No.

In the Supreme Court of the United States

DR. XIULU RUAN,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

A physician otherwise authorized to prescribe controlled substances may be convicted of unlawful distribution under 21 U.S.C. § 841(a)(1) if his prescriptions "fall outside the usual course of professional practice." *United States* v. *Moore*, 423 U.S. 122, 124 (1975). To ensure that physicians are not convicted for merely negligent conduct, however, the federal courts generally permit doctors to advance a "good faith" defense.

The question presented, on which the circuits are deeply divided, is whether a physician alleged to have prescribed controlled substances outside the usual course of professional practice may be convicted under Section 841(a)(1) without regard to whether, in good faith, he "reasonably believed" or "subjectively intended" that his prescriptions fall within that course of professional practice.

PARTIES TO THE PROCEEDING

Petitioner, defendant-appellant below, is Dr. Xiulu Ruan.

Respondent is the United States of America, appellee below. Under this Court's Rule 12.6, Dr. John Patrick Couch, defendant-appellant below, is also considered a respondent.

RELATED PROCEEDINGS

United States v. *John Patrick Couch*, No. 16-16361, United States Court of Appeals for the Eleventh Circuit. Judgment entered Aug. 15, 2017.

United States v. *Xiulu Ruan*, No. 19-11508, United States Court of Appeals for the Eleventh Circuit. Judgment entered Jan. 8, 2020.

United States v. *Ling Cui*, No. 19-12661, United States Court of Appeals for the Eleventh Circuit. Judgment entered May 11, 2020.

United States v. *Lori L. Carver*, No. 17-13402, United States Court of Appeals for the Eleventh Circuit. Judgment entered Oct. 17, 2018.

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United States v. *Bourlier*,
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United States v. *Garrison*,
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United States v. *Godofsky*,
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United States v. *Hurwitz*,
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United States v. *Merrill*,
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United States v. *Singh*,
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United States v. *Wexler*,
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TABLE OF AUTHORITIES—Continued

Page(s)

Miscellaneous

Christopher Brown, *DOJ Keeps Up Pressure on Doctors Who Prescribe Opioids Illegally*, Bloomberg Law, Jan. 24, 2020, https://perma.cc/5WN2-YD2X 36

Ronald W. Chapman II, *Defending Hippocrates: Representing Physicians in the Wake of the Opioid Epidemic*, 43 Champion (Nat'l Ass'n of Crim. Defense Law.) 40 (2019) 33

Joseph Heller, *Catch 22* (S&S Classic ed. 1999) (1961) 31

Deborah Hellman, *Prosecuting Doctors For Trusting Patients*, 16 Geo. Mason L. Rev. 701 (2009) 17, 31

Letter of 30 State Attorneys General to Administrator of DEA, 151 Cong. Rec. 6974 (2005) 32, 34

Brendan LoPuzzo, *A Bitter Pill To Swallow: The Need for a Clearly Defined Course of Professional Practice When Prescribing Opioids for the Legitimate Medical Purpose of Treating Pain*, 47 Hofstra L. Rev. 1397 (2019) 34

TABLE OF AUTHORITIES—Continued

Page(s)

Ramesh Ponnuru, *War on opioid abuse is striking the wrong target*, Pittsburgh Post-Gazette, Mar. 26, 2019, https://perma.cc/4PHS-RTS3 32

Sally Satel, *The Truth About Painkiller Addiction*, The Atlantic, Aug. 4, 2019, https://bit.ly/3rIw0d1 33

Wesley J. Smith, *Pain Doctors Face Greater Scrutiny Than Death Doctors*, National Review, May 3, 2018, https://perma.cc/84R5-S5W9 33

Jacob Sullum, *America's War on Pain Pills Is Killing Addicts and Leaving Patients in Agony*, Reason, Apr. 2018, https://bit.ly/3rRtDVn 33

U.S. Attorney's Office for the Middle District of Florida, *Opioid Epidemic*, https://perma.cc/3VBT-NY4G 36

U.S. Attorney's Office for the Northern District of Alabama, *Project Safe Neighborhoods*, https://perma.cc/P58H-FYX4 36

U.S. Attorney's Office for the Northern District of Georgia, *SCOPE Initiative*, https://perma.cc/826N-TRSS 36

U.S. Dep't of Justice Drug Enf't Admin. Diversion Control Div., *Criminal Cases Against Doctors*, https://bit.ly/3mgT5Cf 35

TABLE OF AUTHORITIES—Continued

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U.S. Dep't of Justice Office of Public Affairs, *Attorney General Sessions Announces New Prescription Interdiction & Litigation Task Force* (Feb. 27, 2018), https://perma.cc/24UZ-BSS2.....35

United States Brief in Opposition, *Volkman* v. *United States*, No. 13-8827 (Jul. 11, 2014).....3, 20, 24, 28

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OPINIONS AND RULINGS BELOW

The opinion of the court of appeals is reported at 966 F.3d 1101. See Petitioner's Appendix ("App."), *infra*, 1a-128a. The order of the Eleventh Circuit denying rehearing is not reported. See App., *infra*, 129a.

JURISDICTION

The court of appeals' judgment was entered on July 10, 2020. The court of appeals denied rehearing on November 4, 2020. App., *infra*, 129a. On November 13, 2020, the Court issued guidance reflecting that the 150-day extension "from the date of the lower court judgment, order denying discretionary review, or order denying a timely petition for rehearing," directed by the Chief Justice on March 19, 2020, remains in effect. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Section 841(a)(1) of the Controlled Substances Act ("CSA"), 21 U.S.C. § 841(a)(1), provides:

> (a) Unlawful acts
>
> 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[.]

21 C.F.R. § 1306.04(a) provides:

> Purpose of issue of prescription.
>
> (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. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. § 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

STATEMENT

The question in this case is whether and to what extent a physician charged with prescribing medication in violation of the CSA may assert a "good faith" defense. To overcome a good faith defense in the Second, Fourth, and Sixth Circuits, the government must prove that the physician did not *reasonably believe* that his prescriptions fell within professional norms. To overcome a good faith defense in the First, Seventh, and Ninth Circuits, the government must prove that the physician *subjectively intended* a prescription to exceed

professional norms. But neither of those "good faith" defenses is available in the Eleventh Circuit. All it takes to convict a physician under the CSA is a finding that the doctor prescribed controlled substances outside generally accepted medical standards.

The Eleventh Circuit's decision deepens a circuit split, is difficult to square with this Court's cases, and resolves a question of surpassing importance. It also invites juries to convict doctors of drug dealing based on nothing worse than simple malpractice.

This case is an ideal vehicle for resolving the question presented. Petitioner objected to the district court's refusal to instruct that good faith is an actual defense. He proposed, without success, a good faith instruction taken nearly verbatim from ones approved by conflicting circuits and, indeed, that even the Solicitor General has endorsed as a "model of clarity and comprehensiveness in defining the unlawful distribution offense." U.S. BIO at 12-13, *Volkman* v. *United States*, No. 13-8827 (Jul. 11, 2014). Because the jury was wrongly instructed on this crucial defense—and because much of the proof at trial consisted of ordinary malpractice—the jury "may have convicted [Petitioner] for conduct that is not unlawful." *McDonnell* v. *United States*, 136 S. Ct. 2355, 2375 (2016).

The issue has now percolated to the boiling point: At least six circuits have flatly rejected the Eleventh Circuit's rule (though they themselves conflict, 3-3, on what the correct good faith defense should be); and only six weeks ago, the Eleventh Circuit reaffirmed its outlier position that a good faith instruction is available only to those whose conduct already falls

within professional norms. The petition for a writ of certiorari should be granted.

A. Statutory Framework

The Controlled Substances Act makes it unlawful for "any person knowingly or intentionally . . . to manufacture, distribute, or dispense" a controlled substance, "[e]xcept as authorized by this subchapter." 21 U.S.C. § 841(a)(1). "[T]his subchapter" authorizes persons who have registered with the Attorney General to distribute controlled substances "to the extent authorized by their registration." *Id.* § 822(b). The Act also directs the Attorney General to accept the registration of a medical doctor or other practitioner if he is "authorized to dispense . . . controlled substances under the laws of the State in which he practices." 21 U.S.C. § 823(f).

In *United States* v. *Moore*, 423 U.S. 122 (1975), this Court acknowledged that the CSA "does not spell out . . . in unambiguous terms" when physicians may be subject to prosecution for federal narcotics offenses. *Id.* at 140. But, drawing on 21 C.F.R. § 1306.04(a) and the CSA's predecessor statute (the Harrison Anti-Narcotic Law, 38 Stat. 785), the Court held that a physician registered with the Attorney General may be prosecuted under Section 841(a)(1) if her "activities fall outside the usual course of professional practice." *Id.* at 124; see *id.* at 136 n.12, 138-143.

To prove that a physician's activities meet that standard, prosecutors typically present evidence establishing the standard of care, coupled with proof that the doctor's prescriptions departed from it. See, *e.g.*, *United States* v. *Sabean*, 885 F.3d 27, 45 (1st Cir. 2018); *United States* v. *Bourlier*, 518 Fed. Appx. 848,

857 (11th Cir. 2013) (per curiam); *United States* v. *Wexler*, 522 F.3d 194, 204 (2d Cir. 2008); *United States* v. *McIver*, 470 F.3d 550, 560-561 (4th Cir. 2006). Lest physicians be convicted based on mere negligence, however, almost all circuits permit physicians to present a defense of good faith.

But not the Eleventh Circuit.

B. Factual Background

1. Petitioner Dr. Xiulu Ruan practiced medicine as a board-certified interventional pain specialist in Mobile, Alabama. He owned, along with his partner Dr. John Patrick Couch, a pain clinic (Physicians' Pain Specialists of Alabama ("PPSA")) and an affiliated pharmacy (C&R Pharmacy). App., *infra*, 5a-6a. Each doctor treated patients at PPSA's two locations. App., *infra*, 6a.

On April 28, 2016, a grand jury indicted Petitioner and Dr. Couch on charges of unlawful distribution of controlled substances under 21 U.S.C. § 841(a)(1), as well as racketeering conspiracy, health care fraud conspiracy, wire fraud conspiracy, and related charges. App., *infra*, 3a-4a. Petitioner (but not Dr. Couch) was also charged with money laundering and conspiracy to commit laundering. App., *infra*, 4a. The indictment included the Section 841(a)(1) violations as predicate offenses for the majority of the non-narcotics charges. See Second Superseding Indictment, Dkt. 269, at 19-20, 28, 41-42 (Apr. 28, 2018). Petitioner and Dr. Couch pleaded not guilty and were tried together.

2. At trial, the government acknowledged "that there were certainly instances where Dr. Ruan and Dr. Couch did a really good job for their patients," and

that, "[b]y and large, their patients were legitimate patients." App., *infra*, 84a. The prosecutors alleged, however, that some of Petitioner's prescriptions fell outside of professional norms. To sustain that allegation, the government devoted much of the trial to evidence that, without careful jury instructions, invited conviction based on simple malpractice.

For example, the government put on three medical experts who testified at length that Petitioner and Dr. Couch had prescribed medication "outside [the] standard of care, . . . outside the usual practice." Tr. 2357:10-11; see also Tr. 661-1061 (Dr. Greenberg); Tr. 2246-2542 (Dr. Vohra); Tr. 4328-4520 (Dr. Aultman). Dr. Aultman testified that the defendants too frequently "jumped to an opioid medication first" when there are "a lot of other things that you can do for patients with chronic pain." Tr. 4437:4-5, 16-22. She and the other experts identified patients who they thought "should have been referred to a psychiatrist," Tr. 731:10-11, or for whom "[t]he ideal thing for the doctor to have done would have been to transfer the patient for detoxification at a licensed detoxification facility," Tr. 743:11-14. See also Tr. 730:24-731:2 (testifying that physical therapy "would have been perfect for" a patient); Tr. 4429:16-17 (similar).

The government's medical experts also faulted Petitioner and Dr. Couch for not having identified or acted upon certain so-called "red flags." See Tr. 749:16-750:9; Tr. 4407:19-4408:15. For example, even though the physician defendants regularly tested patients to confirm that they had taken their prescriptions (and not diverted them to the black market), Dr. Greenberg criticized one such test as "inadequate" and asserted that such testing protocols

demonstrated "the doctor's [un]willingness to spend the tiny bit more money and go ahead and protect his patients the best that he can." Tr. 923:1-4.[1] Greenberg also testified that Petitioner had made "a major mistake" by failing to make further inquiries of a patient who had tested negative for a prescribed drug (a "red flag"). Tr. 735:6-8.[2]

The government's medical experts also claimed that Petitioner had mismanaged his medical practice, through recordkeeping failures, see, *e.g.*, Tr. 746:5-6, 2370:8-19, 4348:12-4349:15, 4518:8-16, and excessive reliance on nurse practitioners and other "physician extenders," see, *e.g.*, Tr. 681:12 ("I normally [examine the patient] by myself."); Tr. 688:17-21 ("it would definitely be outside the usual practice of practicing medicine in the state of Arizona" for a physician extender to decide "what medications the individual would receive"); Tr. 2375:20-24 (similar).

Petitioner and Dr. Couch sharply contested these allegations of malpractice, calling three medical experts of their own who offered a competing account

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[1] Shortly after Dr. Greenberg's testimony, the government alerted the district court that Greenberg "thought he had early-onset dementia and was consulting a neurologist." App., *infra*, 40a. The government stated that it would investigate to determine whether a jury instruction was warranted, see Tr. 1068:13-24; Tr. 1070:16-1071:6, but never presented any further information to the court, App., *infra*, 41a.

[2] See also Tr. 2351:5-2352:18 (testimony that Petitioner had not acted "within [the] standard of care" when he had continued a course of medication after a patient screen had shown "significant inconsistencies"); Tr. 2357:10-11 (testimony that it "was outside [the] standard of care, it was outside the usual practice" to have continued a course of medication for a particular patient).

of Petitioner's and Dr. Couch's compliance with the relevant professional standards. See Tr. 4763-4914 (Dr. Warfield); Tr. 6034-6078 (Dr. Gharibo); Tr. 5205-5341 (Dr. Gudin). Dr. Gharibo, for instance, reviewed patient files and "found Dr. Ruan's treatment in many ways exemplary." Tr. 6044:9. Dr. Gharibo also testified that Petitioner's patient care was "multi-modal and multi-disciplinary" and "clearly in the higher end of the standard of care." Tr. 6049:10-17. Dr. Gudin testified that for "each and every chart" he had reviewed, Petitioner's "prescribing seemed appropriate and certainly within the course of legitimate medical practice." Tr. 5282:19-22. And Dr. Warfield, addressing the role of physician extenders in the practice of pain medicine, testified that "it's not uncommon for a visit to be conducted by a nurse practitioner." Tr. 4793:11-12.

Petitioner and Dr. Couch also took the stand themselves to support their good faith defense. Petitioner testified that he always made an "individualized decision" as to "[w]hat medication to use" "based on the patient's best interest," Tr. 5803:2-5, and that his decisions were always motivated by "caring for [his] patients," Tr. 5920:24-5921:2; Tr. 6032:14-17 (similar); Tr. 5627:17-24 (same for Dr. Couch). Petitioner explained, for example, that he had prescribed especially potent fentanyl medications only for episodes of "very severe breakthrough pain," Tr. 5779:21-24, and that the medication was a "lifesaver" for patients who would otherwise "have to go to [the] ER" during such an episode, Tr. 5780:22-25. And, with respect to patients exhibiting "red flags," Petitioner testified that he would "terminate

the relationship" once he "decide[d] [he] can no longer help" the patient. Tr. 5838:23-5839:1.[3]

To be sure, some of the government's proof was unlikely to be conflated with evidence of simple malpractice. Thus, for example, the government presented evidence about defendants' relationship with pharmaceutical companies to suggest that defendants had placed their financial interests over the well-being of their patients.[4] The government also offered evidence purporting to show that the defendants prescribed medications based on their

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[3] To buttress his good faith defense, Petitioner also sought to introduce videos showing that he had declined to prescribe opioids to patients who turned out to be undercover DEA agents. Petitioner explained to one such "patient" that "it was not appropriate to prescribe controlled substances because of better alternatives." App., *infra*, 85a. Petitioner also sought to call several patients not identified by the government to confirm that his treatment had been exemplary. See App., *infra*, 80a-89a. Cf. Ruan Sentencing Tr. 31:1-11 (statement of former patient) ("[I]f you've never had it, you can't even understand how much [chronic pain] changes you and ruins your life. When we were under Dr. Ruan's care, my husband and I were able to enjoy our retirement. . . . Now we have to wait an hour for my husband's little bit of pain medication that he gets to kick in before we can even do our own landscaping and trim our own hedges and just live a normal life—forget about [going] camping and enjoying things."). The district court excluded both the videos and the additional patient testimony as "not relevant." Status Conf. Tr. 17:11-13 (Jan. 3, 2016); see App., *infra*, 19a-20a, 27a.

[4] There was evidence that defendants had purchased stock in a pharmaceutical company whose products they frequently prescribed (Galena Biopharma), App., *infra*, 10a-11a, and that they had participated in the paid speaker program of another pharmaceutical company (Insys), which was allegedly designed by Insys "not to educate others but to influence how many prescriptions [they] wr[o]te," App., *infra*, 13a (quotation marks omitted).

availability at the affiliated pharmacy. See App., *infra*, 17a.

But that evidence was also hotly contested.[5] And the fact remains that large swaths of the government's proof invited the jury to convict Petitioner based on mere negligence. See, *e.g.*, Tr. 675:19-680:5; 754:10-16; 2255:3-12; 2311:22-2312:3; 2352:10-18; 2357:9-19 (prosecution expert testimony on standard of care).[6]

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[5] Petitioner, for instance, put on evidence that he had bought stock in Galena because he had believed in the company's prospective vaccine for breast cancer. See Tr. 5798:13-5799:7 (discussing stock-analyst research on Galena's value). What is more, in the months following the stock purchase, most of Petitioner's prescriptions of Galena medication were under the company's voucher program, see Tr. 5794:5-5795:19, and, as a former Galena rep acknowledged, those prescriptions "affected [Galena] negatively because Galena paid for all the product in the voucher program," Tr. 1651:15-16; see App., *infra*, 12a (Galena eventually abandoned the program as a result of these prescriptions). One of defendants' experts also testified that physicians "commonly" give paid talks for pharmaceutical companies, Tr. 4906:3-9, and that there is "nothing wrong" with doing so for companies whose products the physician prescribes, Tr. 4878:11-20. Further, some of the medications Petitioner prescribed were "very specialized" and, thus, as Petitioner testified, "[l]ocal pharmacies d[id] not carry them," Tr. 5826:17-18; availability at C&R, Petitioner testified, in no way affected his "clinical judgment" as to whether they were appropriate for his patients, Tr. 5828:3-6.

[6] See also, e.g., Tr. 681:10-12; 686:4-696:3; 724:22-727:14; 737:25-740:1; 742:19-744:18; 746:12-750:18; 750:23-756:11; 794:4-797:6; 1053:19-1054:9; 1061:8-15; 2278:12-13; 2351:5-10; 2362:7-2364:7; 2538:25-2541:9; 4348:7-4348:15; 4357:7-4361:14; 4390:3-11; 4398:19-4401:7; 4407:19-4408:15; 4436:25-4437:22; 4514:15-17; 4519:22-4520:1 (expert testimony on "professional practice").

3. At the close of evidence, Petitioner requested that the district court give the jury the same good faith instruction that two courts of appeals have approved. App., *infra*, 102a; see *United States* v. *Volkman*, 797 F.3d 377, 387 (6th Cir. 2015); *United States* v. *Vamos*, 797 F.2d 1146, 1152 (2d Cir. 1986). Petitioner's proposed instruction stated:

> Good faith in this context means good intentions and the honest exercise of professional judgment as to the patient's needs. It means that the Defendant acted in accordance with what he reasonably believed to be proper medical practice.

App., *infra*, 131a.

The district court refused to give this instruction because "good faith," in its view, is "subjective," and "the standard should be an objective one." App., *infra.*, 134a. Instead, emphasizing that this was "as far as I'm willing to go," App., *infra*, 136a, and that it would otherwise decline even to mention "good faith," *ibid.*, the district court gave the jury the following instruction over Petitioner's objection (*ibid.*; Status Conf. Tr. 42:3-6 (Jan. 3, 2016)):

> A controlled substance is prescribed by a physician in the usual course of a 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 defendants in this case maintain at all times they acted in good faith and in accordance with [the] standard 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.

App., *infra*, 139a (emphasis added).[7]

In short, the district court mentioned "good faith" in passing, but made clear that, regardless of Petitioner's purported good faith, the jury could convict if it found that Petitioner had acted "outside the usual course of professional medical practice."[8]

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[7] In instructing that Petitioner could be convicted if his actions were "*either* not for a legitimate medical purpose *or* were outside the usual course of professional medical practice," App., *infra*, 139a (emphasis added), the district court's instruction complied with Eleventh Circuit law. See App., *infra*, 106a-107a (affirming this aspect of the instruction); *United States* v. *Abovyan*, 988 F.3d 1288, 1305 (11th Cir. 2021) (same, citing the decision in this case). As it happens, there is also a circuit split as to whether the government must prove only one of the test's two prongs (as in the Eleventh Circuit) or both of them (as in the Ninth Circuit). See *United States* v. *Feingold*, 454 F.3d 1001, 1008 (9th Cir. 2006); cf. *United States* v. *Rottschaefer*, 178 Fed. Appx. 145, 147-148 (3d Cir. 2006) (suggesting that there may be "no difference" between the test's two prongs).

[8] In contrast to its refusal to instruct on good faith with respect to the controlled substances charges, the district court told the jury that "[g]ood faith is a complete defense" to the wire and health care fraud counts, and therefore "[a]n honestly held opinion or an honestly formed belief . . . even if . . .mistaken" precludes conviction. Tr. 6342:20-25.

4. Petitioner was convicted on all but two counts in the second superseding indictment and sentenced to 21 years of imprisonment. App., *infra*, 2a-3a. Dr. Couch was convicted on all but one charge and sentenced to 20 years of imprisonment. App., *infra*, 3a. Seven of the counts on which Petitioner was convicted were controlled substances charges.[9] Most of the remaining eight counts relied on the controlled substances offenses as a predicate. See Tr. 6330:5-11 (racketeering conspiracy); Tr. 6344:3-13 & Second Superseding Indictment, Dkt. 269, at 28 (Apr. 28, 2018) (health care fraud conspiracy); Tr. 6349:19-6351:6 (money laundering conspiracy and substantive money laundering). The only convictions that were independent of the controlled substances charges were one count of wire and mail fraud conspiracy and two counts of conspiracy to violate the Anti-Kickback statute.[10]

C. The Court of Appeals' Decision

Petitioner and Dr. Couch appealed, raising, among other issues, the district court's treatment of defendants' good faith defense. See App., *infra*, 102a. Acknowledging that the Eleventh Circuit had previously rejected a good faith instruction like the one they had proposed, see *United States* v. *Joseph*, 709 F.3d 1082, 1097 (2013), Petitioner urged the court to revisit its precedent in light of conflicting case law from other circuits. See Couch Reply 35 (citing *United*

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[9] Petitioner was acquitted on one count of unlawful distribution of controlled substances. App., *infra*, 5a.

