states-20-1410/> [<https://perma.cc/R64X-2U4T>]; see also *Ruan II*, 142 S. Ct. 2370, 2389 (2022) (Alito, J., concurring).

[A]cting 'as a physician' does not invariably mean acting as a *good* physician, as an objective understanding of the "in the course of professional practice" standard would suggest. A doctor who makes negligent or even reckless mistakes in prescribing drugs is still 'acting as a doctor'—he or she is simply acting as a *bad doctor*.

*Id.*

<sup>45</sup> See *Ruan II*, 142 S. Ct. 2370 (2022); see also Moran, *supra* note 37; *Rehaif v. United States*, 139 S.Ct. 2191, 2195 (quoting *United States v. X-Citement Video, Inc.*, 513 U.S. 64, 72 (1994)). "In determining Congress' intent, we start from a longstanding presumption, traceable to the common law, that Congress intends to require a defendant to possess a culpable mental state

"except as authorized" provision of the CSA, the burden shifts to the prosecution to prove beyond a reasonable doubt that the physician acted knowingly and intentionally outside the legitimate scope of their medical practice.<sup>46</sup> This burden shifting should avail a good-faith jury instruction for defendants charged with violating the CSA.<sup>47</sup> Juries are better equipped to recognize good-faith efforts than to assume the state's responsibility of assessing the boundaries of legitimate medical practice.<sup>48</sup>

Ultimately, the Eleventh Circuit failed to consider that criminalizing medical practice is against public policy. Physicians may fear prosecution due to unclear legal limitations set by ambiguous statutory language or because a jury believes, under an objective standard, that a physician did not act as a reasonable person in a similar set of circumstances. By criminalizing good-faith medical practice in the interest of preventing harm from drug abuse and dependence, a different public health crisis could emerge as physicians unintentionally cause serious harm by under-treating or abandoning their patients with chronic pain for fear of prosecution. Ultimately, it may even take success away from the "war on drugs" and add to the opioid crisis, forcing patients to turn to illegal drugs to self-medicate when prescriptions are not available.

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regarding 'each of the statutory elements that criminalize otherwise innocent conduct.'" *Id.* See also Abramowitz & Sack, *supra* note 5. "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." *Id.*

<sup>46</sup> See DeVito, *supra* note 1.

<sup>47</sup> See *Ruan I*, 966 F.3d 1101, 1165-67 (11th Cir. 2020). The court provided a jury instruction stating a good faith defense was only available when, under an objective lens, the physician provided a generally accepted standard of medical care. *Id.* See also Abramowitz & Sack, *supra* note 5 (discussing need for jury instruction to comply with mens rea standard). "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." *Id.*

<sup>48</sup> See *United States v. Moore*, 423 U.S. 122, 142-144 (1975) (holding it is state's duty to assess boundaries of medical treatment of pain); see also Bean & Carbajal, *supra* note 15 (concluding criminalization of medical practice could have chilling effect on patient health and safety).