[10] One of the Anti-Kickback convictions was reversed on appeal for insufficient evidence. App., *infra*, 60a. The government had initially brought three Anti-Kickback charges, but it dismissed one at trial. Tr. 4524:24-4525:8.

States v. *Volkman*, 797 F.3d 377 (6th Cir. 2015)); see also Ruan Reply iii (Petitioner's adoption of this argument).

"Bound by its [prior] holdings," however, the court of appeals affirmed. App., *infra*, 107a. It first rejected Petitioner's proposed good faith instruction as "an incorrect statement of the law." App., *infra*, 105a. Although the requested instruction expressly focused on what Petitioner "reasonably believed," the panel held that the instruction would wrongly permit an acquittal based only on Petitioner's "subjective[] belie[f]." App., *infra*, 106a.

The court of appeals next held that the instruction actually given by the district court was correct. In the panel's view, a physician may assert good faith *only* "as long as [his] conduct also was in accordance with the standards of medical practice generally recognized and accepted in the United States." App., *infra*, 107a. The court did not explain what independent meaning a good faith defense has if it applies only to physicians whose prescriptions already fall within professional norms.

Seeking rehearing, Petitioner again called conflicting circuit authority to the court of appeals' attention. Couch Pet. for Reh'g 6-11; Ruan Pet. for Reh'g iii. Rehearing was denied without comment.

REASONS FOR GRANTING THE PETITION

A medical doctor may be convicted under the Controlled Substances Act, 21 U.S.C. § 841(a)(1), if the government proves that he or she prescribed drugs "outside the usual course of professional practice." *United States* v. *Moore*, 423 U.S. 122, 124 (1975). To ensure that doctors are not convicted of a

federal felony based on simple malpractice, however, nearly all courts of appeals permit physicians to assert a "good faith" defense.

Good faith is the central (and sometimes the only) defense in the hundreds of reported cases charging doctors with a Section 841(a)(1) violation. Indeed, good faith was the central defense in *Moore* itself, where the jury was specifically instructed that the defendant could be convicted only if he prescribed "other than in good faith" and did not make at least "'an honest effort' to prescribe . . . in compliance with an accepted standard of medical practice." 423 U.S. at 139, 142 n.20. And in *United States* v. *Hurwitz*, 459 F.3d 463 (4th Cir. 2006), the court of appeals reversed a physician's conviction precisely because the instructions had deprived the defendant of a good faith defense to Section 841(a)(1) charges. See *id.* at 479-482.

But, in the forty-six years since *Moore* was decided, the courts of appeals have deeply divided on what good faith means, and how a jury should be instructed on it. The Second, Fourth, and Sixth Circuits have held that a physician should be acquitted if she "*reasonably* believed" that her prescription was within the usual course of professional practice. *E.g.*, *United States* v. *Hurwitz*, 459 F.3d 463, 479-482 (4th Cir. 2006). By contrast, the First, Seventh, and Ninth Circuits have held *any* sincere belief (whether reasonable or not) that a prescription was within the bounds of professional practice is grounds for acquittal because a physician holding such a belief lacks the scienter required for a felony conviction. *E.g.*, *United States* v. *Feingold*, 454 F.3d 1001, 1008 (9th Cir. 2006).

The Eleventh Circuit follows neither of those approaches. Under its idiosyncratic precedent, "whether [a physician] had a good faith belief that he dispensed a controlled substance in the usual course of his professional practice *is irrelevant*." *United States* v. *Enmon*, 686 Fed. Appx. 769, 773 (2017) (per curiam) (emphasis added); *United States* v. *Tobin*, 676 F.3d 1264, 1283 (2012). Instead, "[t]he appropriate focus," according to the Eleventh Circuit, is solely on "whether the physician prescribes medicine in accordance with a standard of medical practice generally recognized and accepted in the United States." *United States* v. *Abovyan*, 988 F.3d 1288, 1305 (2021). There is no room for good faith mistakes, reasonable or otherwise.

The present case illustrates the Eleventh Circuit's distinct approach. Two medical doctors, now sentenced to two decades each in federal prison as drug dealers, asserted a defense that would have been submitted to the jury in New York, Virginia, Tennessee, New Hampshire, Indiana, or Arizona. But, because they practiced medicine in Alabama, the court of appeals, "bound by its [prior] holdings" making good faith *irrelevant*, App., *infra*, 107a, affirmed. The court held that a physician charged with narcotics violations may claim good faith *only* "as long as the [physician's] conduct also was in accordance with the standards of medical practice generally recognized and accepted in the United States," *ibid.*—which is of course a situation in which the government has not met its burden in the first place. That is no defense at all.

The Eleventh Circuit's divergent understanding of good faith is deeply mistaken. As that court has all

but acknowledged, stripping good faith of any independent force effectively imposes criminal liability on physicians for merely negligent conduct. See *Tobin*, 676 F.3d at 1283 n.10. This Court should grant certiorari to resolve the entrenched circuit split and to ensure that physicians practicing in the Eleventh Circuit are not convicted of drug trafficking on a basis that would not pass muster in any other part of the country.

I. THE DECISION BELOW CONFLICTS WITH DECISIONS OF OTHER CIRCUITS AND IS DIFFICULT TO RECONCILE WITH DECISIONS OF THIS COURT

Nearly all circuit courts agree that a good faith instruction is essential to "explain[] to the jury a critical difference between" civil and criminal liability. *United States* v. *Sabean*, 885 F.3d 27, 45 (1st Cir. 2018) (quoting *United States* v. *Smith*, 573 F.3d 639, 650 (8th Cir. 2009) (quoting in turn *United States* v. *McIver*, 470 F.3d 550, 560 (4th Cir. 2006))). The circuit courts are deeply divided, however, on what good faith means. As one commentator has observed, most courts "vacillate between more subjective standards—in which a doctor's good faith attempt to conform his conduct to what he believes is a generally accepted standard of medical practice is sufficient—and more objective standards in which the doctor's conduct in this regard must also be reasonable." Deborah Hellman, *Prosecuting Doctors For Trusting Patients*, 16 Geo. Mason L. Rev. 701, 715 (2009).

If nothing else, the Eleventh Circuit cannot be accused of "vacillating." It has simply written good faith out of existence. Once the government has proved that a prescription falls outside the "standard

of medical practice generally recognized and accepted in the United States," the prescribing physician may be convicted as a drug dealer. Full stop.

The Eleventh Circuit's refusal to give the good faith defense any independent content is in sharp conflict with two competing lines of circuit court case law. The court of appeals' decision is also difficult to square with this Court's precedent. Further review to resolve the conflict is warranted.

A. THE COURTS OF APPEALS ARE DEEPLY DIVIDED ON THE MEANING OF THE GOOD FAITH DEFENSE UNDER THE CSA

1. In the Fourth, Second, and Sixth Circuits, physicians are entitled to acquittal if they "reasonably believe" that their conduct complied with professional norms.

In *United States* v. *Hurwitz*, 459 F.3d 463 (2006), the Fourth Circuit reversed a physician's conviction precisely because the jury instructions had deprived the defendant of a good faith defense to Section 841(a)(1) charges. *Id.* at 476; see *id.* at 480-482. As in the present case, Dr. Hurwitz's jury was told that all it needed to find to convict the defendant was that he had prescribed narcotics "beyond the bounds of medical practice." See Hurwitz Tr. 11:17-24, 15:6-9, 16:7-10, 17:12-15, 20:11-14, *United States* v. *Hurwitz*, No. 03-cr-00467 (E.D. Va. Dec. 9, 2004). See also 459 F.3d at 475. The Fourth Circuit rejected that instruction as fatally flawed. As the court explained, "latitude must be given to doctors trying to determine the current boundaries of acceptable medical practice" and "a doctor should not be held criminally liable if

the doctor acted in good faith when treating his patients." *Id.* at 477. The Fourth Circuit therefore held that *some* meaningful good faith instruction must be given to the jury.

The *Hurwitz* panel then turned to the proper standard for good faith. It first rejected the contention that good faith "means the doctor acted according to what *he believed to be proper medical practice*." *Id.* at 478. Instead, because the good faith inquiry "must be an objective one," it cited with approval precisely the rule for which Petitioner contended in the present case—that a physician acts in good faith if he prescribes "in accordance with what he *reasonably* believed to be proper medical practice." *Id.* at 478-480.[11] Just two months ago, the Fourth Circuit reiterated that view, holding that a jury should be "tasked with assessing what a physician *should have* believed," and rejecting as "legally incorrect" "a standard for good faith that is entirely subjective." *United States* v. *Purpera*, No. 19-4158, 2021 WL 406305, at *7-8 (Feb. 5, 2021) (per curiam).

The Second Circuit follows the same approach as the Fourth. The leading decision is *United States* v. *Wexler*, 522 F.3d 194 (2008). In that case, the physician's jury was given substantially the same good faith instruction that the Eleventh Circuit rejected as "incorrect": that the government must prove that the defendant dispensed drugs "other than in good faith," and that "good faith" means "that the doctor acted in accord with what he should have

[11] Concurring only in the result, Judge Widener urged a purely subjective good faith standard because "it is the intent of the actor into which inquiry is made." *Id.* at 483.

reasonably believed to be proper medical practice." *Id.* at 205. In sharp contrast to the court below, the Second Circuit in *Wexler* held that this "reasonable belief" instruction was "necessary." *Id.* at 206. Without it, the court reasoned, a physician might be convicted "for a gross mistake or malpractice," instead of "as a 'drug pusher.'" *Ibid.* A good faith instruction focused on the doctor's "reasonable belief" would "shield [a physician] from criminal liability for any mistake, however gross." *Id.* at 205-206. Accord *United States* v. *Singh*, 390 F.3d 168, 186 (2d Cir. 2004) (government must prove "the lack of good faith" where "good faith" means that "defendant . . . acted in accordance with what he reasonably believed to be proper medical practice"); *United States* v. *Vamos*, 797 F.2d 1146, 1152 (2d Cir. 1986) (same).

The Sixth Circuit is in accord. It, too, has approved "as a model of clarity and comprehensiveness" exactly the "reasonable belief" instruction that the Eleventh Circuit held to be "incorrect" in Petitioner's case: that a physician cannot be convicted if he "dispenses a drug in good faith," where good faith "means that the defendant acted in accordance with what he *reasonably believed* to be proper medical practice." *United States* v. *Volkman*, 797 F.3d 377, 387-388 (2015) (emphasis added). The Solicitor General agreed. See No. 13-18277 U.S. BIO 7, 12 (likewise calling this instruction a "model of clarity and comprehensiveness"). Like the Second and Fourth Circuits, the Sixth Circuit has also rejected a purely subjective intent standard as too permissive. See, *e.g.*, *United States* v. *Godofsky*, 943 F.3d 1011, 1022, 1027 (2019) (rejecting as "extreme" and "incorrect" the argument that a jury must acquit if the doctor acted "in accordance with *what he*

believed to be proper medical practice," and holding that the instruction in *Volkman* is "a correct statement of the law"); *United States* v. *Voorhies*, 663 F.2d 30, 34 (1981) (approving a good faith instruction requiring "an observance of conduct in accordance with what the physician should *reasonably* believe to be proper medical practice" (emphasis added)).

2. The Ninth, First, and Seventh Circuits go further: They require the government to prove that a physician *intentionally* exceeded the bounds of professional practice. Thus, they adopt the more subjective standard for good faith that Judge Widener approved in his separate opinion in *Hurwitz*, but which the Fourth, Second, and Sixth Circuits have rejected.

United States v. *Feingold*, 454 F.3d 1001, 1008 (2006), is the leading case in the Ninth Circuit. The court of appeals held that "a practitioner who acts outside the usual course of professional practice may be convicted under § 841(a) *only* if he does so intentionally." *Id.* at 1007 (emphasis added). Accordingly, the Ninth Circuit explained, it does *not* suffice (as it does in the Eleventh Circuit) "that the distribution . . . was outside the usual course of professional practice." *Id.* at 1008. Rather, the court held, the government must also prove "that the practitioner acted . . . *with intent to distribute [drugs] outside the course of professional practice*." *Ibid.* "In other words," the court of appeals stated, the prosecution must prove "the doctor's intent to act as a pusher rather than a medical professional." *Ibid.*;[12]

[12] The Ninth Circuit affirmed Dr. Feingold's conviction because his jury was expressly instructed that the government

accord *United States* v. *Garrison*, 888 F.3d 1057, 1064 (9th Cir. 2018) (reaffirming this analysis).

The First Circuit is in accord. In *United States* v. *Sabean*, 885 F.3d 27 (2018), the court explained that "a physician's failure to adhere to an applicable standard of care *cannot, by itself, form the basis for a conviction under Section 841(a)*." *Id.* at 45 (emphasis added). Accordingly, the First Circuit held, it was "important" to instruct the jury that "'a *sincere effort* to act in accordance with proper medical practice,' even if flawed, could not undergird a guilty verdict so long as the defendant had acted in 'good faith.'" *Ibid.* (emphasis added). "Because good faith is a defense to criminal charges under Section 841(a) but not to civil liability for medical malpractice, 'inclusion of a good faith instruction is . . . a plainspoken method of explaining to the jury a critical difference between the two standards.'" *Ibid.* (citation omitted).[13]

The Seventh Circuit takes the same view. In *United States* v. *Kohli*, 847 F.3d 483 (2017), the jury was instructed that the prosecution must prove that the physician had "intentionally prescrib[ed] the controlled substance outside the usual course of professional medical practice." *Id.* at 488. Moreover, the instructions emphasized, the defendant could not

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must prove that he did not prescribe in good faith, where good faith means "*sincerity* in attempting to conduct himself in accordance with a standard of medical practice generally recognized and accepted in the country." *Feingold*, 454 F.3d at 1008.

[13] Because the good faith instructions "lucidly explained the government's burden for proving criminal intent" and the "distinction[] between intentional and negligent misconduct," *id.* at 45-46, the court of appeals affirmed.

be convicted "if he merely made an honest effort to treat his patients in compliance with an accepted standard of practical practice." *Id.* at 489. Those instructions, the Seventh Circuit held, "fairly and accurately stated the law." *Id.* at 494.

3. The Eleventh Circuit rejects *both* the "reasonable belief" instruction approved by the Second, Fourth, and Sixth Circuits, and the more defense-friendly "subjective intent" defense approved by the First, Seventh, and Ninth Circuits. In the Eleventh Circuit, "whether [a physician] had a good faith belief that he dispensed a controlled substance in the usual course of his professional practice *is irrelevant*." *United States* v. *Enmon*, 686 Fed. Appx. 769, 773 (2017) (per curiam) (emphasis added).

The leading case is *United States* v. *Tobin*, 676 F.3d 1264 (11th Cir. 2012). Acknowledging that its prior case law had "not always been clear," *id.* at 1282, the court of appeals synthesized its precedents and held that "a jury must determine from an *objective* standpoint whether a prescription is made in the 'usual course of professional practice.'" *Id.* at 1283. The Eleventh Circuit dismissed the concern that such an approach "will create a 'strict liability offense,'" speculating that "[t]he possibility that a practitioner will unknowingly run afoul of the CSA is extremely low." *Id.* at 1283 n.10. Then, in a passage that effectively writes good faith out of existence, the Eleventh Circuit flatly held that "the CSA incorporates the applicable state standard of professional practice, and thus *it holds practitioners to standards to which they are already bound*." *Ibid.* (emphasis added). The court therefore affirmed the

district court's exclusion of "evidence of good faith" as "consistent with [its] holdings." *Id.* at 1283.

Building on that premise a year later, the Eleventh Circuit held that the "reasonable belief" instruction approved by the Second, Fourth, and Sixth Circuits (and the Solicitor General) is legally impermissible. In *United States* v. *Joseph*, 709 F.3d 1082 (11th Cir. 2013), the court rejected as an "incorrect statement of the law" a proposed instruction that good faith "means that the doctor acted in accordance with what he *reasonably* believed to be proper medical practice." *Id.* at 1097. The rejected instruction was identical almost *word-for-word* to the instruction that the Sixth Circuit hailed as a "model." *Volkman*, 797 F.3d at 387-388; accord No. 13-18277 U.S. BIO 7, 12. It was identical in substance to those the Second Circuit had called "necessary" in *Wexler*, 522 F.3d at 205-206, and the Fourth Circuit had cited approvingly in *Hurwitz*, 459 F.3d at 478. But, relying on *Tobin*, the Eleventh Circuit thought the proposed instruction insufficiently "objective." *Joseph*, 709 F.3d at 1097. It approved, instead, an instruction mentioning good faith in passing, but not making it a separate defense.[14]

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[14] The approved instruction provided:

A controlled substance is prescribed by a physician in the usual course of a professional practice and, therefore, lawfully, if the substance is prescribed by him in good faith as a part of his medical treatment for the patient in accordance with a standard of medical practice generally recognized and accepted in the United States.

Joseph, 709 F.3d at 1092.

A few years later, the Eleventh Circuit left no doubt that it meant what it said. The Court sustained an instruction that told the jury, in no uncertain terms, that "whether [a physician] had a good faith belief that he dispensed a controlled substance in the usual course of his professional practice *is irrelevant*." *Enmon*, 686 Fed. Appx. at 773 (emphasis added). All that matters, the court of appeals stated, is "whether the doctor's practice was 'in accordance with a generally-accepted standard of medical practice.'" *Id.* at 772-773 (quoting *United States* v. *Merrill*, 513 F.3d 1293, 1306 (11th Cir. 2008)). That instruction would have been plain error in the First, Second, Fourth, Sixth, Seventh, or Ninth Circuits. Indeed, the Fourth Circuit reversed a conviction precisely because the district court had "informed the jury that it *could not* consider good faith when deciding whether to convict . . . under § 841." *Hurwitz*, 459 F.3d at 476.

The present case is of a piece. Over Petitioner's objection, the district court gave the "same instruction" that the Eleventh Circuit had approved in *Joseph*—mentioning good faith, but making clear that it has no independent force as a defense. App., *infra*, 106a. Purporting to "throw[] [Petitioner] a bone," App., *infra*, 136a, but emphasizing that was "as far as I'm willing to go, given the state of the law on this issue," *ibid.*, the district court adverted to "good faith," but in the very next breath instructed the jury, in its summary paragraph, that good faith makes not a dime's worth of difference:

> *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.

App., *infra*, 139a (emphasis added). Affirming, the Eleventh Circuit held that the instruction correctly told the jury that "good faith was a defense to a Controlled Substances Act violation," but only "*as long as the appellants' conduct also was in accordance with the standards of medical practice* generally recognized and accepted in the United States." App., *infra*, 107a (emphasis added). Such a defense—which leaves no room for *any* kind of mistake (reasonable or otherwise)—is no defense at all.

Petitioner called the panel's attention to conflicting out-of-circuit precedent; he urged the court to revisit its decisions refusing to permit even a "reasonable belief" instruction. See Couch Reply 35; Ruan Reply iii; Couch Pet. for Reh'g 6-12; Ruan Pet. for Reh'g iii. But the Eleventh Circuit stuck to its guns.

And there is no prospect that, without this Court's intervention, the court of appeals will reconsider its divergent position. Just six weeks ago, the Eleventh Circuit restated its view that a conviction under the CSA turns exclusively on "whether the physician prescribes medicine in accordance with a standard of medical practice generally recognized and accepted in the United States." *United States* v. *Abovyan*, 988 F.3d 1288, 1305 (2021) (quoting *Merrill*, 513 F.3d at 1306); see also *Merrill*, 513 F.3d at 1306 (rejecting physician's

good faith instruction on these grounds). Accordingly, the court held, "the law requires *only* that the jury find the doctor prescribed a drug . . . not 'in the usual course of professional practice.'" *Abovyan*, 988 F.3d at 1308 (citing the present case) (emphasis added). In the Eleventh Circuit, good faith—whether based on subjective intent (as in the First, Seventh, and Ninth Circuits), or based on a "reasonable belief" (as in the Second, Fourth, and Sixth Circuits)—simply has no independent role to play in CSA prosecutions.

B. THE COURT OF APPEALS' DECISION IS DIFFICULT TO SQUARE WITH THIS COURT'S CASE LAW

Although this Court has not had occasion to decide whether and in what way a good faith defense must be permitted under the CSA, its case law strongly suggests that the Eleventh Circuit's rule is mistaken.

The Court's earliest cases arose under the Harrison Anti-Narcotic Law, 38 Stat. 785, "the predecessor of the CSA." *United States* v. *Moore*, 423 U.S. 122, 132 (1975). In *Linder* v. *United States*, 268 U.S. 5 (1925), a physician was charged under Section 2 of the statute with dispensing narcotics to an addicted patient. The requirements of Section 2 extended to physicians unless they had acted "in the course of . . . professional practice only." *Id.* at 13 (quoting 38 Stat. at 786). Notably, a separate section of the Act—Section 8, covering possession of narcotics—expressly provided for a good faith defense, whereas Section 2 did not. *Id.* at 14. Nevertheless, this Court construed Section 2 to permit prescriptions issued "in good faith." *Id.* at 20. Applying that standard, the Court vacated the defendant's

conviction because the evidence showed that the physician lacked any "*conscious design* to violate the law." *Id.* at 17 (emphasis added).

A year later, in *Boyd* v. *United States,* 271 U.S. 104 (1926), "[t]he disputed question was whether the defendant issued the prescriptions in good faith." *Id.* at 105. This Court agreed that, if the jury had been authorized to convict *only* because a prescribed dosage exceeded medical standards (which suffices in the Eleventh Circuit), that "would be plainly in conflict with what this court said in the Linder Case." *Id.* at 107. The Court affirmed the conviction, however, because the instructions had appropriately advised the jury to acquit if the physician had acted "honestly and in good faith" in an "effort to cure disease." *Id.* at 108.

Nothing in the CSA dilutes, much less abrogates, the good faith defense recognized in both *Linder* and *Boyd*. To the contrary, as the Court explained in *Moore*, Congress (even while strengthening the drug laws) was concerned that "physicians be allowed reasonable discretion in treating patients and testing new theories." 423 U.S. at 143. And, consistent with that principle, the *Moore* jury was expressly instructed that it could convict *only* if the defendant acted "other than in good faith" and did not make at least "'an honest effort' to prescribe . . . in compliance with an accepted standard of medical practice." *Id.* at 139, 142 n.20. See No. 13-18277 U.S. BIO 12 (*Moore* "implicitly endorsed the jury instructions given").

The Eleventh Circuit's treatment of the good faith defense is difficult to reconcile with *Linder* and *Boyd*. In the Eleventh Circuit, "[t]he appropriate focus" is *solely* on "whether the physician prescribes

medicine in accordance with a standard of medical practice generally recognized and accepted in the United States." *Abovyan*, 988 F.3d at 1305. Petitioner's jury was therefore told, point blank, that it could convict the defendant if it found that his prescriptions had exceeded professional norms, no matter whether they had been issued "for the purpose of curing disease or relieving suffering" or whether there was otherwise "reason or occasion for the excess." *Boyd*, 271 U.S. at 106-107. That is "plainly in conflict with what this Court said" in *Linder* and *Boyd*. *Id.* at 107.

II. THE COURT OF APPEALS WRONGLY DECIDED AN IMPORTANT AND RECURRING QUESTION

A. The Eleventh Circuit's refusal to recognize a good faith defense is deeply mistaken. It misconstrues the CSA and threatens doctors with felony convictions merely for prescriptions that a prosecutor (or lay jury) retroactively decides, typically (as here) based on sharply divided expert opinions, exceeded professional norms.

A meaningful good faith instruction helps ensure that convictions under the CSA are consistent with the "basic principle" that "an injury is criminal only if inflicted knowingly." *Rehaif* v. *United States*, 139 S. Ct. 2191, 2196 (2019). "The cases in which [this Court] ha[s] emphasized scienter's importance in separating wrongful from innocent acts are legion." *Ibid.* Indeed, Section 841(a), by its terms, criminalizes only "knowing[]" and "intentional[]" conduct, 21 U.S.C. § 841(a)(1), and, under "a longstanding presumption," that requirement applies

to "each of the statutory elements," *Rehaif*, 139 S. Ct. at 2195.

But the Eleventh Circuit's rule reads any meaningful scienter requirement out of the statute. If all it takes to convict a doctor of drug trafficking is that she "knowingly or intentionally" *dispensed* a controlled substance outside the course of professional practice, 21 U.S.C. § 841(a)(1), the only physicians who will get acquitted are those who prescribed medicine in their sleep. Such a vacuous scienter requirement is especially inappropriate where, as here, "the act underlying the conviction"—a doctor prescribing medicine—"is by itself innocuous." *Arthur Andersen LLP* v. *United States*, 544 U.S. 696, 703 (2005).

In the Eleventh Circuit good faith is merely "a bone" to be "throw[n]" in the doctor's direction. It lacks any concrete significance. As the court below emphasized, good faith applies *only* "as long as the appellants' conduct also was in accordance with the standards of medical practice generally recognized and accepted in the United States." App., *infra*, 107a.

Put another way, good faith is an available defense in the Eleventh Circuit only when it doesn't serve any purpose. That is a rule only Joseph Heller's Major Major would appreciate.[15]

There is, moreover, the question of basic fairness. If Petitioner had been prosecuted in the Second, Fourth, or Sixth Circuits, his jury would have been told that a "reasonable belief" is sufficient grounds to acquit. Had he been prosecuted in the First, Seventh, or Ninth Circuits, his jury would have been told that it could convict only if Petitioner subjectively intended to exceed professional norms. Because he was instead prosecuted in the Eleventh Circuit, Petitioner's jury was invited to convict based solely on a finding that his prescriptions fell "outside the usual course of professional practice." App., *infra*, 105a.

Without this Court's intervention, "federal case law from around the country [will continue to] exhibit[] no clear standard for criminal liability in the context of doctors prescribing controlled narcotics." Hellman, 16 Geo. Mason L. Rev. at 715.

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[15] "What shall I say to the people who do come to see you while you're here?"

"Tell them I'm in and ask them to wait."

"Yes, sir. For how long?"

"Until I've left."

"And then what shall I do with them?"

"I don't care."

"May I send them in to see you after you've left?"

"Yes."

"But you won't be here then, will you?"

"No."

Joseph Heller, *Catch 22* 100 (S&S Classic ed. 1999) (1961).

B. The circuit conflict implicated by this petition also raises weighty questions of overdeterrence and federalism.

1. As some thirty state attorneys general have observed, "adequate pain management is often difficult to obtain because many physicians fear [federal] investigations and enforcement actions if they prescribe adequate levels of opioids." Letter of 30 State Attorneys General to Administrator of DEA, 151 Cong. Rec. 6974 (2005). What is at stake in prosecutions of this sort is not just the liberty of doctors, but also the well-being of patients suffering debilitating pain. Overdeterrence of prescribing needed medication is a problem of considerable public importance.

Depriving physicians of a meaningful good faith defense to CSA charges leads to just such overdeterrence and chills the practice of pain medicine. As this Court explained in *Moore*, "Congress understandably was concerned . . . that physicians be allowed reasonable discretion in treating patients and testing new theories." 423 U.S. at 143. "[L]atitude" must therefore "be given to doctors trying to determine the current boundaries of acceptable medical practice." *Hurwitz*, 459 F.3d at 477. A good faith instruction is a critical means by which such "latitude" is given. Depriving doctors of a meaningful good faith defense puts them at risk of draconian prison sentences any time they approve a course of treatment that might be said (with the benefit of hindsight) to have departed from professional norms.

In the process, "patients in pain" will increasingly become "collateral damage." Ramesh Ponnuru, *War*

on opioid abuse is striking the wrong target, Pittsburgh Post-Gazette, Mar. 26, 2019, https://perma.cc/4PHS-RTS3. Physicians will "reduce[ ] patients' dosages or cut them off altogether, leaving them in misery." Sally Satel, *The Truth About Painkiller Addiction*, The Atlantic, Aug. 4, 2019, https://bit.ly/3rIw0d1. For some patients—like Petitioner's, see note 3, *supra*—undertreated chronic pain can make it impossible to live a normal life. See Jacob Sullum, *America's War on Pain Pills Is Killing Addicts and Leaving Patients in Agony*, Reason, Apr. 2018, https://bit.ly/3rRtDVn ("[T]he doctors were getting tired of all the scrutiny, so they were booting all the opioid patients. . . . [E]very morning is a challenge to get out of bed. . . . It's horrible. I can't expect to live a life like this."). Indeed, overzealous enforcement can make physicians "so afraid of the feds they leave some pain patients in the lurch, thereby unintentionally pushing them toward suicide—assisted and otherwise." Wesley J. Smith, *Pain Doctors Face Greater Scrutiny Than Death Doctors*, National Review, May 3, 2018, https://perma.cc/84R5-S5W9.

And the daunting task faced by juries in such cases compounds the problem. "[F]ederal drug trafficking cases against physicians are the only realm in which juries are tasked with applying complicated medical concepts to vague elements in order to determine if a physician should be convicted and sentenced to decades in prison due to a medical disagreement." Ronald W. Chapman II, *Defending Hippocrates: Representing Physicians in the Wake of the Opioid Epidemic*, 43 Champion (Nat'l Ass'n of Crim. Defense Law.) 40, 41 (2019). In such cases, "it is essentially up to a jury of untrained individuals to

make medical decisions as to what is appropriate prescription practice." Brendan LoPuzzo, *A Bitter Pill To Swallow: The Need for a Clearly Defined Course of Professional Practice When Prescribing Opioids for the Legitimate Medical Purpose of Treating Pain*, 47 Hofstra L. Rev. 1397, 1430 (2019). The good faith defense helps to ensure that juries distinguish negligent, even grossly negligent, doctors from drug pushers.

2. In addition to the risk of over-deterrence, the court of appeals' interpretation criminalizes mal-practice law in a way that "intrudes on the police power of the States," *Bond* v. *United States*, 572 U.S. 844, 860 (2014), and "significantly change[s] the federal-state balance," *Jones* v. *United States*, 529 U.S. 848, 858 (2000). Doctors who prescribe controlled substances inappropriately are a danger to the public; so are incompetent surgeons, anesthesiologists, and cardiologists, not to mention arsonists and felons carrying firearms. But States—not the federal government—have the primary authority to protect the public from those dangers. See *Jones*, 529 U.S. 848 (arsonists); *United States* v. *Bass*, 404 U.S. 336 (1971) (felons carrying firearms); Letter of 30 State Attorneys General, *supra*.

Further, state medical boards, not federal prosecutors, are best suited to police the boundaries of professional competence. "The structure and operation of the CSA presume and rely upon a functioning medical profession regulated under the States' police powers." *Gonzales* v. *Oregon*, 546 U.S. 243, 270 (2006). Indeed, Congress required the Attorney General to consider the "recommendation of the appropriate State licensing board or professional

disciplinary authority" before taking even the *administrative* step of denying a doctor authorization to dispense controlled substances. 21 U.S.C. § 823(f). It is therefore quite unlikely that it intended to have lay jurors substitute for state medical officials at a criminal trial. Yet that is just what the Eleventh Circuit requires. See *United States* v. *Tobin*, 676 F.3d 1264, 1283 n.10 (2012) (holding that the "CSA incorporates the applicable state standard of professional practice, and . . . holds practitioners to [its] standards").

C. The question presented arises in virtually every CSA prosecution of physicians and other practitioners. A Westlaw search for "841(a) & doctor! & 'good faith' & prescription!" returns 228 cases—with well over half of them decided in the last ten years. Westlaw Edge Search (March 28, 2021).

There is every reason to expect this trend to continue. In 2018, the then-Attorney General announced the creation of the Department of Justice Prescription Interdiction & Litigation (PIL) Task Force with the mission of "fight[ing] the prescription opioid crisis."[16] The Drug Enforcement Administration's website lists fifty investigations that resulted in the arrest and prosecution of a registered physician for prescribing opioids in 2020 and a total of more than one hundred such investigations since 2018.[17] As a result, "[m]edical providers can find

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[16] U.S. Dep't of Justice Office of Public Affairs, *Attorney General Sessions Announces New Prescription Interdiction & Litigation Task Force* (Feb. 27, 2018), https://perma.cc/24UZ-BSS2.

[17] U.S. Dep't of Justice Drug Enf't Admin. Diversion Control Div., *Criminal Cases Against Doctors*, https://bit.ly/3mgT5Cf.

themselves stuck in the middle between aggressive prosecutors and patients in need of pain treatment." Christopher Brown, *DOJ Keeps Up Pressure on Doctors Who Prescribe Opioids Illegally*, Bloomberg Law, Jan. 24, 2020, https://perma.cc/5WN2-YD2X.

The Eleventh Circuit is likely to be Ground Zero for such prosecutions in the future. The Middle District of Florida alone boasts "two full-time Opioid Fraud Prescription Abuse Unit prosecutors."[18] The U.S. Attorney's Office for the Northern District of Georgia runs an Operation SCOPE with a mission "to prosecute those who are illegally prescribing, or distributing, painkillers."[19] And the U.S. Attorney's Office for the Northern District of Alabama "combats the opioid epidemic in Alabama by aggressively pursuing enforcement against drug dealers,"[20] which is what, in the Eleventh Circuit, all doctors who prescribe opioids beyond the usual course of practice are.

These may all be commendable initiatives. But their success should be tested by juries that are correctly instructed on the law.

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[18] U.S. Attorney's Office for the Middle District of Florida, *Opioid Epidemic*, https://perma.cc/3VBT-NY4G.

[19] U.S. Attorney's Office for the Northern District of Georgia, *SCOPE Initiative*, https://perma.cc/826N-TRSS.

[20] U.S. Attorney's Office for the Northern District of Alabama, *Project Safe Neighborhoods*, https://perma.cc/P58H-FYX4.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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April 5, 2021

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 17-12653

UNITED STATES OF AMERICA,

Plaintiff–Appellee,

v.

XIULU RUAN, JOHN PATRICK COUCH,

Defendants–Appellants.

Argued: Aug. 23, 2019
Decided: July 10, 2020

Appeal from the United States District Court
for the Southern District of Alabama
(No. 1:15-cr-00088-CG-B-2)
Callie V. S. Granade, Senior District
Judge, Presiding

Before: WILSON and NEWSOM, Circuit Judges, and COOGLER,* District Judge.

COOGLER, District Judge:

Following a seven-week trial in the United States District Court for the Southern District of Alabama, pain management physicians Xiulu Ruan ("Ruan") and John Patrick Couch ("Couch") (together, "the appellants") were convicted by a jury of conspiring to run a medical practice constituting a racketeering enterprise in violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962(d); conspiring to violate the Controlled Substances Act, 21 U.S.C. §§ 846 & 841(a)(1), by dispensing Schedule II drugs, fentanyl, and Schedule III drugs outside the usual course of professional practice and without a legitimate medical purpose; conspiracies to commit health care fraud and mail or wire fraud in violation of 18 U.S.C. §§ 1347(a) & 1349; and conspiracies to receive kickbacks in relation to a Federal health care program in violation of 18 U.S.C. § 371 and 42 U.S.C. § 1320a-7b(b). In addition, Ruan and Couch were individually convicted of multiple counts of substantive drug distribution in violation of the Controlled Substances Act, 21 U.S.C. § 841(a)(1). Ruan was further convicted of a money laundering conspiracy in violation of 18 U.S.C. § 1956(h) and two counts of substantive money laundering in violation of 18 U.S.C. § 1957. Ruan was sentenced to 252 months' imprisonment, to be followed by four years of supervised release, and ordered to pay over $15 million in restitution. Couch was sentenced to 240

* Honorable L. Scott Coogler, United States District Judge for the Northern District of Alabama, sitting by designation.

months' imprisonment, followed by four years of supervised release, and ordered to pay over $16 million in restitution.

In this broad-sweeping appeal, Ruan and Couch challenge their convictions, various evidentiary rulings at trial, and the district court's jury instructions. Ruan also challenges his sentence and the district court's order of restitution. After thorough review and having had the benefit of oral argument, we affirm in large part the decisions of the district court, but we reverse the district court's ruling that sufficient evidence supported one of the illegal kickback conspiracy convictions. We thus remand the cases for resentencing.

I. Background

A. Procedural History

A Southern District of Alabama grand jury indicted Ruan and Couch on April 30, 2015, charging conspiracy to distribute controlled substances, 21 U.S.C. § 846, and conspiracy to commit health care fraud, 18 U.S.C. § 1347(a). After a raid of their medical clinic and pharmacy by the Federal Bureau of Investigation ("FBI"), a Superseding Indictment issued on April 28, 2016, charging 22 counts. The Superseding Indictment alleged that Ruan and Couch's medical clinic was essentially a "pill mill," which prescribed controlled substances for no legitimate medical purpose or outside the usual course of professional practice. Ruan and Couch were both charged with one count of conspiracy to commit racketeering, 18 U.S.C. § 1962(d) (Count 1); three counts of conspiracies to violate the Controlled Substances Act by dispensing Schedule II and III controlled substances and fentanyl outside the usual

course of professional practice and without a legitimate medical purpose, 21 U.S.C. §§ 841(a)(1) & 846 (Counts 2–4); one count of conspiracy to commit health care fraud, 18 U.S.C. § 1347(a) (Count 15); three counts of conspiracy to violate the Anti-Kickback statute, 18 U.S.C. § 371 (Counts 16–18); and one count of conspiracy to commit wire and mail fraud, 18 U.S.C. § 1349 (Count 19). Couch was charged with five additional counts of illegal drug distribution involving prescribing controlled substances to named individuals, 18 U.S.C. § 2(a) and 21 U.S.C. § 841(a)(1) (Counts 5–7 and 13–14). Ruan was charged with five additional counts of illegal drug distribution involving prescribing controlled substances to named individuals, 21 U.S.C. § 841(a)(1) (Counts 8–12), and three counts of conspiracy to commit money laundering and substantive money laundering, 18 U.S.C. §§ 1956(h) & 1957 (Counts 20–22). The Superseding Indictment also contained numerous forfeiture provisions.

Ruan and Couch pled not guilty. Their joint trial commenced in Mobile, Alabama, on January 6, 2017, and lasted 31 days. The government called more than 50 witnesses, including 15 of their former patients or their relatives; 12 of their former staff members, including nurse practitioners with whom they had worked closely; four pharmaceutical company employees; seven representatives from various medical insurance companies; three medical experts; the director of the Alabama Department of Public Health; and 12 law enforcement agents and analysts. The government also introduced numerous charts from insurers and the Drug Enforcement Administration ("DEA") reflecting the volume and cost to insurers of prescriptions for controlled

substances that Ruan and Couch had written, compared to other physicians in Alabama and nationally. Both Ruan and Couch testified in their defense, and they also called five former patients, 11 additional former employees, and three medical experts of their own. The government dismissed Count 18 at the close of its case. Ruan and Couch moved for judgments of acquittal under Federal Rule of Criminal Procedure 29 at the close of the government's case, and again at the close of all the evidence, and the district court denied their motions.

On February 23, 2017, the jury convicted Couch on all counts against him. Ruan was acquitted on Count 10 but convicted on all other counts. Ruan and Couch renewed their motions for judgment of acquittal or new trial, and the district court denied the motions.

On May 25 and 26, 2017, the district court imposed below-guidelines sentences of 252 (Ruan) and 240 (Couch) months of imprisonment, each to be followed by four years of supervised release. Ruan was ordered to pay $15,239,369.93 in restitution and Couch $16,844,569.03. Ruan and Couch are currently incarcerated. This appeal followed.[1]

B. Trial Evidence[2]

1. The Appellants' Clinic and Pharmacy

The appellants were board-certified doctors specializing in pain management. They co-owned a

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[1] As necessary, additional procedural details are set forth with each issue below.

[2] Because the appellants challenge the sufficiency of the evidence against them at trial, the following facts have been

medical clinic, Physicians Pain Specialists of Alabama ("PPSA"), and a pharmacy, C&R Pharmacy ("C&R"). PPSA had two locations in Mobile, Alabama, one on Springhill Avenue and one on Airport Boulevard. C&R was connected to PPSA's Airport Boulevard location, and its sole business was dispensing drugs prescribed at PPSA. The Springhill office contained an in-office dispensary for workers' compensation patients. Ruan worked primarily at the Airport location and Couch primarily at Springhill, but once a week they would switch locations. In May 2015, when an FBI raid shut down PPSA and C&R, they had 57 employees and served over 8,000 patients.

The appellants' medical practice was lucrative. From January 2011 to May 2015, the period covered by the Superseding Indictment, Couch made over $3.7 million from PPSA, and Ruan made over $3.9 million. C&R received a service fee for each prescription it filled—more than 70,000 during those years—netting Ruan and Couch each more than $555,000 from their pharmacy.

2. The Controlled Substances Act

On the first day of trial government witnesses told the jury that the Controlled Substances Act categorizes controlled substances into five schedules, based on their abuse potential and medical value. The Act makes it a crime for anyone to, among other things, dispense a controlled substance, with the exception that licensed health care professionals may dispense Schedule II, III, and IV controlled

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established by viewing the evidence presented at trial in the light most favorable to the government. *See United States v. Schlei*, 122 F.3d 944, 952 (11th Cir. 1997).

substances with a prescription. *See* 21 U.S.C. §§ 841(a)(1), 828. However, such prescriptions are only lawful if they are issued for a legitimate medical purpose in the usual course of the licensed health care professional's professional practice. *See* 21 C.F.R. § 1306.04.

From January 2011 to May 2015, the appellants wrote nearly 300,000 prescriptions for controlled substances, over half of which were Schedule II drugs. Schedule II drugs are the most powerful and dangerous drugs that can be lawfully prescribed, and they include many pharmaceutical opioids such as fentanyl, hydrocodone, morphine, oxycodone, methadone, hydromorphone, and oxymorphone. Opioids are dangerous because, while they can help mask pain, their use can create physical and psychological dependence that can lead to addiction. Side effects from opioid use include lethargy, confusion, falls, and depressed breathing.

Opioids can be particularly dangerous when combined with two Schedule IV controlled substances: benzodiazepines and carisoprodol. Benzodiazepines, such as Xanax and Valium, are psychoactive drugs that treat a wide range of conditions including insomnia or anxiety. Carisoprodol is a muscle relaxant marketed under the brand name Soma. The combination of these three types of drugs—which the government referred to as the "Holy Trinity" at trial—is popular among substance abusers because of its euphoric effect, yet it is highly addictive and can increase the chances of the user's death. Together, the appellants prescribed nearly 12.5 million units of Schedule II opioids, and opioid prescriptions accounted for nearly 75% of their total controlled-

substance prescriptions. Most of the rest of their controlled-substance prescriptions were for benzodiazepines and Soma, the other components of the "Holy Trinity."

3. Ruan and Couch Prescribed Millions of Doses of Opioids Based on Their Financial Interests

The government sought to prove that Ruan and Couch prescribed millions of doses of opioids and other controlled substances outside the usual course of professional practice and, thus, illegally. Over Ruan and Couch's objection, the government used Alabama's Prescription Database Monitoring Program ("PDMP"), a database of all controlled substance prescriptions dispensed statewide that is available to doctors and other health personnel, to pull Ruan and Couch's prescribing data. The government focused especially on Ruan and Couch's frequent prescribing of a version of fentanyl called transmucosal immediate-release fentanyl ("TIRF"), which the Food and Drug Administration ("FDA") had approved in 2011 to treat "breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy." The two types of TIRFs that Ruan and Couch prescribed were Subsys, manufactured by Insys Therapeutics ("Insys"), and Abstral, manufactured by Galena Biopharma ("Galena"). Subsys is an under-the-tongue oral spray, and Abstral is an under-the-tongue dissolving tablet, but both penetrate the blood-brain barrier more quickly than medications absorbed digestively, working in five minutes compared to 45 minutes for most other opioids. Not surprisingly, TIRFs are expensive, with average doses costing

anywhere from $3,000 to over $20,000 per month. And although it is not illegal for a doctor to prescribe TIRFs "off-label" to patients who do not have cancer, insurers would usually only pay for on-label uses of TIRFs. From January 2011 to May 2015, Ruan and Couch prescribed more than 475,000 doses of TIRFs to over 1,000 patients. From 2012 to 2014, they sharply increased both the number of patients receiving TIRF prescriptions and the dosages prescribed. This practice placed the appellants among the top TIRF prescribers nationwide: they often surpassed the next highest prescriber by more than double. Despite these high numbers of TIRF prescriptions, no more than 15% of PPSA patients had cancer.[3]

One of the ways in which the government sought to prove that Ruan and Couch's prescribing of Abstral and Subsys deviated from the usual course of professional practice was that their prescribing habits tracked financial incentives rather than their patients' medical needs. One of the government's medical experts, Dr. Tricia Aultman ("Dr. Aultman"), testified that prescribing drugs based on one's own financial interest is outside the usual course of professional practice.

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[3] For each doctor, the government used prescription records to identify the 25 patients receiving the most Abstral and Subsys prescriptions. Comparing those lists to PPSA's medical records showed that more than half of those patients—14 on each list—did not have cancer and were thus receiving TIRFs off-label. For those 28 patients, insurers paid more than $5.5 million for Abstral and Subsys during the time covered by the Superseding Indictment.

i. The Appellants' Investments in Galena Stock

A DEA agent created a line chart showing the micrograms[4] of Abstral prescribed by Ruan and Couch each month from January 2011 to May 2015. Ruan and Couch prescribed very little Abstral until late 2013—the most Couch prescribed was 76,800 mcg one month, and some months he did not prescribe any, and Ruan's prescriptions maxed out at 128,000 mcg per month. However, in April 2013, Galena initiated a study to gather data on how Abstral was working on patients. As former Galena sales representative David Corin ("Corin") testified, Galena offered doctors $500 per patient to enroll in the study but limited it to 25 patients per doctor. Couch negotiated with Galena for an exception to enroll up to 75 of his patients for a fee of $2,500 per patient. Immediately after Galena approved that arrangement, Couch began prescribing over 1.5 million mcg of Abstral per month.

Similarly, in September 2013, Ruan prescribed only 25,600 mcg of Abstral. But in October 2013, his prescriptions rose to 192,000 mcg. Around that time, a Galena sales representative visited PPSA in Mobile. Shortly thereafter, Couch and Ruan began purchasing Galena stock. Between November 2013 and January 2014, they purchased more than $1.3 million of stock, both individually and through PPSA. In a February 2, 2014, email to Couch, Ruan wrote that they could "play a big role" in increasing the value of Galena stock. A few day later Ruan emailed another doctor, writing that although he had never purchased stock

[4] Fentanyl is so powerful that, unlike other opioids, it is measured in micrograms (one millionth of a gram) ("mcg"), not milligrams ("mg").

before, he decided to invest in Galena to help "generate enough profit to pay for [his] divorce settlement." And in a February 17, 2014, email between Ruan and a colleague, Ruan indicated that he suspected Galena would have a "substantial market share growth at the end of March." Ruan's prescribing of Abstral greatly increased during this time. For example, in January 2014, Ruan prescribed over 1.4 million mcg; in February he prescribed over 2.3 million mcg; and in March his prescriptions rose to over 2.6 million mcg. Galena's stock price increased dramatically from October 2013 to the start of 2014, more than tripling in price.

However, Corin testified that in January 2014, members of Galena's board of directors were given a "blackout period" in which they were briefly permitted to sell their stock; they did so—"millions of dollars' worth"—and the price "dropped dramatically." Ruan and Couch "were very upset," and a Galena representative flew to Mobile in February 2014 to calm them down because they were "important individuals for Galena" and the company's "highest Abstral prescribers." Ruan and Couch demanded that Galena fire its CEO and board. Between March and October 2014, their Abstral prescribing plummeted. Ruan reached a low of 624,000 mcg in August 2014, but that month, Galena fired its CEO, and in November, the new CEO came to Mobile to meet Ruan and Couch at Ruan's demand. After that visit, their Abstral prescriptions again spiked, with Couch prescribing over 2 million mcg and Ruan prescribing over 1.8 million mcg in November. A similar dip in Ruan and Couch's Abstral prescribing in February 2015 matched a significant dip in Galena's stock price in February 2015, followed by another visit by the

CEO to Mobile, and a rebound in Ruan and Couch's prescribing.

Corin also explained that Galena initiated a voucher program in August 2013, where patients could receive up to three vouchers for 32 tablets of Abstral. Because TIRFs were so expensive, the purpose of the program was to help patients afford the drugs while they awaited insurance approval and to allow doctors to titrate patients onto the medication, with one voucher being issued at a time until an appropriate dose was found for a full prescription. However, Ruan and Couch would use all three prescriptions at once. Galena started losing money as a result of this practice because Galena would pay for all 96 pills instead of whatever vouchers were needed to titrate the patients, and Couch and Ruan were the top two prescribers in the country, accounting for 30% of the total prescriptions for Abstral. Under the voucher program, the pharmacy filling the prescriptions got paid the same as if the prescription was fully covered by insurance. And 91% of the Subsys and Abstral prescriptions Ruan and Couch wrote were filled by their patients at their own pharmacy, C&R. Galena had to abandon the voucher program in March 2014, and Ruan and Couch slowed their prescribing of Abstral in response to the cessation of the voucher program.

When PPSA was shut down in May 2015, national Abstral sales dropped "significantly." In fact, Galena was forced to sell its license for Abstral because it could not make up the lost revenue.

ii. The Appellants' Participation in Insys's Speaker Program

Natalie Perhacs ("Perhacs"), a former sales representative for Insys, testified that Insys also sought to influence Ruan and Couch's prescribing with money. Perhacs first met Ruan and Couch when she was a sales representative for a respiratory equipment company. Eventually, Ruan recommended Perhacs for a job at Insys. Perhacs became the Insys drug representative for Ruan and Couch. She explained that Insys had created a speaker program in August 2012 in which it paid doctors to talk about Subsys to other doctors, usually over a meal at a restaurant. Pharmaceutically-funded speaker programs are lawful, but payments made to doctors are required to be disclosed to the public. Both Ruan and Couch had been speakers for Insys since before she started. The stated goal of the speaker program was to educate doctors and get them to write more prescriptions, but Perhacs stated that Ruan and Couch would do speaker programs when no other prescribers showed up. She stated that PPSA was one of the top ten prescribers of Subsys, and Ruan and Couch were "whales" (the top prescribing doctors). She indicated that the actual purpose of the speaker program was to influence Ruan and Couch into continuing to prescribe Subsys, and Ruan and Couch were paid for their involvement in these dinners. In 2013, Ruan and Couch were each paid to host one program per week, and although no prescribers, or the same prescribers, would show up to speaking programs, they were rarely canceled because the point was not to educate others but to "influence how many prescriptions [the appellants] write." If a program was

canceled, Perhacs could be fired or face a financial penalty.

In November 2013, Ruan approached a Galena sales representative about becoming a speaker for Abstral because of his high-prescribing of TIRF medications, generally. However, Galena decided it would not make sense to have Ruan be a speaker because there were no other doctors in the area prescribing TIRF medications, and the purpose of the speaker program was to educate other doctors.

In early 2014, after the appellants started prescribing more Abstral, the competing TIRF medication, Insys employees grew concerned about losing market share. On an email including top Insys executives, the Vice President of Sales said that "Dr. Ruan and Dr. Couch are killing us." In April 2014, Insys reduced, but did not stop, the appellants' speaking programs.

A few months later, in June 2014, Ruan learned that a Michigan doctor, the top national Subsys prescriber, had been indicted for receiving kickbacks from Insys in part related to his acceptance of honoraria received from the speaker program. In that criminal complaint, which Ruan saw, Ruan and Couch are identified by prescriber number as the number three and five prescribers, respectively. The next day, Ruan began planning for Insys to donate all of his subsequent speaker fees to universities, in one case establishing a scholarship in his name.

Nonetheless, Insys paid Couch more than $100,000 and Ruan over $166,000 for speaking engagements from 2013 until the FBI raided PPSA in May 2015. In 2016, Perhacs pled guilty to conspiracy

to violate the Anti-Kickback statute by paying kickbacks to the appellants to prescribe Subsys through the speaker program.

iii. The Appellants Ordered Unnecessary Drug Tests and Used Their Pharmacy Inappropriately

Prescribing certain drugs when they had a financial self-interest to do so was not the only example of illegal conduct by Ruan and Couch: the government also sought to prove that they ordered unnecessary drug tests for patients solely because they would generate revenue. Government expert Dr. Rahul Vohra ("Dr. Vohra") explained that in pain management, drug testing patients can be a valuable clinical tool because it can tell a doctor whether the patients are not taking the drugs prescribed or are taking other drugs that they should not be. This testing comes in two forms: an in-office "cup" screening, which is instantaneous but less accurate, and an off-site test with gas chromatography and mass spectroscopy (GC-MS), which takes longer but is more accurate. In 2013, Ruan began ordering off-site GC-MS testing for every patient because, in his words, off-site testing "generates revenue," while in-office urine tests "pays nothing." Ruan negotiated with the off-site drug testing company, threatening to work with a competitor unless the company could start immediately because he was "losing about $8,000 a day from not testing and ... cannot just wait." Later that year, when PPSA switched to an electronic medical records system, and nurses forgot to order the GS-MS tests in the system for every patient, Ruan forwarded to Couch a discussion from the testing

company about the missing orders, estimating an annual lost profit of over $800,000. He told Couch, "[I]f we do not run GC-MS, there is no revenue."

Dr. Aultman and Dr. Vohra also explained that the proper way for a doctor to use drug screening is to counsel patients whose tests are inconsistent, indicating potential diversion or abuse of drugs, or to eventually "fire" them as patients. Yet the government presented evidence that Ruan and Couch rarely fired patients whose drug screens were inconsistent because they would lose the revenue. For example, a patient who was selling his medications was released from the practice only after his sixth or seventh inconsistent drug test using his five-year-old son's urine. Another patient, a former felon with numerous drug screens not showing prescribed drugs, was also continuously prescribed more opioids. An email Ruan wrote to a medical student was introduced, in which Ruan stated that "[i]n private practice the more you fire, the more revenue you lose." Instead, he opined, "when one patient tests positive for street drugs, that gives you more reason to do more frequent urine drug screens, which pays three times more than an office visit." While Ruan and Couch did not often fire patients with inconsistent drug screens, they did fire patients whose insurance would no longer pay for their TIRFs. For example, despite a history of drug abuse and three trips to the emergency room caused by her overusing TIRFs, Ruan dismissed patient Kathleen Burns only after her insurance stopped covering Subsys.

The government also put on evidence that Ruan and Couch used their pharmacy, C&R, inappropriately. Insys helped them prescribe more

Subsys by ensuring it would be in stock at C&R. C&R was "having trouble filling [Subsys] as often as it was written." This was even though, in 2014, C&R was ordering from wholesalers more than 42 times as much Subsys as the average U.S. pharmacy. Insys's owner and its CEO came to Mobile, and it was arranged that C&R would purchase Subsys directly from Insys, cutting out the wholesalers. Ruan and Couch also asked Galena to cut out the wholesalers and ship Abstral directly to C&R, but it refused. However, Galena did offer a rebate program under which C&R received 8.75% of the purchase price for all Abstral it dispensed. C&R dispensed nearly $13 million of Abstral, approximately half of which occurred after the rebate agreement, making its rebate to C&R more than half a million dollars.

Additionally, Ruan and Couch often prescribed medications based solely on what was in stock at C&R, rather than on the patient's medical needs. Nurse practitioners testified that Ruan "strongly encouraged" patients to use C&R and that staff took patients' prescriptions directly to C&R. One testified that Ruan "wanted to know what we [C&R] had in stock" before writing prescriptions. Dr. Greenberg opined that Ruan and Couch should have disclosed to patients that they owned C&R, but they rarely did.

4. Ruan and Couch Often Prescribed Opioids Without Seeing Patients, Obtaining Informed Consent, or Keeping Accurate Records

Another way that the government sought to establish that PPSA operated outside the usual course of professional practice was to show that Ruan and Couch prescribed powerful opioids without actually

seeing patients. The government's medical experts testified that before prescribing controlled substances, a doctor should see the patient, take a medical history, and do an exam. A doctor who conducts a thorough evaluation of each patient can normally see 20 to 25 patients per day, but PPSA routinely processed 150 to 200 patients daily, often quadruple-booking patients for the same time. This worked because many PPSA patients never saw Couch and rarely saw Ruan. In fact, one patient for whom Couch signed multiple prescriptions and another patient's wife who came to half of her husband's appointments could not identify Couch in court because they had never met him. Others said they had met him only once, despite multiple PPSA visits during which he signed prescriptions for them. Instead, patients were seen by nurse practitioners who were not doctors, namely Justin Palmer, Stacy Madison, Bridgette Parker, Matt Bean, and Sharon Noland.

The jury was able to see this practice firsthand as DEA task force officer Patrick Kelley ("Kelley" or "Officer Kelley") went undercover to PPSA as a patient under the alias "Shawn Brennan" in August 2014. Kelley testified, and undercover videos of his PPSA office visits were played for the jury. The DEA arranged for a local chiropractor to refer Kelley to Couch with medical records, including normal MRI results. Although Kelley was first turned away from PPSA because he did not have insurance, he was admitted later that same day after the chiropractor called PPSA to vouch for him. Rather than see Couch, Kelley saw a nurse practitioner, Stacy Madison ("Madison), who took a brief medical history from Kelley but did not question him about his pain levels,

even though he had deliberately left that question blank on the new patient form. Kelley was asked to bend forward as far as he could without pain, and he was able to touch the floor. Nonetheless, he was asked whether he had previously taken anything that helped with his pain. Kelley started his answer with the caveat that he was "going to have to admit to some criminal activity" and said that he had "blue" pills called "Roxy"— purposefully using street names for Roxicodone 30 mg, an "immediate release" version of oxycodone that is popular among substance abusers. Couch made a 42-second appearance at the end of that visit and signed a 90-pill prescription for Roxicodone 30 mg. Kelley returned for four more visits, never saw Couch again, and received Roxicodone prescriptions each time. At his third visit, the nurse practitioner, now Bridgette Parker ("Parker"), increased his dose to 110 pills. Kelley never filled the prescriptions, which a check of Alabama's PDMP would have revealed, and urine tests did not show the drugs in his system, but no one at PPSA ever discussed that with him. Parker also gave Kelley signed prescriptions, dated for a month later than his visit, although regulations provide that physicians must write a separate prescription for each 30-day supply of a Schedule II drug and prohibit a single prescription with refills. The prescriptions Kelley received at three of these visits to PPSA were the basis for Couch's convictions for illegal drug distribution on Counts 5–7.

Two undercover DEA agents posed as patients of Ruan's as well, but Ruan never prescribed either patient opioids. The government moved *in limine* to exclude videos of these visits, arguing that they did not show anything illegal and Ruan was merely trying

to prove that he practiced "good medicine." The district court agreed, so the jury never saw them.

Nurse practitioner Justin Palmer ("Palmer") also offered extensive testimony for the government, particularly about Couch's practice. Palmer had worked at PPSA since July 2010, first working with both Couch and Ruan but after about a year working almost exclusively with Couch. Palmer stated that he would see roughly 30 patients a day on Couch's behalf, often starting hours before Couch arrived at the office. Some patients believed Palmer was a doctor, referring to him as "Dr. Justin." Palmer's visits were billed to insurance as if Couch was the one seeing the patients. Palmer also wrote prescriptions for opioids under Couch's signature, even though Palmer was not authorized to prescribe Schedule II drugs. When Couch went on vacation, "he would leave prescription pads that were presigned so [Palmer] could write what [he] needed to." Couch continued doing this even after PPSA's practice administrator told him it was illegal and risky. In time, Palmer began forging Couch's signature on prescriptions. PPSA and C&R staff knew Palmer was doing this, and nurses and the pharmacist would ask him to sign Couch's name on prescriptions and records. At one point, Couch caught Palmer forging his name on a prescription for Adderall, a Schedule II drug, and fired him—but only for "10 minutes"—before deciding to give him a second chance and rehiring him. Palmer stated that he believed that Couch continued to be aware of his forgery because Palmer was seeing patients when Couch was on vacation or out of the office. Palmer estimated that, between 2011 and 2012, he had forged Couch's signature 15 to 20 times a day.

Palmer also purchased Galena stock when Ruan and Couch did. After that, he and Couch discussed candidates that they believed could be suitable for Abstral, and it was suggested that Palmer find people to put on the drug. Palmer also confirmed that he prescribed TIRF drugs to non-cancer patients for breakthrough pain, such as migraines that did not respond to other medication.

Palmer testified that, while at PPSA, he observed what he believed to be drug-seeking behavior from patients, such as patients needing more and more medication, saying that they had lost medication, coming back early for refills, or saying that they had new pain. He stated that he would often have to argue with patients because he believed that their pain was not as severe as they were reporting. The government asked:

Q: Did you feel like you were overwriting?

A: I did.

Q: Approximately what percentage of the patients did you feel like were overwritten?

A: At least—at least half, half to maybe more.

Palmer also stole and abused medications from PPSA while working there. After a PPSA employee caught Palmer actively injecting drugs while at work, Couch suspended him with pay for two weeks. According to Palmer, nurse practitioners Parker and Madison also used drugs while working for Couch. Prior to trial, Palmer pled guilty in this action to conspiracy to distribute controlled substances outside the usual course of professional practice and without a legitimate medical purpose.

Nurse practitioner Sharon Noland ("Noland") also testified for the government. She had worked at PPSA since November 2011, working solely for Ruan until May 2014. She testified that Ruan would prescribe certain drugs—which Noland called the "flavor of the day"—based on what speaker programs he was doing and what was being pushed by "drug reps," even if the patient's pain was controlled on an existing regimen. She described that Ruan was "very involved with the practice," agreeing with the government's characterization that he tended to "micromanage." Noland said that she witnessed Palmer signing prescriptions as Couch.

Nurse practitioner Parker also testified. She had worked at PPSA from September 2012 to January 2015, working solely for Couch since December 2013. Parker testified that although TIRF medications were indicated for cancer, Ruan used it off-label "for anything we could use it on." Parker also testified that Ruan would change patients' medications, adding TIRF medications to their regimen, when their prior medications were working. Ruan would also change patients from one TIRF medication to another without explanation. Parker confirmed that Palmer would sign Couch's name on prescriptions, and she stated that she believed that half of the patients at PPSA were overmedicated, basing her opinion on the fact that the patients "looked ... overmedicated, wanted more medication." Parker also abused prescription drugs while at work, even going into withdrawal, and Couch agreed to help pay for her treatment. Like Palmer, Parker pled guilty prior to trial in this case to conspiracy to distribute controlled substances.

Ruan was aware of Couch's practice of permitting Palmer and others to see patients and write prescriptions on Couch's behalf. In July 2014, for example, Ruan sent an email to Couch asking Couch to "talk to Justin [Palmer] on cutting down" the amount of Roxicodone 30 mg he prescribed in light of news reports that Alabama had the most opioid prescriptions in the country, which Ruan feared could increase regulatory scrutiny of PPSA.[5] Couch responded that "[w]e," meaning he and Palmer, would not "write triple digit dispentions [sic] of short acting opioids." And although Ruan usually signed his own prescriptions, he often did so without seeing patients. Several nurse practitioners testified that they would line up at Ruan's office for him to sign prescriptions. One patient testified that he did not meet Ruan until

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[5] The full email reads as follows:

I noticed you have quite a few [patients] on Roxicodone 30mg ... and Oxycontin 80mg.

Based on the diversion study done in FL pill mills, these two are the most[ ] thought of in South FL, therefore [they are] considered [the] biggest reg [sic] flag[s]. I think you should talk to Justin [Palmer] on cutting down Roxicodone 30mg usage, especially [because] we are trying to convince [the] AL board of medical examiners that we have a great system to keep [patients] satisfied[ ] and addicts out. We [do not] want Roxicodone 30mg [to] mess things up, or at least contradict[ ] .. what we promote. I believe I have two [patients] on oxycodone 30mg, one of them is a W/C, cannot handle all others. Also, try to use Oxycontin 60mg instead of 80mg may also help.

Now, everyone in the nation knows that AL state prescribes the most pain killers in the nation, [so] we will need to adjust our routine regimen a bit. One of the things I have done is to wean off on [benzodiazepines], or ask their [primary care physician] to write their [benzodiazepine], as [benzodiazepine] prescription is also one of the things they look at and[ ] [w]e would rather be careful than sorry. Please remind [Palmer] about this stuff.

his "fourth or fifth visit" when Ruan "stuck his head in the door" to introduce himself.

The government's experts also explained to the jury that the usual course of professional practice is to obtain patients' informed consent before administering drugs and to have accurate records supporting every prescription. But there was evidence presented that many patients received no warnings before receiving prescriptions for powerful opioids. And many PPSA records contained numerous errors, including not listing all prescriptions written or explaining why a prescription was changed. Patients testified that exams and tests listed in their medical records did not occur.

5. Specific Prescriptions Were Illegal

Aside from evidence pertaining to how Ruan and Couch operated PPSA, the government also put on evidence that Ruan and Couch treated approximately three dozen specific PPSA patients outside the usual course of professional practice or prescribed them medications for no legitimate medical purpose. Fourteen patients, or their family members, testified at trial, criticizing the care they received. The government's three medical experts, Dr. Aultman, Dr. Vohra, and Dr. David Greenberg ("Dr. Greenberg"), reviewed other patients' files and offered their opinions that the appellants' treatment of those individuals did not meet the usual course of professional practice standard. Evidence was presented that Ruan and Couch rapidly increased patients' opioid dosages beyond the minimum necessary for pain control and failed to refer patients for mental-health treatment, surgery, or physical therapy that their records indicated would have been

appropriate. They prescribed powerful opioids to people displaying red flags for diversion and abuse, like criminal records, inconsistent drug screens, and drug-seeking behavior. Some patients testified that they were overmedicated on opioids, making their lives worse.

For example, patient Randall Blackmon ("Blackmon") testified that he saw Couch on his first visit to PPSA but only saw Palmer on subsequent visits. Blackmon was prescribed morphine, methadone, and Subsys, even though he did not have cancer; a physical examination was never conducted; and no one warned him that Subsys could interact negatively with his existing medications. He took 1600 mcg of Subsys four times a day for eight months, and he claimed that it made him lethargic and ruined his quality of life. Towards the end of the eight months, he presented to his primary care physician in such a dire state on Subsys that he was taken directly to the emergency room. At that point he learned that Subsys was only recommended for cancer patients, and his insurance stopped covering it. By that time his insurance had paid over $21,500 per month for his Subsys.

Similarly, patient Joyce Barber ("Barber") was never treated by Couch, only Madison. She was prescribed Subsys with no warnings of the risks, and although she did not have cancer, PPSA staff reported to her insurer that she had uterine cancer so that her Subsys prescription would be covered. Barber testified that Subsys made her feel like she was in a fog, and when Madison increased her prescription from 200 mcg to 400 mcg, she became addicted, slept all day, and had no quality of life.

Patient Tina Goellner never saw Couch as a patient of PPSA. She recounted that, although she told staff at her first visit that she did not want to be prescribed narcotics for her pain because she was worried about becoming addicted, she was prescribed Subsys anyway and told that she should not worry because she did not have an "addictive personality." Subsys made her sleepy within two minutes of taking it, and when her dosage was increased rapidly from 200 mcg four times a day, to 400 mcg four times a day, to 800 mcg four times a day, she began sleeping all day.

Patient Tamison Blanks ("Blanks") testified that she saw Couch once for five minutes despite going to regular appointments at PPSA for over 11 months. Although she was already taking Soma and hydrocodone (brand name Norco), she was prescribed 600 mcg of Subsys to use four times a day on her first visit, with no warnings. She described her dosage as "very strong" and said that she became a "monster" on Subsys. She described an instance where the Subsys numbed her to the point that she lay on a heating pad for so long that it burnt her breast, requiring a visit to the emergency room. She also said that at one of her appointments at PPSA, nurse practitioner Parker had abused opioids to the point that she was talking incoherently and fell asleep for about 10 minutes. Blanks commiserated with Parker's predicament because she had been in the same situation, and left that appointment and immediately checked in to a rehabilitation center.

In an attempt to contrast testimony like the foregoing, Ruan and Couch sought to call patients who would have testified that they approved of their

treatment by Ruan and Couch and that their treatment enabled them to have a better quality of life. However, the district court ruled that because the appellants were not charged with illegally prescribing medication to all of their patients, and the government acknowledged that they had many patients to whom they provided legitimate care,[6] this "good patient" evidence was irrelevant to the charges and would waste time in an already lengthy trial. They were thus prohibited from calling patients not identified in the Superseding Indictment or otherwise presented throughout the government's case, but they were, however, able to call as witnesses patients whose files were discussed by the government's experts.

6. The Appellants Engaged in Fraud, Accepted Kickbacks, and Ruan Laundered the Proceeds

Aside from violating the Controlled Substances Act, the government also presented evidence that the appellants engaged in fraud. Ruan and Couch lied to insurers, telling them that some patients had cancer so that insurers would pay for their TIRF prescriptions. BlueCross BlueShield of Alabama ("BCBS"), which insured a large portion of PPSA's patients, paid less for nurse practitioner visits than for doctor visits and had a policy requiring a physician to actually see a patient before billing for services under the physician's name, yet Ruan and Couch routinely billed BCBS for office visits conducted entirely by nurse practitioners under the doctor's

[6] Indeed, despite the Superseding Indictment calling PPSA a "pill mill," by the time of trial the government began referring to it as a "money mill" instead.

identification number. The appellants also billed for more complex office visits than they actually conducted, resulting in more revenue.

To support the charges alleging conspiracies involving kickbacks, Perhacs testified that the fees Ruan and Couch received from the Insys speaking engagements were solely to induce them to prescribe more Subsys. Separately, the government sought to prove that the company that managed PPSA's in-house workers' compensation dispensary gave illegal kickbacks to Ruan and Couch in exchange for referring their patients. Christopher Manfuso ("Manfuso") testified that Ruan and Couch treated patients with work-related injuries covered by workers' compensation insurance, which most workers get through a state program. For patients' convenience, Alabama's workers' compensation program permits doctors to have an in-office dispensary for workers' compensation patients. Unlike a pharmacy, a dispensary provides only prepackaged medication. Insurers, including the workers' compensation program, "apply a steep discount" to medication dispensed at a pharmacy and billed electronically. But in a dispensary, the state sets the prices for medications, and Alabama's fee schedule is "quite generous compared to commercial insurance." Accordingly, "there's more money to be made" with a dispensary than sending workers' compensation patients to a pharmacy, even one owned by the doctor; the revenues can be "about a hundred percent higher."

The appellants ran such a dispensary at PPSA's Springhill location to dispense drugs to patients covered by workers' compensation insurance. In 2011,

Industrial Pharmacy Management ("IPM") approached the appellants about taking over the management of their dispensary. When working with an outside company like IPM to manage a dispensary, the management company usually fronts the money to purchase the medications under the doctor's DEA number and then reimburses itself from the gross receipts. The management company then deducts its management fee, usually 30%, and any additional costs, and the doctor is left with the remaining profit. With their previous management company, Ruan had been receiving around $40,000 a month in profit from PPSA's dispensary. To "induce [the appellants] to sign up with" IPM, Manfuso, an IPM representative, offered to deviate from the standard payment model and guarantee Ruan $45,000 a month—regardless of how much or how little the dispensary actually profited—because it was "the only way [he] could get the business." Over the next two years, Ruan executed several variations of this contract with IPM, negotiating on behalf of both himself and Couch. Ruan's guarantees fluctuated between $45,000 and $53,000 a month. Couch received guaranteed payments in the $15,000-to-$20,000 range. To hide this difference from Couch, Ruan insisted that Manfuso send the checks to his house, not to PPSA.

After several years, the FBI raided and shut down IPM for paying kickbacks, and Michael Drobot, Manfuso's direct boss at IPM, pled guilty to providing kickbacks in a California prosecution. Manfuso then opened his own company, Comprehensive RX Management ("CRM"). Ruan demanded even higher guarantees from CRM, upwards of $80,000 a month at one point. All told, Ruan received more than $2.4

million and Couch received nearly $1 million from IPM and CRM.

Manfuso recalled that his interactions with Ruan were "[e]xtremely atypical" of the hundreds of other doctors with whom Manfuso worked. In determining how to stock the formulary (the dispensary's inventory of drugs), Ruan was interested in the profit margins of various drugs, not clinical information. Manfuso also ultimately pled guilty to violating the Anti-Kickback statute.

Finally, to support the three money laundering counts, the government presented evidence that Ruan had 23 different bank accounts and used proceeds from illegal activities to purchase two luxury cars, worth over $100,000 each.

7. The Defense Case

Ruan and Couch testified in their defense, both stating that their various policies and practices were within the usual course of professional practice. Couch denied ever giving Palmer permission to sign his name on a prescription. On cross-examination, the government asked Ruan about the email that he sent to Couch regarding Palmer writing fewer Roxicodone prescriptions. The following exchange occurred:

Q: Okay. Now, is this one of the things you told [Couch] is: Please remind [Palmer] about this stuff.

A: That's what it said.

Q: Because you knew that [Palmer] was writing [prescriptions for Roxicodone]; correct?

A: He was initiating, I thought, not that he was—he saw the follow up and he initiated

it. Dr. Couch had to approve. So if he initiated it, Dr. Couch do [sic] not want to turn it down.

Q: But you had knowledge that [Palmer] was—you wanted [Palmer] to cut down the [Roxicodone]; is that correct?

A: Initially, yes. That's my intention; that's right.

Q: And Dr. Couch told you back that he reviewed it with [Palmer] and it says: We do not write triple digits; is that correct?

A: Yes, that's what it says.

Q: It says "we?"

A: Right.

Ruan and Couch also called various PPSA employees and five patients identified by the government who testified favorably as to their course of treatment at PPSA. They called three experts, Dr. Carol Warfield ("Dr. Warfield"), Dr. Christopher George Gharibo, and Dr. Jeffrey A. Gudin. Dr. Warfield opined that Dr. Couch's prescribing habits were within the usual course of professional practice and for a medical purpose. Specifically, Dr. Warfield reviewed files for five of Couch's patients, and she testified that the medications Couch prescribed were in the usual course of medical practice and for a legitimate purpose. The other experts testified similarly.[7]

[7] Where necessary below, additional trial evidence is discussed regarding some issues.

C. Forfeiture and Ruan's Sentence

Immediately following the verdict, Ruan signed a forfeiture agreement, stipulating that he "w[ould] not oppose the entry of a Preliminary Order of Forfeiture, forfeiting the above-listed assets and sums of money." He agreed to forfeit various bank accounts, two real properties, and 18 cars, and to the entry of a money judgment "for a sum of money of at least $5,000,000." The following week, the district court entered a Preliminary Order of Forfeiture pursuant to this agreement. This order became final at sentencing.

In Ruan's presentence investigation report ("PSR"), the probation officer applied a base offense level of 38 under U.S.S.G. § 2S1.1, based on an underlying offense of drug conspiracy for which the government asserted that Ruan was accountable for the equivalent of 309,872 kilograms of marijuana. Ruan then received a two-level enhancement under U.S.S.G. § 2S1.1(b)(2)(B) because he had been convicted of violating 18 U.S.C. § 1956. He received another two-level enhancement for abusing a position of public trust, pursuant to U.S.S.G. § 3B1.3. Finally, Ruan received a two-level obstruction-of-justice enhancement for testifying falsely at trial pursuant to U.S.S.G. § 3C1.1. The PSR calculated the adjusted offense level as 44, but because the offense level exceeded the maximum level used in the guidelines, which is 43, the PSR treated Ruan's total offense level as 43. Because Ruan had no criminal history, he was attributed a criminal history category of I.

Based on an offense level of 43 and a criminal history category of I, the PSR noted that the guideline imprisonment range was simply "life." However, the statutorily-authorized maximum sentences for each of

the convictions were less than the applicable range. Specifically, the PSR noted that the maximum term of imprisonment was: (1) 20 years for each of Counts 1, 2, 4, 8, 9, 11, and 12; (2) 40 years for Count 3; (3) 10 years for each of Counts 15, 18, 19, 20, 21, and 22; and (4) 5 years for each of Counts 16 and 17. Pursuant to U.S.S.G. § 5G1.2(b), the probation officer converted the statutory maximum penalties to months and added them together, arriving at a guideline range of 3,000 months. The probation officer also determined that Ruan owed restitution totaling $17,261,859.14 to various insurance companies that had paid for illegal prescriptions.

Ruan objected to the PSR and filed a sentencing memorandum, and the government responded to his objections. Ruan first objected that the government's drug-quantity calculation grossly overestimated the number of relevant prescriptions. The government responded that the district court needed only to approximate the quantity of controlled substances that were within the scope of the criminal activity that Ruan jointly undertook. The government explained that to reach that total drug quantity, the government requested data of all controlled substances that PPSA prescribed during the relevant period, and then reduced the list to only morphine, oxycodone, methadone, hydromorphone, oxymorphone, and fentanyl. The government then calculated the total number of grams prescribed of each individual drug by first multiplying the number of units of the drug prescribed by its strength and converting that result to grams. Then, the government calculated the total amount of each drug and converted these totals to their marijuana equivalents. In determining how many of those prescriptions were illegal, the

government acknowledged that not all prescriptions were illegal. However, the government noted that there was testimony from several witnesses, including nurse practitioners Palmer and Parker, who roughly estimated that 50% of the patients were illegally prescribed controlled substances. However, the government also stated that the ascribed offense level would still have been appropriate even if only 10.6% of the prescriptions written by Ruan and Couch were illegal. The government argued that sufficient evidence at trial was presented for the court to find that at least 10.6% of the prescriptions were written outside the usual course of professional practice, including: the manner in which Ruan and Couch prescribed opioids was consistent across time and patients; Couch rarely saw patients during follow up office visits; prescriptions were written in Couch's name by Palmer, which both doctors knew about; 5,793 prescriptions were written in Couch's name when he was out of the state or country; patients were seen and prescribed opioids before Couch would arrive to work at PPSA; and Couch and Ruan prescribed medication when they had a financial self-interest to do so.

Ruan disagreed, contending that the drug quantity should have been based on what was proven at trial through expert or patient testimony, and he argued that any reliance on Palmer's or Parker's statements as to 50% of the prescriptions being unlawful would be improper because (1) there was no established basis for their opinions, (2) they worked at a different location than Ruan, and (3) they lacked the ability or expertise to reach their conclusions. Ruan also offered DEA publications, which he stated

showed that the average sentence for cases with between 1 and 5 distribution counts was 83.4 months.

Ruan also adopted Couch's arguments at sentencing, among them that other circuits followed a more nuanced approach in calculating drug quantities attributed to physicians because doctors' prescriptions were presumed to be legal. He also asserted that courts should exclude any prescriptions that merely breach the civil malpractice standard because that standard did not establish criminality. He noted that, despite the government having Palmer on the stand for several hours, the reference to the 50% figure lasted mere seconds, and the government could have elicited more details from Palmer, such as explaining whether the term "overmedicated" referred to a breach of the civil standard of care or to prescriptions outside the usual course of professional practice.

Ruan's second objection to the PSR was to the restitution calculation. The government explained that it calculated restitution by taking the total paid for medications by insurers BCBS, United Healthcare, Medicare, and Tricare, and first deducted the payments each made for non-controlled substances and Schedule IV and V controlled substances. Then, the government deducted 15% of the total each insurer paid for TIRF prescriptions, based on testimony that no more than 15% of PPSA patients were cancer patients. The government finally deducted 50% from the amounts each insurer paid for the remaining Schedule II prescriptions based on the testimony that 50% of PPSA patients were overmedicated. Ruan responded, with regard to the illegal TIRF prescription percentage of 85%, that off-

label TIRF prescriptions were not inherently illegal. He pointed out that insurance companies, including BCBS, sometimes approved such prescriptions, and that Dr. Aultman had agreed that prescribing off-label is not illegal. He also argued that the 50% figure as to the remaining Schedule II drugs was speculative, and the government should provide specific evidence as to why each prescription paid for by each insurer was fraudulent.

Ruan's third objection was to the obstruction-of-justice enhancement. In response, the government stated that Ruan testified falsely when he stated that he was unaware that Palmer was forging Couch's prescriptions. In an email, Ruan reminded Couch to talk to Palmer about not prescribing "red flag" drugs, and testimony from other PPSA employees and patients established that nearly everyone was aware that Palmer was prescribing controlled substances in Couch's name. The government pointed out that Ruan had a financial interest in that activity because prescriptions forged by Palmer could be filled at C&R.

At sentencing, Ruan reiterated these arguments.[8] He also argued that: (1) he prescribed half the number of drugs that Couch did; (2) he exercised greater oversight over his nurse practitioners than Couch had; (3) he had an excellent national reputation; and (4) despite some mistakes, he practiced good medicine and legitimately helped patients. The government responded that: (1) Ruan was the leader of PPSA and that every aspect of the

[8] The district court ruled on the appellants' common objections at Couch's sentencing, which was the day before Ruan's. Ruan's attorney participated in these portions of Couch's sentencing.

illegal activity was led and directed by him; (2) he made a variety of decisions in his practice based on whether he would make money off of them rather than whether it would benefit the patient being treated; and (3) he had a variety of valuable assets that he attempted to hide.

The district court found that Ruan was the leader of the fraud offenses and racketeering enterprise. The court noted that Ruan was the "better doctor"—insofar as he had more board certifications and degrees—but it was his making the business decisions that necessitated a higher sentence. The district court stated that it recalled testimony that 50% of the prescriptions written were not for a legitimate medical purpose and stated that using this testimony was a reasonable way for the government to calculate the drug-quantity and restitution amounts. The court found that the government had showed that at least 10.6% of the prescriptions were written outside the usual course of professional practice, and it concluded that the appropriate base offense level was 38. The district court also found that the obstruction-of-justice enhancement was appropriate because it concluded that the email from Ruan to Couch about Palmer was a clear indication that Ruan was aware of Palmer forging prescriptions. The court sentenced Ruan to 252 months' imprisonment, varying downward because Ruan did not have a criminal history and because the court believed that the sentence reflected the seriousness of the offense and the need for punishment, deterrence, and incapacitation. It also ordered Ruan to make restitution as described in the PSR. Lastly, the district court finalized a preliminary order of forfeiture as to Ruan.

II. Discussion

A. Sufficiency of the Evidence

Ruan challenges the sufficiency of the evidence on all counts against him. Couch joins Ruan's arguments as to their joint convictions—Counts 1–4, 15–17, and 19.[9]

This Court "review[s] the sufficiency of the evidence *de novo*, viewing the evidence and all reasonable inferences and credibility choices in favor of the government and the jury's verdict." *United States v. Ignasiak*, 667 F.3d 1217, 1227 (11th Cir. 2012). "A conviction must be affirmed unless there is no reasonable construction of the evidence from which the jury could have found the defendant guilty beyond a reasonable doubt." *Id.* As we explain below, we conclude that the evidence presented at trial was sufficient to convict the appellants on all of the counts that are challenged, except Count 16 charging both appellants with conspiring to violate the Anti-Kickback statute based on their operation of PPSA's in-house workers' compensation dispensary.

1. Counts 8, 9, 11, and 12: Substantive Drug Distribution Against Ruan[10]

Counts 8, 9, 11, and 12 of the Superseding Indictment alleged that Ruan's prescribing of opioids

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[9] Couch does not challenge on appeal the sufficiency of the evidence on Counts 5–7, substantive drug distribution charges based on the prescriptions he wrote for Officer Kelley, or on Counts 13 and 14, substantive drug distribution charges based on prescriptions he wrote for his patients Kenneth Daves and Patrick Chausse.

[10] We discuss the various counts of conviction slightly out of order for ease of analysis.

to four specific patients violated 21 U.S.C. § 841(a)(1), and 18 U.S.C. § 2. In the medical context, drug distribution in violation of § 841(a)(1) requires proof that either "1) the prescription was not for a 'legitimate medical purpose' *or* 2) the prescription was not made in the 'usual course of professional practice.'" *United States v. Joseph*, 709 F.3d 1082, 1102 (11th Cir. 2013) (quoting *United States v. Tobin*, 676 F.3d 1264, 1282 (11th Cir. 2012)). "The mens rea required for a conviction under section 841(a)(1) is 'knowledge, not willfulness.'" *Id.* (quoting *Tobin*, 676 F.3d at 1279–80). Ruan was charged and convicted as both a principal, 21 U.S.C. § 841(a)(1), and an aider and abettor, 18 U.S.C. § 2. To sustain a conviction under 18 U.S.C. § 2, "the prosecution must show that 'the defendant associated [him]self with a criminal venture, participated in it as something [ ]he wished to bring about, and sought by [his] actions to make it succeed.'" *Id.* (quoting *United States v. Pantoja-Soto*, 739 F.2d 1520, 1525 (11th Cir. 1984)).

i. Count 8: Prescriptions Ruan Wrote on February 26, 2015 for Diane Greathouse

Count 8 charged that six prescriptions Ruan wrote for patient Diane Greathouse ("Greathouse") on February 26, 2015—two for 400 mcg each of the TIRF medications Abstral and Subsys, one for 40 mg of OxyContin (an extended release oxycodone), and one for 10 mg of Norco—amounted to unlawful drug distribution. Government expert witness Dr. Greenberg reviewed Greathouse's file and testified at trial that those prescriptions were not for any legitimate medical purpose and that Ruan's overall treatment of Greathouse, including prescribing them,

was outside the usual course of professional practice. In support, Dr. Greenberg stated that Ruan prescribed Greathouse Abstral and Subsys, two TIRF medications that are intended for cancer treatment, although she did not have cancer. Additionally, in his opinion, Ruan's choice to prescribe both Abstral and Subsys, different formulations of the same drug, "makes no sense." Dr. Greenberg further explained that Ruan was already prescribing Greathouse such high doses of opioids that she could be "in a stupor and ready to fall into a coma", but then had tried to counteract those effects, not by discontinuing the opioids but by improperly prescribing Provigil, an amphetamine, to the mixture of drugs. He also noted that Ruan had previously prescribed Greathouse a naloxone (brand name Narcan) injector, which is used as an antidote for fentanyl overdoses, without her informed consent and without ensuring that her family members, who would be the ones using it in case of her overdose, had CPR or other relevant training.

Ruan's principal argument in support of his claim that the evidence was insufficient to convict him on Count 8—as well as on Counts 9, 11, and 12—is that Dr. Greenberg's testimony was unreliable. Ruan draws our attention to the fact that on the Monday following Dr. Greenberg's testimony at trial, which had concluded the previous week, government counsel alerted the district court and defense counsel, through a motion filed under seal, that Dr. Greenberg had notified them over the weekend that he thought he had early-onset dementia and was consulting a neurologist. During a hearing outside the presence of the jury, government counsel expressed misgivings about some of Dr. Greenberg's testimony, represented

that he had offered to refund monies and not charge for his trial testimony and that the government intended to accept his offer, but indicated that the government wanted to gather more information before deciding whether to ask for a specific jury instruction on the issue.

Despite this troubling circumstance, Ruan cannot succeed on his insufficiency of the evidence argument. Neither Ruan nor Couch asked the district court to provide the jury with the government's disclosure concerning Dr. Greenberg's mental health. Rather, at the in-chambers hearing, Couch's attorney noted that the standard for competency is "fairly liberal," recounted that Dr. Greenberg had been cross-examined, and mentioned that "we don't think that there's anything there." Ruan's attorney said nothing. The district judge stated, "I don't think there's any question that he was competent to testify," suggested that the issue merely related to Dr. Greenberg's credibility, and decided to await more information from the government, if any materialized. No further information was presented by the end of trial.

Considering the foregoing, to the extent Ruan asserts that the jury should have been made aware that Dr. Greenberg thought he may have a mental health issue, our review of that claim is limited to plain error because Ruan never preserved the issue. *See* Fed. R. Crim. P. 52(b) ("A plain error that affects substantial rights may be considered even though it was not brought to the court's attention."). And although Dr. Greenberg was the sole government expert witness relating to the four substantive drug distribution counts charged against Ruan, defense counsel rigorously cross-examined him, during which

time, as discussed in further detail below, he admitted to several errors and omissions in his testimony and even changed his opinion on several points. Thus, the jury was aware that Dr. Greenberg's testimony was not infallible. We thus cannot say that, even if the jurors had known of Dr. Greenberg's disclosure to government counsel, they "could not have found [Ruan] guilty under any reasonable construction of the evidence." *Ignasiak*, 667 F.3d at 1229 (quoting *United States v. Merrill*, 513 F.3d 1293, 1299 (11th Cir. 2008)).

Aside from Dr. Greenberg's credibility, Ruan also argues that the evidence was insufficient to convict him on Count 8 because the jury heard during Dr. Greenberg's cross-examination that (1) the medications Ruan prescribed Greathouse alleviated her pain and enabled her to continue working, (2) the Centers for Disease Control and Prevention recommend Narcan when a patient is at risk for opioid overdose, and (3) the FDA authorizes the manufacture of larger doses of Subsys and Abstral than what Ruan prescribed. We are not persuaded that reasonable jurors could not have found guilt after hearing this evidence. Dr. Greenberg testified that if Greathouse was able to work it would only be because of the amphetamines Ruan prescribed her and prescribing those was "simply way below the rational standard of care for dealing with people who are in a near overdose state." He further explained that subsequent studies had shown that Narcan did not always work as intended when given by a family member instead of a medical professional and would not help a patient, like Greathouse, who was also taking other drugs with sedative effects, including benzodiazepines. The jury was entitled to credit Dr. Greenberg's testimony.

Sufficient evidence supports Ruan's conviction on Count 8 for drug distribution.

ii. Count 9: Prescriptions Ruan Wrote on April 27, 2015 for Kim Lowe

Count 9 was based on three prescriptions Ruan wrote on April 27, 2015, to patient Kim Lowe ("Lowe") for 600 mcg of Fentora, which is a fentanyl lozenge, and 80 mg and 15 mg of the opioids OxyContin and oxycodone, respectively. Dr. Greenberg reviewed Lowe's file and testified at trial that those prescriptions were not for any legitimate medical purpose and that Ruan's overall treatment of Lowe since January 2009 was outside the usual course of professional practice. Dr. Greenberg specifically stated that Ruan acted outside the usual course of professional practice when he: (1) failed to take down Lowe's history of illnesses and medications; (2) failed to refer her for mental health treatment despite her general complaints of "severe pain over her entire body" lasting more than 20 years, which Dr. Greenberg opined was a "red flag" for a psychiatric problem given that there are few diseases that can cause such symptoms; (3) failed to obtain Lowe's informed consent prior to prescribing her a combination of oxymorphone (brand name Opana), OxyContin, Xanax, oxycodone (brand name Percocet), Lunesta sleeping pills, and Soma; (4) prescribed Lowe, who did not have cancer, the fentanyl lozenge, which Dr. Greenberg described as an "end-of-life drug that is only approved by the FDA for people who are in the last stages of their lives with cancer"; (5) failed to counsel her when she ran out of medications prematurely, which suggested that she was either

taking more than what was prescribed or diverting medications; and (6) ignored positive urine screening test results for hydrocodone and fentanyl at a time when Ruan was not prescribing her those medications.

Ruan points out that on cross-examination, Dr. Greenberg was shown a part of Lowe's medical file dating back to 2008 that he had never seen before that revealed that Ruan did in fact do an initial exam, record Lowe's medical history, and review information from her referring physician when he first saw her as a patient. Dr. Greenberg was also shown where Lowe kept a pain diary and communicated her perceived levels of pain to Ruan. Additionally, Lowe herself testified for the defense, stating that Ruan did more than just prescribe opioids; his treatment of her included a back brace, various nerve and facet blocks, injections, epidurals, physical therapy, and ointments. Although Lowe believed that the medications Ruan prescribed medically benefited her, she also had trouble remembering that she had been a patient of Ruan's since 2009, believing instead that she had only seen him for the past three years. The jury was entitled to credit Dr. Greenberg, a physician, over Lowe, and even if Lowe felt that she benefitted from the medications Ruan prescribed, a reasonable jury could nonetheless conclude that the manner in which Ruan prescribed them was outside the usual course of professional practice. Sufficient evidence supports Ruan's conviction on Count 9 for drug distribution.

iii. Count 11: Prescription Ruan Wrote on November 25, 2014 for Deborah Walker

Count 11 addressed a prescription for the opioid Opana that Ruan wrote for patient Deborah Walker ("Walker") on November 25, 2014. Dr. Greenberg testified that Walker came to Ruan 11 months earlier, in January 2014, seeking pain medication shortly after completing a 19-month prison sentence. Dr. Greenberg considered prison time a "giant red flag" for drug-seeking behavior but noted that he did not see any indication that Ruan had asked Walker whether she was incarcerated due to a drug-related crime. He also criticized Ruan's failure to refer Walker to a psychiatrist when it was noted in her file that she had bipolar disorder with schizophrenic features. Dr. Greenberg also opined that Ruan should have suspected diversion and counseled Walker on such matters when a urine test performed during that January 2014 visit did not detect Soma and hydrocodone, drugs that he thought Ruan had recently prescribed her. In Dr. Greenberg's view, it was improper for Ruan to have prescribed Opana because it is the "most sought[ ]after prescription drug by people who are heroin addicts or other I.V.-type abusers of I.V. opioid drugs." He also condemned Ruan's addition of prescriptions for Soma and hydrocodone at subsequent visits.

During a visit to Ruan in April 2014, Walker tested positive for several drugs, including hydromorphone, that Ruan had not prescribed, which suggested to Dr. Greenberg that Walker was receiving opioids from other doctors or off the street. Dr. Greenberg testified that he did not believe that Ruan

was checking the PDMP, which would have revealed that Walker was indeed receiving pain medications from 12 or 13 different doctors. Dr. Greenberg opined that the prescription Ruan wrote for Walker for Opana in November 2014 was merely the last in a long line of medically illegitimate prescriptions that were written by Ruan outside the usual course of professional practice.

Dr. Greenberg was subject to extensive cross-examination related to his review of Walker's file. He admitted that he had missed that Walker had been a patient of Ruan's in 2011, before going to prison, and that Ruan had prescribed the Soma and hydrocodone before her period of incarceration, which could have explained why those drugs were not present in the drug screen in January 2014, after she had been incarcerated for 19 months. Dr. Greenberg was also shown portions of Walker's physical file from 2008, before PPSA migrated to electronic record-keeping, showing that she had been advised about the dangers of developing a dependency on opioids and mixing opioids with alcohol. Dr. Greenberg admitted that such warnings and informed consent were within the scope of professional medical practice.

The jury also heard from Walker's husband,[11] who testified that his wife had a drug addiction and served time for burglary and stealing to support her drug habit. He described how Ruan rapidly increased her opioid dosages beyond the minimum necessary for pain control, stating that her prescribed medications

[11] By the time of trial, Walker had died. Prior to Walker's husband's testimony, the jury was informed of her death and told that there were no allegations that Ruan or Couch was responsible.

would put her in an "almost comatose" state, that the dosages were so great that she would immediately fall asleep after taking the medications, and that she routinely fell asleep while cooking and he would come home from work to find their home filled with smoke. Given this testimony, we find that the totality of the evidence was sufficient for the jury to determine that Ruan dispensed controlled substances to Walker outside the usual course of professional practice as charged in Count 11.

iv. Count 12: Prescription Ruan Wrote on October 10, 2012 for John Bosarge

Count 12 alleged that a prescription Ruan wrote for morphine sulfate (brand name MS-Contin) on October 10, 2012, to patient John Bosarge ("Bosarge") was for no legitimate medical purpose and outside the usual course of professional practice. Dr. Greenberg considered Bosarge, who was an opioid-dependent 50-year-old, a "high risk" patient because he suffered from psychiatric and cardiac problems as well as high blood pressure. Dr. Greenberg opined that Ruan's treatment of Bosarge was outside the usual course of professional practice because, rather than prescribe the "absolute minimum" dose of opioids that would have helped his pain yet addressed his opioid dependence, he combined the opioid prescriptions with prescriptions for Xanax, a "sedative-hypnotic" drug, which created a risk of an "accidental respiratory arrest," and butorphanol, an "agonist-antagonist" drug, which could cause, if a patient is not detoxed from opioids first, the patient to go into a painful withdrawal. Dr. Greenberg emphasized that

the warning labels on those medications warned against prescribing them together.

Ruan argues that the charged prescription was merely a continuation of Bosarge's prior treatment with his referring physician, but the jury heard evidence that morphine like Ruan prescribed Bosarge is a stronger opioid than the hydrocodone he was previously taking before the referral to Ruan. The jury was entitled to credit Dr. Greenberg's opinion that Ruan's treatment of Bosarge fell outside the usual course of professional practice, and sufficient evidence supports Count 12.

2. Counts 2, 3, and 4: Drug Distribution Conspiracies Against Couch and Ruan

Counts 2, 3, and 4 charged the appellants with conspiracies to dispense Schedule II drugs, fentanyl, and Schedule III drugs, respectively, in violation of 21 U.S.C. §§ 846 and 841(a)(1). "In order to secure a conviction for unlawful dispensation under § 841(a)(1), the government must prove that the defendant 'dispensed controlled substances for other than legitimate medical purposes in the usual course of professional practice, and that he did so knowingly and intentionally.'" *United States v. Azmat*, 805 F.3d 1018, 1035 (11th Cir. 2015) (quoting *Ignasiak*, 667 F.3d at 1227). "To establish a conspiracy in violation of § 846," the government must prove that: "(1) there was an agreement between two or more people to commit a crime (in this case, unlawfully dispensing controlled substances in violation of § 841(a)(1)); (2) the defendant knew about the agreement; and (3) the defendant voluntarily joined the agreement." *Id.* (footnote omitted). "A conspiracy conviction will be

upheld if 'the circumstances surrounding a person's presence at the scene of conspiratorial activity are so obvious that knowledge of its character can fairly be attributed to him.'" *Id.* (quoting *United States v. Figueroa*, 720 F.2d 1239, 1246 (11th Cir. 1983)).

v. Counts 2 and 4: Schedule II and III Drugs

The appellants argue that the prescriptions they wrote for these drugs were legitimate, but the evidence at trial indicated significant activities by Ruan and Couch that were outside the course of professional practice. They altered their prescribing habits where they had a financial interest, like when they increased their Abstral prescriptions after purchasing stock in the company, decreased their Abstral prescriptions after a drop in stock price and a change in voucher rules, and increased them again after C&R entered a rebate agreement with Galena. Insys maintained Ruan and Couch as weekly speakers in order to influence their prescription habits. Palmer was forging prescriptions with Couch's signature, and he did this for his patients and for those of other PPSA nurses, something that Ruan was aware of and acquiesced to. Couch and Ruan would leave blank prescription pads, which sometimes only had the doctors' signatures on them, for use by the nurses when the doctors were out of the office. Additionally, the patient files examined for trial by the government's experts suggested that there were serious gaps in patients' quality of care, including taking insufficient steps to safeguard high-risk patients, ignoring signs of potential drug diversion, and failing to get adequately informed consent before prescribing drugs, including for off-label use. The jury

was free to disbelieve Ruan and Couch and reasonably could infer that the appellants were participating in a conspiracy to unlawfully distribute controlled substances.

vi. Count 3: Fentanyl

Count 3 charged a conspiracy to distribute fentanyl, also a Schedule II drug.[12] The jury was asked to find whether the conspiracy involved more than 40 grams, a quantity triggering a 5-year mandatory minimum sentence under 21 U.S.C. § 841(b)(1)(B)(vi). The only argument the appellants raise regarding this count is that there was insufficient evidence to support the jury's finding that they prescribed over 40 grams of fentanyl in a manner outside the usual course of professional practice or for no legitimate medical purpose.

The government's chart listing the appellants' top 28 patients receiving the most Subsys or Abstral prescriptions without a cancer diagnosis showed that the appellants prescribed a total of 67.311 grams of fentanyl to those patients off-label. The appellants claim that the jury could not consider the full 67.311-gram amount because the government only presented testimony specifically addressing 10 of those patients, who were prescribed a total of 33 grams. More specifically, government expert Dr. Greenberg testified about five patients who were prescribed a total of 14.958 grams, the fentanyl prescribed to the patients who testified was 16.621 grams, and the fentanyl prescribed to patients whose relatives testified was 1.487 grams. However, government

[12] The Schedule III conspiracy involved hydrocodone, which was reclassified to Schedule II in 2014.

experts Dr. Aultman and Dr. Vohra testified about an additional five patients who were prescribed fentanyl not included in the chart and testified that the appellants' treatment of them was outside the usual course of professional practice. The government points to PDMP data showing that these five patients received 8.83 grams of fentanyl, which, combined with the 33 grams, surpasses the 40-gram threshold.

While the jury was shown PDMP data throughout the trial, we do not think that they were sufficiently presented with the specific data showing that these five patients received 8.83 grams of fentanyl. But even if the jury erred in finding that over 40 grams was prescribed, the error was harmless because the 5-year mandatory minimum sentence was well below the sentences the appellants received. We find no error with the jury's guilty verdict with regard to Count 3.

3. Count 15: Health Care Fraud Conspiracy Against Couch and Ruan

Count 15 alleged that the appellants engaged in a conspiracy to fraudulently obtain money from a health care benefits program in violation of 18 U.S.C. § 1347(a). A health care fraud conspiracy exists when defendants agree to submit false claims to health care benefit programs. *United States v. Gonzalez*, 834 F.3d 1206, 1214 (11th Cir. 2016). The defendants must have known that the claims submitted were actually false. *Id.* "A person makes a false claim if the treatments that were billed were 'not medically necessary[ ] or were not delivered to the patients.'" *Id.* (quoting *United States v. Medina*, 485 F.3d 1291, 1304 (11th Cir. 2007)). To sustain a conviction, the

government "had to establish beyond a reasonable doubt that: (1) a conspiracy existed to commit health care fraud under 18 U.S.C. § 1347; (2) [the appellants] knew of the conspiracy; and (3) [the appellants] knowingly and voluntarily joined it." *Id.*

The Superseding Indictment alleged and the government sought to prove at trial that the appellants agreed to commit health care fraud in four ways: (1) falsely certifying to insurers that some patients had cancer so that the insurers would pay for their TIRF prescriptions; (2) billing BCBS for office visits conducted by nurse practitioners using Couch's physician identification number; (3) billing insurers for drug tests that were medically unnecessary; and (4) billing insurers for PPSA office visits at which patients were prescribed medically unnecessary drugs. If sufficient evidence supports any one of these methods, we must uphold the health care fraud conspiracy conviction. *See United States v. Ross*, 131 F.3d 970, 984 (11th Cir. 1997).

First, the evidence was sufficient to convict the appellants of conspiring to defraud a health care benefits program by falsely certifying to insurers that some patients had cancer so that insurers would pay for their TIRF prescriptions. *See Gonzalez*, 834 F.3d at 1215–16 (submitting a false claim to an insurer encompasses lying about a patient's condition to the insurer). DEA Special Agent Michael Burt testified that Ruan signed a letter to Cigna confirming that his patient Kathleen Burns's prescription for Subsys had been "for breakthrough cancer pain," when she did not have cancer.[13] Similarly, Perhacs, the former

[13] Dwight Burns, Kathleen Burns's husband, confirmed Burt's testimony. By the time of trial, Kathleen Burns had died.

pharmaceutical sales representative for Insys, testified that Couch signed a form sent to Insys to get insurance approval for Abstral,[14] listing patient Ronald Ivy's diagnosis as bladder cancer, yet his medical file had no mention of any cancer. Several witnesses, including DEA Diversion Investigator Michelle Penfold and Couch's nurse practitioner Palmer, discussed how a Subsys prescription for Joyce Barber listed a diagnosis of "[u]terine cancer." Barber herself testified that when her insurance company later called her to verify that she had cancer and she told them truthfully that she did not, they stopped covering Subsys. And Dr. Aultman, when testifying regarding her review of several patient files, noted that a prescription Couch wrote for Brenda Ward had "cervical cancer" written on it even though her medical record contained no verification of that diagnosis.

We also find that the evidence was sufficient to convict the appellants for conspiring to defraud BCBS. Cindy McKenzie, a BCBS employee who oversees and manages fraud activities, testified that the appellants routinely billed for office visits conducted entirely by nurse practitioners, like Palmer, under Couch's identification number. This practice is called incident to billing, and while some insurers allow it,[15] BCBS

Prior to her husband's testimony, the jury was informed of her death and told that there were no allegations that Ruan or Couch was responsible.

[14] Insys had a unit in its home office, called the "Internal Reimbursement Center," to assist physicians in obtaining insurance approval for Insys.

[15] Medicare, TriCare, and others allowed "incident to billing," allowing submission of bills under a doctor's provider

did not. Rather, BCBS paid about 30% less for nurse practitioner visits than for doctor visits, and it expressly required a physician working with a nurse practitioner to also "see[ ] and render[ ] services to the patient" to bill BCBS under the doctor's name. In October 2014, BCBS clarified its policy, effective January 1, 2015, to permit only the "provider who is physically conducting or affirming the [patient's history] and performing an in-person examination" to submit a bill. BCBS notified providers of this change, and Ken Cross, PPSA's practice manager, testified that he told the appellants that they at least needed to see their patients every visit. Yet Palmer saw dozens of BCBS patients every day without Couch. BCBS found no records of PPSA visits billed under Palmer's name, only those billed under Ruan's and Couch's. McKenzie testified that "[t]hat's a false claim."

Although Ruan testified that he personally saw all of his patients, he acquiesced in Couch's practice of permitting Palmer and others to see patients independently. This is evidenced by the July 2014 email in which Ruan asked Couch to "talk to Justin [Palmer]on cutting down" the amount of Roxicodone 30 mg he prescribed in light of news reports that Alabama had the most opioid prescriptions in the country. Couch responded that "[w]e," meaning he and Palmer, would not "write triple digit dispentions [sic] of short acting opioids."

We also find that the evidence was sufficient to convict the appellants for conspiring to defraud a

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number if the doctor was involved in the treatment, through participation or oversight.

health care benefits program by billing for expensive off-site urine screen tests that were medically unnecessary. Ruan ordered them for every patient because they generated more revenue than in-house tests. And the jury heard from several sources that the appellants rarely discussed inconsistent test results with patients, whether to counsel them into compliance or fire them as patients. Ruan himself had stated that "[i]n private practice the more you fire, the more revenue you lose." Instead, he opined, "when one patient tests positive for street drugs, that gives you more reason to do more frequent urine drug screens, which pays three times more than an office visit."

Finally, because we have already found that the evidence is sufficient to convict the appellants of illegally prescribing drugs, like Abstral and Subsys, outside the course of professional practice, we find that their billing insurers for PPSA office visits at which patients were prescribed these drugs that C&R then dispensed, is an alternative object of the health care fraud conspiracy. Indeed, for Abstral and Subsys, the appellants were either the top or among the top billers of BCBS, Medicare, Tricare, and United Healthcare. While not all of these prescriptions were illegal, some were. In sum, the evidence was sufficient to convict Ruan and Couch for health care fraud conspiracy.

4. Counts 16 and 17: Conspiracies to Receive Kickbacks Against Couch and Ruan

Counts 16 and 17 charged the appellants with conspiring, in violation of 18 U.S.C. § 371,[16] to violate

[16] That statute provides:

the Anti-Kickback statute in two different ways. The statute provides in part that:

> Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind ... in return for referring an individual to a person for the furnishing or arranging 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 ... shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b)(1).

vii. Count 16: PPSA's Workers' Compensation Dispensary

Count 16 charged the appellants with violating the Anti-Kickback statute by conspiring together and with Michael Drobot and Manfuso to accept kickbacks in exchange for letting IPM and CRM run their in-office workers' compensation dispensary. The appellants argue that their convictions on Count 16 must be vacated because there was no "Federal health care program" associated with PPSA's workers'

If "two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both."

18 U.S.C. § 371.

compensation dispensary. As we explain below, we agree.

As noted, to prove a violation of the Anti-Kickback statute, the government needed to prove that the appellants (1) knowingly and willfully (2) received remuneration (3) in return for referring individuals to a person for the furnishing of medication (4) paid for by a "Federal health care program." *See* 42 U.S.C. § 1320a-7b(b)(1). The statute defines a "Federal health care program"—Medicaid and Medicare are common examples—as "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, *which is funded directly in whole or in part, by the United States Government*." 42 U.S.C. § 1320a-7b(f) (emphasis added). Because the 42 U.S.C. § 1320a-7b(b) offense was alleged as an 18 U.S.C. § 371 conspiracy, federal jurisdiction was premised on the existence of a "Federal health care program," in addition to that also being an element of the substantive crime. In short, the government had to show that federal funds passed through PPSA's workers' compensation dispensary.

In determining whether federal jurisdiction exists, the court examines the sufficiency of the evidence offered by the government. *United States v. Key*, 76 F.3d 350, 353 (11th Cir. 1996) ("Whether the government proved the jurisdictional element is measured as a challenge to the sufficiency of the evidence."). "All evidence and inferences therefrom are viewed in the light most favorable to the verdict." *Id.* The relevant inquiry in making this determination is whether a reasonable jury could have found the

jurisdictional element to have been satisfied beyond a reasonable doubt. *Id.*

In *United States v. Dennis*, 237 F.3d 1295 (11th Cir. 2001), this Court examined at length the amount of evidence sufficient to prove federally-insured status in a bank-fraud prosecution. In that case, a government agent testified that the two banks involved were federally insured. *Id.* at 1304. However, this Court found the testimony "equivocal," and although the jurisdictional nexus was established for one of the banks through an official bank document containing the phrase "MEMBER FDIC," there was no such evidence relating to the other bank. *Id.* Regarding the second bank, this Court found the agent's testimony alone insufficient to establish the element:

> The agent's conclusion that the bank was federally insured appears to be premised upon his belief that because a bank is a 'national bank,' it is necessarily a 'federally insured bank.' This reasoning lacks legal support. A 'national bank' is not necessarily 'federally insured.' As demonstrated by pertinent statutory provisions, the two concepts are distinct and not synonymous.

Id. at 1305. This Court held that the evidence was insufficient to prove beyond a reasonable doubt that the bank in question was federally insured and vacated the conviction for bank fraud. *Id.*

The evidence here is similarly equivocal. The government relied on two items to satisfy the requirement that the kickbacks must have been paid in exchange for referring individuals for services paid

for by federal funds. First, the government relied on exhibits showing that the U.S. Department of Labor paid for office visits for several workers' compensation patients. But the exhibits showed that the U.S. Department of Labor paid for physician *services*, not prescriptions.

Second, the government put on evidence that, while most of PPSA's workers' compensation patients were covered by state-funded insurance, at least some patients who received medications from PPSA's workers' compensation dispensary were longshoremen who were covered by an insurance provider by the name of "FARA." FBI Special Agent Amy White read into evidence a July 2012 email from Manfuso, in which he told Ruan:

> FARA is a federal longshoreman insurance program that has requested that you no longer dispense to their patients. Since they are a federal program, and not an Alabama workers' comp state program, the laws and regulations that apply to their patients are different. ... Alabama workers' comp law supports that the patient has the right to choose where to get their medications. Alabama work comp insurance companies cannot legally tell you not to dispense to their patients. Federal law unfortunately does not state that the patient has the right to choose where to get their medication. The insurance company that covers an injured federal worker—in this case that's FARA—has the ability to direct the patient to a certain pharmacy service to get their medication. In other words, FARA is allowed to tell you that they don't want you to

> dispense to their patients and they would like you to send their patients to an outside pharmacy.

There were other subsequent emails from Manfuso to Ruan where Manfuso repeatedly instructed Ruan to "immediately stop dispensing to FARA patients" because FARA was refusing to cover their medications. The government claimed that FARA was a "Federal health care program." However, none of the documents offered by the government at trial contained any indication that federal monies actually passed through the dispensary. The appellants argue that FARA is merely an insurance program administrator that covered several patients at the dispensary. The only evidence at trial relating to FARA are the emails from Manfuso to Ruan, which do nothing more than note that FARA is an insurance company. Moreover, FARA is not named in 42 U.S.C. § 14402(d), the statute listing Federal health care funding programs, like Medicare and Medicaid. We find that this evidence was insufficient to establish beyond a reasonable doubt that FARA paid for prescriptions with federal funds or that federal monies otherwise passed through PPSA's workers' compensation dispensary. Because this element of the offense was not proven, the appellants' convictions for conspiracy to violate the Anti-Kickback statute charged in Count 16 cannot stand. Accordingly, we reverse and vacate the appellants' convictions on Count 16, and we vacate their sentences as to this count.

viii. Count 17: Insys's Speaker Program

Count 17 alleged that the appellants conspired with each other, Perhacs, and others to violate the

Anti-Kickback statute through their participation in Insys's speaker program. The evidence clearly showed that Insys was using its program as a cover to funnel money to its top prescribers—Couch and Ruan. In the words of Perhacs, Insys selected the appellants to speak because they were "whale[s]"—"in [Insys's] top 10 list"—and that the entire point of the speakers' program was "[t]o influence [the appellants] to keep prescribing a lot of Subsys." People outside of PPSA office staff rarely attended these dinners, and the ones who did were sometimes "the same prescriber, time and time again." In contrast, a representative for Galena, the pharmaceutical company manufacturing Subys's competitor, Abstral, testified that when Ruan requested to be a speaker for Abstral, Galena declined because "he was treating all of the patients in the area, it didn't make sense for him to be a speaker because there would be nobody to speak to."

The appellants contend that the government failed to prove that they acted willfully to violate the Anti-Kickback statute. "Willfully" means that the act was committed voluntarily and purposely, with the intent to do something the law forbids. *See United States v. Starks*, 157 F.3d 833, 837–38 (11th Cir. 1998). Ruan points to testimony by Perhacs that Insys selected him as a speaker because he was a respected pain management physician. He also argues that Perhacs testified against him in hopes of receiving a sentence reduction. But there was sufficient evidence for the jury to believe that the speaking program was a sham, and Insys only reduced them after the appellants had been prescribing more and more of the competitor product, Abstral, for months. Additionally, Ruan showed consciousness of guilt when he began to direct Insys to dispose of the money by donating his

speaking fees to various universities. Sufficient evidence supports the conviction on Count 17.

5. Count 19: Mail or Wire Fraud Conspiracy Against Couch and Ruan

Count 19 charged the appellants with conspiring with Perhacs, Palmer, and Parker to commit mail or wire fraud in violation of 18 U.S.C. § 1349. To prove such a conspiracy, "the government need not demonstrate an agreement specifically to use the interstate wires to further the scheme to defraud." *United States v. Hasson*, 333 F.3d 1264, 1270 (11th Cir. 2003). Instead, "it is enough to prove that the defendant knowingly and voluntarily agreed to participate in a scheme to defraud and that the use of the interstate wires in furtherance of the scheme was reasonably foreseeable." *Id*. "A scheme to defraud requires proof of material misrepresentations, or the omission or concealment of material facts ...." *Id.* at 1270–71.

The Superseding Indictment charged, and the government sought to prove at trial, that the appellants conspired to make three types of misrepresentations to insurers. The first misrepresentation was that they routinely billed BCBS for more expensive doctor visits when only a nurse practitioner saw the patient. As discussed in the previous section devoted to Count 15, the evidence was sufficient to convict the appellants of health care fraud conspiracy for these actions. And since the government established that PPSA submitted these bills electronically, the use of the mails or wires element is met. The second misrepresentation, also discussed in the section regarding Count 15 above,

was that they lied to insurers about patients being diagnosed with cancer to induce those companies to pay for TIRF prescriptions. The jury saw that PPSA and the insurers sent forms and letters related to coverage via fax and mail. The third misrepresentation was that Ruan selected the most lucrative controlled substances to stock at PPSA's workers' compensation dispensary, and then he and Couch prescribed those drugs, making their medical decisions based on profit, not the needs of patients. As discussed in the section devoted to Count 16 above, Manfuso testified that while he and Ruan frequently discussed the profit margin of various drugs for the formulary, Ruan never talked with him about the drugs' clinical aspects. Because the evidence showed that these discussions occurred over email between Ruan in Alabama and Manfuso in Maryland, the element of the use of interstate mail in furtherance of the scheme was satisfied.

6. Count 1: RICO Conspiracy Against Couch and Ruan

Count 1 charged the appellants with conspiring to violate RICO based on predicate acts of drug distribution and mail or wire fraud. To establish a conspiracy to violate RICO under 18 U.S.C. § 1962(d), "the government must prove that the defendants 'objectively manifested, through words or actions, an agreement to participate in the conduct of the affairs of the enterprise through the commission of two or more predicate crimes.'" *United States v. Starrett*, 55 F.3d 1525, 1543 (11th Cir. 1995) (quoting *United States v. Russo*, 796 F.2d 1443, 1455 (11th Cir. 1986)). "A RICO conspiracy differs from an ordinary conspiracy in two respects: it need not embrace an

overt act, and it is broader and may encompass a great variety of conduct." *Id.* (quoting *United States v. Pepe*, 747 F.2d 632, 659 (11th Cir. 1984)).

The appellants first contend that the jury could not have reasonably found that PPSA was a RICO "enterprise" because they operated it as separate medical practices at two different locations. We disagree. Ken Cross, the appellants' former practice manager, testified that PPSA, as well as C&R, were legal entities jointly owned by the appellants. The RICO definition of an "enterprise" is broad, including "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4). While Ruan and Couch generally saw their own patients and divided their income proportionate to revenues generated from patients that each treated, they also made financial and business decisions together, such as buying Galena stock with PPSA funds. Ruan also negotiated with IPM and CRM on behalf of himself and Couch to manage the PPSA workers' compensation dispensary. They discussed practice-management issues, such as Palmer's prescribing habits, via email, shared in the profits of C&R, and even worked at each other's primary location once a week. The jury had abundant evidence to conclude that the appellants were members of an "enterprise" as RICO defines the term because not only were PPSA and C&R jointly owned but Ruan and Couch were also associated in fact.

There was also sufficient evidence presented to establish the commission of two or more predicate crimes. As detailed in the previous sections, the jury reasonably concluded that the appellants committed

least two of the 13 drug distribution and mail or wire fraud counts charged. We thus conclude that the jury reasonably determined that RICO's predicate acts requirement was satisfied.

7. Counts 20, 21, and 22: Money Laundering Conspiracy and Substantive Money Laundering Against Ruan

Count 20 charged Ruan with conspiring with Manfuso and others to commit money laundering in violation of 18 U.S.C. § 1956(h). "That section makes it a crime to conspire to commit money laundering in violation of 18 U.S.C. § 1956 or § 1957." *United States v. Moran*, 778 F.3d 942, 962 (11th Cir. 2015). "Under § 1956(h), 'only two elements of conspiracy need be proven: (1) an agreement between two or more persons to commit a money-laundering offense; and (2) knowing and voluntary participation in that agreement by the defendant.'" *Id.* (quoting *United States v. Broughton*, 689 F.3d 1260, 1280 (11th Cir. 2012)). Here, the government alleged that the object of the 18 U.S.C. § 1956(h) conspiracy charged in Count 20 was 18 U.S.C. § 1957 money laundering. That section prohibits "knowingly engag[ing] or attempt[ing] to engage in a monetary transaction in criminally derived property of a value greater than $10,000 and is derived from specified unlawful activity." 18 U.S.C. § 1957(a). Additionally, Counts 21 and 22 charged Ruan with substantive money laundering in violation of 18 U.S.C. § 1957(a). For these counts, the "monetary transaction[s] in criminally derived property" were alleged to be Ruan's purchase of two expensive automobiles. The "specified unlawful activity" underlying all three counts was

alleged to be health care fraud conspiracy in violation of 18 U.S.C. § 1347(a), conspiracy to violate the Anti-Kickback statute in violation of 18 U.S.C. § 371, and conspiracy to distribute controlled substances in violation of 21 U.S.C. § 846.

In support of these counts, evidence was submitted that Ruan had 23 different bank accounts, some under his own name and others in the names of various companies he controlled, such as XLR Exotic Autos, LLC. Ruan received millions in profits from PPSA and C&R as well as speaker payments from Insys. Some of this money made its way into XLR Exotic Autos' bank account. In August and September 2014, Ruan used Erin Bauer, his personal assistant, to arrange two car purchases for him. Ruan wired $124,355.87 from XLR Exotic Autos' bank account to an auto dealer in Dallas to purchase a 2011 Audi R8 Spyder. The following month, he wired $110,000 to a different dealer in San Diego as partial payment for a 1994 Lamborghini Diablo.

Ruan asserts that there was insufficient evidence to convict him of conspiring to commit money laundering because PPSA and C&R had legitimate income and the purpose of purchasing the vehicles was not to funnel money back into a criminal venture. He relies largely on *United States v. Miles*, 360 F.3d 472 (5th Cir. 2004), but that case is distinguishable because it involved money laundering *promotion* under 18 U.S.C. § 1956(a)(1)(A)(i), which criminalizes financial transactions involving funds that are derived from specified illegal activity, where the "transactions are intentionally aimed at promoting specified unlawful activity." *Id.* at 476. Here, the object of the money laundering conspiracy was 18

U.S.C. § 1957(a), which the Fifth Circuit in *Miles* recognized is different: it allows prosecutions for the "mere expenditure of unlawfully obtained funds" as long as the expenditure is more than $10,000. *Id.* at 477–78 (citing *United States v. Brown*, 186 F.3d 661, 670–71 (5th Cir. 1999) (explaining that in § 1957(a), "Congress established a $10,000 per transaction threshold for convictions for simply spending dirty money")). This Court has similarly noted that because there is no need to establish the intent to conceal or promote, and in light of the $10,000 threshold, 18 U.S.C. § 1957 "prohibits a wider range of activity than money 'laundering,' as traditionally understood." *Moran*, 778 F.3d at 963 (quoting *United States v. Wetherald*, 636 F.3d 1315, 1325 n.2 (11th Cir. 2011)).

Thus, all that was required of the government as to Counts 21 and 22 was to prove two elements: (1) Ruan knowingly engaged in a financial transaction greater than $10,000 and (2) at least $10,000 of that money came from a "specified unlawful activity." Ruan argues that there was insufficient evidence that he used funds from specified unlawful activity to purchase the cars. But to the extent that Ruan is guilty of conspiracy to commit health care fraud, conspiracy to receive kickbacks, and distribution of controlled substances, his challenge to his money laundering convictions also fails. As detailed above, Ruan made millions from health care fraud and distribution of controlled substances. The government traced those proceeds to the XLR Exotic Autos bank account used to purchase the cars. No more was required.

Having concluded that the evidence was sufficient to convict the appellants on all of the counts

challenged, except Count 16, we now turn to the appellants' challenges to various evidentiary rulings at trial.

B. Evidentiary Challenges

1. Admission of PDMP Data

The appellants challenge the government's use of prescribing data pulled from Alabama's PDMP and similar databases from Florida and Mississippi. The PDMP is a database of all controlled substance prescriptions dispensed—dispensed meaning that the patient actually receives the medication—in Alabama. The Alabama Department of Public Health ("ADPH") maintains the PDMP database, and the government called state pharmacy director Nancy Bishop, who oversees the PDMP, to explain the system and offer the records.

Alabama law established the PDMP to "materially assist state regulators and practitioners authorized to prescribe and dispense controlled substances in the prevention of diversion, abuse, and misuse of controlled substances prescription medication." Ala. Code § 20-2-210; *see also* Miss. Code Ann. § 73-21-127; Fla. Stat. § 893.055(2)(a). Each doctor or pharmacist who dispenses controlled substances is required by law to report the following information to the PDMP database: the patient's name, the prescriber's name, the medication prescribed, the dosage amount, the quantity of medication dispensed, the date the provider wrote the prescription, and the date the pharmacy filled the prescription. Ala. Code § 20-2-213(d). Similarly, federal law requires pharmacies to keep copies of filled controlled substances prescriptions for at least

two years. 21 C.F.R. § 1304.04(a), (h)(2), (h)(4); *see* 21 U.S.C. § 828.

Access to the PDMP database is limited. Ala. Code § 20-2-214. Pharmacists and doctors can see information on their own dispensing and prescribing as well as their patients' information; state and local law enforcement may access the database for investigation; and federal law enforcement may do so on a showing of probable cause. Additionally, data may be shared with other states' monitoring programs.

Bishop explained that pharmacists enter the prescription information into the database either directly or via software that automatically transmits it to the PDMP as they dispense the medication. The ADPH includes a disclaimer on each page of the printed PDMP report stating that it "does not warrant the above information to be accurate or complete" because the report is "based on the search criteria and the data provided by the dispensing entities." Addressing this disclaimer, Bishop agreed that she could not guarantee that each pharmacist input the data correctly. But she testified that doctors and pharmacists throughout the state access the database on a daily basis. The appellants themselves accessed it in their practice. Bishop described the PDMP as a "tool for the prescribers and the dispensers to use to make the best clinical decision for their patient."

Bishop queried the database for all controlled substance prescriptions written by the appellants from January 2011 through May 2015 and for the top prescribers of Abstral and Subsys in the state. The PDMP data was also used to create the summary exhibits showing the number of the appellants'

patients receiving certain other drugs, the percentage of prescriptions by drug schedule, the number of prescriptions written on dates the appellants were out of the office, and their prescribing of various drugs over time.

At trial, the appellants objected to the admission of the PDMP data on the grounds that it contained multiple levels of hearsay and violated their Confrontation Clause rights because it was based on testimonial evidence. The district court overruled those objections. The appellants reassert those arguments on appeal.

ix. Hearsay

We address the appellants' hearsay objections first. This Court reviews evidentiary rulings for abuse of discretion. *See United States v. Todd*, 108 F.3d 1329, 1331 (11th Cir. 1997). Hearsay is an out of court statement offered for its truth. Fed. R. Evid. 801(c). Hearsay is inadmissible unless it falls within an enumerated exception. Fed. R. Evid. 802. When evidence contains multiple levels of hearsay, each statement must meet a hearsay exception to be admissible. Fed. R. Evid. 805.

The appellants argue that the PDMP reports contain three types of out of court "statements" that were offered for their truth: (1) the prescriptions written by doctors for controlled substances, which are transmitted to pharmacies; (2) the information about the prescriptions that the dispensing pharmacists put into the PDMP database; and (3) the reports that PDMP users can create from the data. However, the prescriptions that were written by Ruan and Couch—or in some cases Palmer, a co-

conspirator—are not hearsay because they constitute an opposing party's statement. *See* Fed. R. Evid. 801(d)(2)(D) & (E). Additionally, the PDMP reports themselves are not hearsay because they are a "data compilation" pursuant to Federal Rule of Evidence 803(6). *See United States v. Glasser*, 773 F.2d 1553, 1558–59 (11th Cir. 1985) (computer printouts containing compilations of various mortgage account transactions which were the basis of the prosecution are admissible under the business records exception); *United States v. Fujii*, 301 F.3d 535, 539 (7th Cir. 2002) ("Computer data compiled and presented in computer printouts prepared specifically for trial is admissible under Rule 803(6), even though the *printouts* themselves are not kept in the ordinary course of business."); *United States v. Arias-Izquierdo*, 449 F.3d 1168, 1184 (11th Cir. 2006) (citing *Fujii* for the proposition that a mere printout of "electronically stored information" is not an additional statement for hearsay purposes).[17]

That leaves the pharmacists' statements that they filled the prescriptions written by the doctors. We agree with the district court that these statements are the business records of the reporting pharmacies and are thus admissible under the business records

[17] Rule 803(6), as amended effective December 1, 2011, no longer lists a "data compilation" as an example of a business record. *See* Fed. R. Evid. 803(6). The December 1, 2011, amendments to the Federal Rules of Evidence were stylistic changes to simplify the rule language, with "no intent to change any result in any ruling on evidence admissibility." Fed. R. Evid. 803 advisory committee's notes 2011 Amendments. Thus, case law construing former Rule 803(6) remains viable and is applicable here. And, Rule 101(b)(4) defines "record" as including a "data compilation." Fed. R. Evid. 101(b)(4).

exception to the hearsay rule. *See* Fed. R. Evid. 803(6). The business records exception provides, in pertinent part:

> A record of an act, event, condition, opinion, or diagnosis [is admissible] if:
>
> (A) the record was made at or near the time by—or from information transmitted by—someone with knowledge;
>
> (B) the record was kept in the course of a regularly conducted activity of a business, organization, occupation, or calling, whether or not for profit;
>
> (C) making the record was a regular practice of that activity;
>
> (D) all these conditions are shown by the testimony of the custodian or another qualified witness, or by a certification that complies with Rule 902(11) or (12) or with a statute permitting certification; and
>
> (E) the opponent does not show that the source of information or the method or circumstances of preparation indicate a lack of trustworthiness.

Fed. R. Evid. 803(6). This Court has recognized that "[t]he touchstone of admissibility under the business records exception to the hearsay rule is reliability, and a trial judge has broad discretion to determine the admissibility of such evidence." *United States v. Bueno-Sierra*, 99 F.3d 375, 378 (11th Cir. 1996) (per curiam).

The appellants argue that the requirement found in subsection (D) of the business records exception is not met because the custodian of the records—Bishop,

an ADPH employee—did not actually enter any data into the PDMP and admitted that she could not vouch for the data's reliability. They contend that the government should have offered witnesses from each of the pharmacies across Alabama, Florida, and Mississippi who actually entered prescription data into the database. But this Court has held that "the proponent of a document ordinarily need not be the entity whose first-hand knowledge was the basis of the facts sought to be proved." *Bueno-Sierra*, 99 F.3d at 379. The proponent must merely "establish that it was the business practice of the recording entity to obtain such information from persons with personal knowledge and the business practice of the proponent to maintain the records produced by the recording entity." *Id.* We are satisfied that Bishop did that here. She testified that the pharmacists, who have knowledge of the prescriptions, enter the data in the database at the same time they dispense the controlled substances. Thus, subsection (A)'s requirement that "the record[s were] made at or near the time by—or from information transmitted by—someone with knowledge," is met. Bishop further explained that federal law and regulations require keeping prescription records, and state law requires submitting the data to the PDMP. This makes keeping the records part of the pharmacies' "regularly conducted activity" as well as a "regular practice" of their business, as required by subsections (B) and (C) of the business records exception. *See also United States v. Towns*, 718 F.3d 404, 407–10 (5th Cir. 2013) (finding that logs and records a business keeps because it is required to do so by state or federal regulations meet this standard). Bishop further testified that the ADPH considered the PDMP reports

its "business records" and relies on the records through its "daily" assistance to doctors and pharmacists in accessing the database as "a tool for the prescribers and the dispensers ... to make the best clinical decision for their patient." She thus established that it was the ADPH's "business practice" to obtain and maintain the records. *See Bueno-Sierra*, 99 F.3d at 379.

Finally, the PDMP report itself does not lack trustworthiness under subsection (E). The appellants point to the disclaimer the ADPH lists on each page of the report stating that it "does not warrant the above information to be accurate or complete" because the report is "based on the search criteria and the data provided by the dispensing entities." While we understand that the prescription data is only as reliable as the individual putting it into the system, pharmacists have every incentive to ensure the data they enter is accurate. Inaccurate data could lead to dangerous drug interactions and overdoses as well as giving drugs to addicts or to those who might sell them on a secondary market. Doctors and pharmacists use the system every day to look up patients' medication histories. The appellants themselves accessed it thousands of times in their practice. The appellants have failed to demonstrate the untrustworthiness of the pharmacists' out of court statements that they filled the prescriptions reported in the PDMP.

Because the PDMP reports comprised records of regularly conducted activity made by persons with knowledge whose job duties entailed making those records, and Bishop, as custodian, certified that information and there was no evidence of untrustworthiness, we find that the district court

properly admitted the PDMP data under the business records exception to the hearsay rule.[18]

x. Confrontation Clause

We now turn to the appellants' claim that the admission of the PDMP data violated their Sixth Amendment rights under the Confrontation Clause.[19] A defendant's claim that an evidentiary ruling deprived him of a constitutional right is reviewed *de novo*. *Ignasiak*, 667 F.3d at 1227. "In *Crawford v. Washington*[, 541 U.S. 36, 53–54 (2004)], the Supreme Court held that the Confrontation Clause bars the admission of the *testimonial* statements of a witness who did not appear at trial unless the witness was unavailable and the defendant had a prior opportunity to cross-examine him or her." *United States v. Caraballo*, 595 F.3d 1214, 1227 (11th Cir. 2010). "Testimonial statements are ones 'that declarants would reasonably expect to be used prosecutorially.'" *United States v. Wilson*, 788 F.3d 1298, 1316 (11th Cir. 2015) (quoting *Crawford*, 541 U.S. at 51). The appellants contend the reports are "testimonial" because the PDMP may assist law enforcement in prosecuting violators of controlled substance laws.

We disagree for several reasons. First, a statement is testimonial when its "primary purpose ... is to establish or prove past events potentially

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[18] We need not address the government's arguments that the PDMP data was also admissible under the public records and residual exceptions to the hearsay rule. *See* Fed. R. Evid. 803(8) & 807.

[19] A criminal defendant has the right "to be confronted with the witnesses against him." U.S. Const. amend. VI.

relevant to later criminal prosecution," *Davis v. Washington*, 547 U.S. 813, 822 (2006), and when the statement is "formal," akin to "affidavits, depositions, prior testimony, or confessions," *Caraballo*, 595 F.3d at 1228 (internal quotation marks omitted). On the other hand, "[c]ertain statements 'by their nature [are] not testimonial—for example, business records or statements in furtherance of a conspiracy.'" *Wilson*, 788 F.3d at 1316 (quoting *Crawford*, 541 U.S. at 56). Because the PDMP reports are business records as explained above, they are not testimonial and do not violate the Confrontation Clause. *See United States v. Naranjo*, 634 F.3d 1198, 1213–14 (11th Cir. 2011) (bank records and checks not testimonial).

Second, even if the reports were not business records, they are nonetheless not testimonial. Pharmacists are required by law to enter the PDMP data for the primary purpose of aiding physicians in treating patients, such as combating addiction. *See* Ala. Code §§ 20-2-210, 213(d). In *United States v. Barker*, the Fifth Circuit found a nurse's report about a sexual assault non-testimonial, even though she knew at the time she wrote it that it would be given to police and could be used in a prosecution, because her primary purpose in writing the report was to "medically evaluate and treat" the victim. 820 F.3d 167, 171–72 (5th Cir. 2016). Similarly, here, the fact that the pharmacists may be aware when they input the data that law enforcement also has access to the database if needed during an investigation does not transform the data entry into the type of formal statement required for testimonial evidence. The district court's admission of the PDMP data did not violate the appellants' Confrontation Clause rights.

2. Exclusion of Other Evidence

Next, the appellants argue that the district court erroneously excluded three additional categories of evidence: (1) information about patients who received legitimate medical care by Ruan and Couch (hereinafter "good patient" evidence); (2) relatedly, videos of undercover agents posing as patients attempting to obtain opioids from Ruan and being denied; and (3) the testimony of Debi Phillips ("Phillips"), PPSA's former operations manager, on various issues. Rather than contend that the district court abused its discretion in deeming this evidence irrelevant under Federal Rule of Evidence 401,[20] the appellants argue that its exclusion violated their Fifth and Sixth Amendment rights to present a complete defense.[21]

"Whether the exclusion of evidence violated a constitutional guarantee is a legal question reviewed *de novo*." *United States v. Sarras*, 575 F.3d 1191, 1209 n.24 (11th Cir. 2009). "[T]he Constitution guarantees criminal defendants a meaningful opportunity to present a complete defense." *United States v. Mitrovic*, 890 F.3d 1217, 1221 (11th Cir. 2018) (quoting *Nevada v. Jackson*, 569 U.S. 505, 509 (2013)). However, this Court has recognized that this right "is not absolute,

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[20] *See Todd*, 108 F.3d at 1331 (a district court's evidentiary rulings are reviewed for an abuse of discretion).

[21] The Sixth Amendment to the United States Constitution guarantees defendants the right to have "compulsory process for obtaining witnesses in his favor." U.S. Const. amend. VI; *See also United States v. Ramos*, 933 F.2d 968, 974 (11th Cir. 1991) ("A criminal defendant's right to present witnesses in his own defense during a criminal trial lies at the core of the fifth and fourteenth amendment guarantees of due process.").

and is subject to reasonable restrictions." *Id.* (citing *United States v. Scheffer*, 523 U.S. 303, 308 (1998)). "[S]tate and federal rulemakers have broad latitude under the Constitution to establish rules excluding evidence from criminal trials. Such rules do not abridge an accused's right to present a defense so long as they are not 'arbitrary' or 'disproportionate to the purposes they are designed to serve.'" *Id.* (quoting *Scheffer*, 523 U.S. at 308). Indeed, the "trial judge's role as gatekeeper is to ensure that the factfinder bases its decision only on relevant and reliable information." *Id.* at 1222 (citing *United States v. Frazier*, 387 F.3d 1244, 1272 (11th Cir. 2004)). Thus, "[w]hile a criminal defendant must be given every meaningful opportunity to present a complete defense, in doing so he must comply with the procedural and evidentiary rules designed to facilitate a search for the truth." *Id.* (quoting *Frazier*, 387 F.3d at 1272).

The appellants rely largely on *United States v. Hurn*, 368 F.3d 1359 (11th Cir. 2004), for their position that, even if a particular rule of evidence would normally bar the admission of certain evidence, there may sometimes be compelling reasons to grant an exception to evidentiary rules. *See id.* at 1363 n.2 ("[T]he fact that a particular rule of evidence requires the exclusion of certain evidence is not dispositive, as particular applications of a generally valid rule may unconstitutionally deny a defendant his rights under the Compulsory Process or Due Process Clauses."). In *Hurn*, this Court pointed to four circumstances in which a district court's exclusion of a criminal defendant's evidence might violate the Constitution:

> First, a defendant must generally be permitted to introduce evidence directly pertaining to any of the actual elements of the charged offense or an affirmative defense. Second, a defendant must generally be permitted to introduce evidence pertaining to collateral matters that, through a reasonable chain of inferences, could make the existence of one or more of the elements of the charged offense or an affirmative defense more or less certain. Third, a defendant generally has the right to introduce evidence that is not itself tied to any of the elements of the crime or affirmative defense, but that could have a substantial impact on the credibility of an important government witness. Finally, a defendant must generally be permitted to introduce evidence that, while not directly or indirectly relevant to any of the elements of the charged events, nevertheless tends to place the story presented by the prosecution in a significantly different light, such that a reasonable jury might receive it differently.

Id. at 1363 (footnotes omitted). The Court explained that two considerations are appropriate in analyzing a defendant's claim that his constitutional right to present a defense was violated: (1) whether the right was actually violated, and (2) if so, whether that error was harmless beyond a reasonable doubt. *Id.* at 1362–63.

Keeping these principles in mind, we address each of the appellants' categories of excluded evidence in turn.

xi. "Good Patient" Evidence and Undercover Videos

The government's case against the appellants was built upon several dozen PPSA patients whose treatment was alleged to be illegal out of the roughly 8,000 patients PPSA had in 2015. Specifically, the government presented live testimony of 14 patients—or family members of deceased patients—who criticized the appellants' prescription of opioids and other medications to them. The government also created a list of the appellants' "top 28" patients who received Subsys or Abstral and whose medical records did not indicate a diagnosis of cancer. Experts reviewed these patients' files and gave their opinions that Ruan and Couch's care of these patients did not meet minimum standards.

The appellants wished to present evidence about patients not identified by the government and whose treatment was not alleged to be illegal. These "good patients" would have testified about how their quality of life improved through the care they received at PPSA. The district court concluded that this evidence was irrelevant and would waste time in an already lengthy trial because the government did not allege that PPSA was entirely a sham practice or that all of the appellants' prescriptions were illegal.[22] The

[22] Federal Rule of Evidence 401 defines relevant evidence as that which "has any tendency to make a fact [of consequence] more or less probable than it would be without the evidence." Even if evidence is relevant, Rule 403 nonetheless vests district courts with wide discretion to exclude evidence if "its probative value is substantially outweighed by a danger of ... unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."

appellants could, however, put on evidence favorable to them from any patients identified or called by the government in its case in chief. Indeed, Couch called five patients and Ruan called three.

The appellants argue that the district court impaired their right to present a complete defense by excluding this "good patient" evidence, particularly the testimony of Michael Tiller, one of Couch's patients. Tiller intended to testify that he believed that Subsys was beneficial to him, despite the off-label use; he generally approved of Couch's treatment of him and trusted him as his physician; and his experiences at PPSA were consistent with his experiences at other physicians' facilities.[23] The appellants contend that Tiller's proposed testimony satisfies the first, second, and fourth categories of evidence summarized in *Hurn*.

The first *Hurn* circumstance is implicated when evidence is excluded that directly pertains to a formal element of a charged offense. *See* 368 F.3d at 1363. The appellants contend that Tiller's testimony would have helped disprove Counts 2, 3, and 4—conspiracies to knowingly or intentionally prescribe controlled substances outside the usual course of professional practice or without a legitimate medical purpose. We disagree. The appellants were not charged with illegally prescribing medicine to all their patients, and the jury was aware that they had thousands of patients to whom they may have provided legitimate care. However, a finding that even one prescription

[23] Couch submitted a written proffer to the district court regarding only Tiller's proposed testimony but contends that he would have called additional "good patients" if the court had permitted him to do so.

was illegal—or for the RICO count, at least two acts of racketeering activity—sufficed to convict for the Controlled Substances Act violations. Thus, whether Tiller approved of his treatment by Couch does not "directly pertain" to whether the appellants' treatment of the many other patients identified by the government was outside the course of professional practice. *See Hurn*, 368 F.3d at 1363.

The second category of *Hurn* evidence is that which, though not directly bearing on an element of the offense charged, tends to prove collateral matters relating to the defense. *See* 368 F.3d at 1364. The appellants argue that Tiller's testimony would have tended to prove that Couch was operating a legitimate practice, a collateral matter. In discussing this category, the *Hurn* court addressed the introduction of evidence that tends to negate the *mens rea* of an offense. *Id.* at 1364–65. *Hurn* cited as an example *United States v. Sheffield*, 992 F.2d 1164 (11th Cir. 1993), in which the defendant, an Air Force employee, was convicted of embezzling Air Force property by ordering subordinates to make fishing lures with base property and on government time. *Id.* at 1165. This Court held that evidence should have been admitted of a legitimate custom on an Air Force base of making retirement presents for high-ranking officials using base materials because it would have rebutted the *mens rea* element of the offense of embezzlement. *Id.* If the defendant was acting pursuant to a legitimate custom when he ordered the production of the lures, he did not possess the state of mind necessary for the offense of embezzlement. *Id.* at 1170.

Here, however, Tiller's testimony does not tend to negate the *mens rea* element of the Controlled

Substances Act offenses— knowingly or intentionally prescribing controlled substances outside the usual course of professional practice or without a legitimate medical purpose. Nowhere did the government allege that Couch's treatment of Tiller was outside the usual course of professional practice, and nothing Tiller would have testified about would have been probative of Couch's actions towards the patients that the government asserted were provided with illegal prescriptions, like Officer Kelley, who received powerful opioids from Couch after only a cursory visit with him and without a showing of medical need.

Nor have the appellants established that the fourth type of evidence in *Hurn* is implicated in this case—that which "complete[s] the picture" of the charged crimes and presents the government's evidence in a more favorable or different light that might influence a reasonable juror. *See* 368 F.3d at 1367. This circumstance recognizes that defendants have a right to combat "the government's selective presentation of entirely truthful evidence [that] cast[s] a defendant in an inaccurate, unfavorable light" or that makes "entirely legitimate, normal, or accepted acts appear unusual or suspicious." *Id.* at 1366–67. The *Hurn* court held that a defendant should be allowed "to introduce additional evidence to dispel this unjustified taint, even if that evidence does not directly or indirectly bear on a particular element of an offense." *Id.* at 1367. For instance, in *Todd*, 108 F.3d at 1333, the defendant was convicted of embezzling from his company's employee retirement fund plan. The government used evidence that the defendant and his family members who worked at the company all received extremely high salaries to prove the defendant's greed and motive to steal. *Id.* This

Court reversed the defendant's conviction because he was not permitted to introduce evidence that all employees who worked at his company, not just his family members, received large salaries and benefits. *Id.* at 1334. Such evidence would have "complete[d] the picture," *See Hurn*, 368 F.3d at 1367, by putting "a different spin" on the defendant's intent, *See Todd*, 108 F.3d at 1334. Similarly in *Sheffield*, this Court noted that the retirement gift evidence, aside from being probative of the defendant's intent or lack thereof to embezzle, also should have been admitted to "put the charges against Mr. Sheffield in context, 'to complete the story of the crime on trial.'" 992 F.2d at 1170 (quoting *United States v. Mills*, 704 F.2d 1553, 1559 (11th Cir. 1983)).

But here, the "good patient" evidence was not necessary to "complete the picture," because it was undisputed that the appellants treated thousands of patients and there was no allegation that they mistreated them all. Indeed, the government told the jury in its opening:

> [T]here were definitely some [patients] that were treated very appropriately in this office. There is no question about that, that there were certainly instances where Dr. Ruan and Dr. Couch did a really good job for their patients. We're not here because of that. We're here for the times that they were prescribing these drugs outside the usual course of professional practice.

The admonition was repeated in closing: "By and large their patients were legitimate patients. And I told you right from the very start and it has always been our contention that a majority of the patients that went there had legitimate pain needs and were in need of

legitimate pain treatment." Thus, there was no need to dispel the "taint" that PPSA was a sham practice. PPSA only accepted patients with insurance and refused patients paying cash. Diagnostic tools such as nerve conduction tests, fluoroscopes, electromyographs, and MRIs were frequently used to discover the source of patient pain. Ken Cross, PPSA's former manager and a government witness, described PPSA in 2014 as "one of the best, well-rounded pain centers in this area." In sum, Tiller's testimony "was not necessary to correct any misleading impressions that may have been created by the government's evidence." *See Hurn*, 368 F.3d at 1367.

For the same reasons, Ruan was not prejudiced by the district court's exclusion of undercover videos of DEA agents acting as "patients" seeking opioids from him but being denied. As noted, the government introduced videos at trial from Officer Kelley's appointments with Couch at PPSA, which comprised Counts 5–7 against him for illegal drug distribution. The DEA had also sent two undercover patients to see Ruan, but neither received opioid prescriptions. A nurse practitioner examined each patient, and each was then seen by Ruan, who told them that it was not appropriate to prescribe controlled substances because of better alternatives. One was referred for surgery, and the other given an anti-inflammatory ointment. At a pretrial conference, the government successfully moved to prevent Ruan from introducing these videos at trial. Akin to Tiller's testimony, these videos do not refute the inculpatory evidence against Ruan demonstrating that at other times, Ruan did prescribe opioids to patients outside the usual course of professional practice or without a legitimate medical purpose, such as in the four patient files

reviewed by Dr. Greenberg comprising Counts 8, 9, 11, and 12.

Before concluding that there was no theory under which the appellants' constitutional rights were violated by the district court's evidentiary rulings, we emphasize that we have carefully considered the appellants' contention that the government's closing arguments compounded the prejudice they suffered from the inability to present "good patient" evidence. Specifically, the appellants point to three statements made by the prosecutor in rebuttal closing: "The defendants had the same subpoena power as the United States of America. That means they can subpoena anybody they want to come in this courtroom, just like the United States can."; "The[appellants] could call anybody they wanted to in connection with this case."; and later, "We called for you 14 patients in comparison to the few patients the defense called ....". The appellants contend that these statements implied that Ruan and Couch could not find witnesses who benefitted from their treatment to rebut the many witnesses that testified for the government, even though the government had obtained a motion *in limine* prohibiting evidence of "good patients." They raised this issue in their motion for a new trial, which the district court denied.

However, when viewed in context, at least the first two statements are not as egregious as they first appear. The prosecutor was not discussing the ability of the appellants to call patient-witnesses in their favor but was instead addressing the adequacy of the government's own charts, specifically the appellants' ability to call statisticians or other experts to critique those charts:

> Now, both attorneys told you that all this is is [sic] numbers, that the government just put up all these charts, pie charts, picture charts. *The defendants had the same subpoena power as the United States of America. That means they can subpoena anybody they want to come in this courtroom, just like the United States can.* If those charts aren't accurate, if those charts weren't what was happening, don't you think they would have brought you somebody to tell you that this chart is not right?
>
> This isn't what the facts showed. This isn't what the numbers are. And they want to tell you that numbers don't mean anything. But numbers control. You can't wait to be 16. You can't wait to be 21, you can't wait to make a 100 on a test. Most everything we do has to do with numbers. And if these numbers weren't correct, these charts weren't correct, they'd be the first one to show you and tell you with evidence and with witnesses.
>
> In connection with that, they could also have called doctors who would have said that they referred people to these doctors. That didn't happen.
>
> *They could call anybody they wanted to call in connection with this case.*

The third remark, however, gives us pause. The prosecutor argued that "[i]t doesn't have to be 50, it doesn't have to be 1000" inappropriate prescriptions; one prescription outside the usual course of professional practice "is breaking the law." She then recounted several of the patients the government had called and, in transitioning to discuss one called by the

defense, commented that "[w]e called for you 14 patients in comparison to the few patients the defense called." This statement is troubling because the government knew that the appellants were prevented from having patients testify that their quality of life had improved through care received by Ruan and Couch.

"[A] prosecutor must refrain from improper methods calculated to produce a wrongful conviction." *United States v. Rodriguez*, 765 F.2d 1546, 1559 (11th Cir. 1985). For example, a prosecutor may not make "improper suggestions, insinuations and assertions calculated to mislead the jury." *Id.* (quoting *United States v. Phillips*, 664 F.2d 971, 1030 (5th Cir. 1981)). To establish prosecutorial misconduct, a defendant must establish that the remarks were improper and that they prejudicially affected his substantial rights. *United States v. Lopez*, 590 F.3d 1238, 1256 (11th Cir. 2009). "A defendant's substantial rights are prejudicially affected when a reasonable probability arises that, but for the remarks, the outcome of the trial would have been different. When the record contains sufficient independent evidence of guilt, any error is harmless." *Id.* (quoting *United States v. Eckhardt*, 466 F.3d 938, 947 (11th Cir. 2006)). In determining whether a prosecutor's remarks had a reasonable probability of changing the trial's outcome, this Court may look to:

> (1) the degree to which the challenged remarks have a tendency to mislead the jury and to prejudice the accused;
>
> (2) whether they are isolated or extensive;

> (3) whether they were deliberately or accidentally placed before the jury; and
>
> (4) the strength of the competent proof to establish the guilt of the accused.

Id. (quoting *Davis v. Zant*, 36 F.3d 1538, 1546 (11th Cir. 1994)).

The prosecutor's remarks were improper, but when examined in the context of the entire trial, the appellants cannot show that the remarks prejudiced them. As mentioned, the jury knew that the appellants treated thousands of patients and were not alleged to have mistreated them all. The three remarks were a minor portion of lengthy closing arguments in a lengthy trial, and the evidence of the appellants' guilt for violating the Controlled Substances Act was substantial. Additionally, the district court repeatedly instructed the jury that the attorneys' arguments were not evidence. *See Rodriguez*, 765 F.2d at 1560 (curative instructions considered in determining prejudice from prosecutorial misconduct). For all of these reasons, we conclude that the district court's exclusion of "good patient" evidence did not violate the appellants' constitutional right to present a complete defense.

xii. Phillips's Testimony

The appellants also argue that three separate limitations placed on the testimony of PPSA's former operations manager, Phillips, violated their rights to present a complete defense. First, the government put on evidence that PPSA's electronic medical records frequently contained descriptions of physical examinations conducted by the doctors that never actually happened. The government often asked the

PPSA patients that it called to testify about having a light shown in their eyes or having their thyroid checked, with the patients saying it did not happen, despite the medical record purportedly showing otherwise. To rebut this evidence, the appellants called Phillips to explain PPSA's billing practice and operations. She testified that the electronic records system PPSA used relied on templates to pre-populate office visit notes with exams performed, even if the exams were not actually performed. Using a sample patient file that Phillips did not actually work on, Couch asked her to explain how a biller at the office would have reviewed the doctor's notes for an office visit to determine that the bill had been coded correctly for submission to insurance companies. Because Phillips did not prepare the bill for the patient, she was permitted to explain only "what was generally looked at." Phillips nonetheless testified at length, explaining that a biller typically reviewed the recorded "chief complaint, history of present illness, review of systems," and diagnostic code. But when Couch sought to ask her about a specific physical exam listed in the sample bill, the court concluded that she lacked personal knowledge. The appellants say that if allowed, Phillips would have explained that these pre-populated fields were not used to select the billing level that PPSA submitted to insurers, and they submitted a proffer to that extent.

The appellants contend that this evidence triggers the second *Hurn* factor, collateral evidence relative to proving a defense, *see* 368 F.3d at 1367, because it rebuts the government's evidence suggesting that the appellants committed fraud by listing unnecessary or unperformed examinations in order to increase billing revenue. We find no prejudice

because the government successfully proved health care and mail or wire fraud through other illegal acts unrelated to Phillips's testimony about billing codes, such as that PPSA falsely certified to insurers that some patients had cancer so that the insurers would pay for their TIRF prescriptions, and that PPSA improperly billed BCBS for office visits conducted by nurse practitioners using Couch's physician identification number. We thus find that the excluded evidence could not have affected the trial's outcome.

The second limitation on Phillips's testimony that the appellants challenge occurred after the government cross-examined her about PPSA's practice of billing insurers for visits conducted by physicians when only Palmer saw patients. Phillips testified that Palmer was in collaboration with Couch. On redirect examination, Couch sought to ask Phillips whether "there [is] guidance out there on billing for a practice when a nurse practitioner and a doctor bill in collaboration?" The government objected that the question was too general to elicit a relevant answer and reminded the court that BCBS had different requirements than other insurers. The court sustained the objection, and Couch did not rephrase the question in a more specific way.

The appellants contend that Phillips would have testified that she consulted the Alabama Board of Medical Examiners' guidance and was satisfied that PPSA's collaborative practice followed the relevant guidelines, and they submitted a proffer to that effect. According to the appellants, evidence that Phillips made efforts to ensure that the doctors' collaborative practice was compliant with the law would negate any intent to defraud health care companies by billing for

services performed by nurse practitioners. Thus, they contend the exclusion of this testimony was error under the first *Hurn* category because it would disprove one of the elements of health care and mail or wire fraud charged in Counts 15 and 19: the intent to defraud.

We again disagree. The specific charge was that the appellants violated a policy specific to BCBS requiring doctors to actually see patients before using the higher billing number. Neither the Alabama Board of Medical Examiners' guidance on collaborative practice nor the fact that other insurers may not have had that same policy was relevant to the charge.

The third limitation on Phillips's testimony challenged by the appellants occurred as she was recalling Officer Kelley's first undercover visit to PPSA, when he was turned away because he did not have insurance until his "referring chiropractor," Dr. Wetzel, who was working with the DEA, made a call to PPSA requesting that they make an exception for a cash-only patient. Phillips testified that she overheard PPSA's new patient coordinator, Shannon Hackworth, speaking with Dr. Wetzel and that Hackworth was "upset" and "crying." Phillips then spoke to Dr. Wetzel for a few minutes, after which Officer Kelley was permitted to keep his appointment and pay cash "only for that visit." The district court sustained the government's hearsay objection regarding what Dr. Wetzel told Phillips, explaining that it was "already in that [PPSA] accepted him ... because of Dr. Wetzel's insistence ... [T]here's nothing else that's relevant." Couch then attempted to elicit from Phillips that Dr. Wetzel was angry, made

comments that Phillips perceived as threats, and vouched for his "patient" Officer Kelley by saying that he was a business owner and had sufficient funds to pay for his visit. However, the district court sustained the government's objection to relevance, finding that Couch was not charged with giving Officer Kelley an appointment but with illegally prescribing him controlled substances.

The appellants argue that Phillips's testimony would have placed Officer Kelley's first visit in a different light and completed the picture for the jury, *See Hurn*, 368 F.3d at 1363, by explaining why Phillips decided to allow a cash-only patient into PPSA—she felt pressured by Dr. Wetzel's allegedly threatening call.

However, we don't see an error of constitutional magnitude here. The fact that Dr. Wetzel's call precipitated Officer Kelley's admittance to the practice had been established during Officer Kelley's own testimony and was not in dispute. There was no evidence that either Palmer or Couch knew about the call, and thus it could not have affected their decisions to prescribe Officer Kelley drugs that he did not need. In other words, information that Phillips felt threatened by Dr. Wetzel's insistence that PPSA take Officer Kelley in would have not given the jury a reason to acquit Couch of the charges related to his conduct during Officer Kelley's visits.

3. Expert Testimony

The appellants also argue that government expert Dr. Aultman was not qualified to give her opinions, and that the district court improperly limited their cross-examination of her. The district

court overruled these objections at trial. A district court's decisions regarding the admissibility of expert testimony will not be set aside unless we determine that the court abused its discretion. *Frazier*, 387 F.3d at 1259. "By definition ... under the abuse of discretion standard of review there will be occasions in which we affirm the district court even though we would have gone the other way had it been our call." *Id.* (quoting *In re Rasbury*, 24 F.3d 159, 168 (11th Cir. 1994)). In order to reverse, we must find that the district court "has made a clear error of judgment, or has applied the wrong legal standard." *Id.* (citing *Maiz v. Virani*, 253 F.3d 641, 662 (11th Cir. 2001)).

We first address Dr. Aultman's qualifications. The proponent of the expert's testimony must show that the expert is qualified based on her "knowledge, skill, experience, training, or education." *Frazier*, 387 F.3d at 1261 (emphasis omitted) (quoting Fed. R. Evid. 702).[24] Based on her training and experience, we find that Dr. Aultman was qualified as an expert to testify as to whether Ruan and Couch's treatment of

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[24] Rule 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

some patients was outside the usual course of professional practice. Dr. Aultman has a medical degree and completed a residency in internal medicine. She has practiced for over twenty years in Mississippi: at the time of trial she was a hospitalist, but she has also practiced general medicine in a private clinic and palliative care in a hospice setting. She regularly prescribes opioids, benzodiazepines, and muscle relaxers to patients with acute and chronic pain, and she has prescribed fentanyl to hospice patients. She has previously testified as an expert witness in federal court cases involving illegitimate pain-medication prescriptions and has reviewed patient files for the DEA since 2002. Dr. Aultman testified generally about the doctor-patient relationship, examination and prescribing practices, pain assessments, and documenting patient information. She also testified specifically regarding her review of the medical files of four PPSA patients and Officer Kelley, opining that the appellants' treatment of these patients was outside the usual course of professional practice, as shown by a lack of accurate patient histories and the infrequent use of non-opioid treatment options. Her testimony pertained to Counts 1–7 and 15, as each depended on allegations of prescribing outside the usual course of professional practice.

We are not concerned, although the appellants say we should be, that Dr. Aultman is not a board-certified pain management physician and does not have her own specialty clinic like PPSA. This Court has held that a "proffered physician need not be a specialist in the particular medical discipline to render expert testimony relating to that discipline." *McDowell v. Brown*, 392 F.3d 1283, 1297 (11th Cir.

2004) (quoting *Gaydar v. Sociedad Instituto Gineco–Quirurgico y Planificacion*, 345 F.3d 15, 24 (1st Cir. 2003));[25] *See also Gayton v. McCoy*, 593 F.3d 610, 617 (7th Cir. 2010) ("[C]ourts often find that a physician in general practice is competent to testify about problems that a medical specialist typically treats.");[26] *Dickenson v. Cardiac & Thoracic Surgery of E. Tenn.*, 388 F.3d 976, 979–80, 982 (6th Cir. 2004) (reversing a district court's exclusion of a cardiac thoracic surgeon's testimony on the standard of care applicable to pulmonologists); *Doe v. Biological, Inc.*, 971 F.2d 375, 385 (9th Cir. 1992) ("The fact that the experts were not licensed hematologists does not mean that they were testifying beyond their area of expertise. Ordinarily, courts impose no requirement that an expert be a specialist in a given field, although there may be a requirement that he or she be of a certain profession, such as a doctor."); *United States v. Viglia*, 549 F.2d 335, 336–37 (5th Cir. 1977) (pediatrician may testify about drug's effect on obese persons despite no experience treating obese patients). Despite not being a pain management specialist, Dr. Aultman's familiarity with prescribing opioids and

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[25] In *McDowell*, the court allowed a neurologist to testify regarding the standard of care of jail nurses. *Id.* Granted, the court looked to Georgia state law to determine the qualifications of an expert, rather than the Federal Rules of Evidence, but we don't find any serious differences between the two regarding this issue. *Id.* at 1295–97.

[26] In *Gayton*, the Seventh Circuit held that a physician was not unqualified to testify about a heart-related death merely because he was not a cardiologist, but it ultimately upheld the exclusion of the physician's testimony because he lacked the necessary qualifications. *Id.* at 617–18.

treating chronic pain qualified her to opine on the appellants' conduct.

Additionally, the appellants questioned Dr. Aultman on cross-examination about her experience treating pain. They even established that as a hospitalist, she did not have her own clinical practice and that when a patient "presented with a significant amount of pain that was beyond [her] specialization, [she] referred that patient" to someone else. "A district court's gatekeeper role ... 'is not intended to supplant the adversary system or the role of the jury.'" *Maiz*, 253 F.3d at 666 (quoting *Allison v. McGhan*, 184 F.3d 1300, 1311 (11th Cir. 1999)). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking [debatable] but admissible evidence." *Id.* (quoting *Allison*, 184 F.3d at 1311). We find no abuse of discretion in the admission of Dr. Aultman as an expert, and the weight of her testimony was for the jury to evaluate.

We turn now to the appellants' claim that the district court improperly limited their cross-examination of Dr. Aultman. First, Couch sought to elicit a statement from Dr. Aultman that she could not practice pain management in Mississippi under a 2016 requirement by that state's medical licensing board that pain management doctors have either completed a residency in that sub-specialty or be board certified in it, or otherwise have completed 100 hours of specialized continuing medical education. The district court did not abuse its discretion in sustaining the government's relevance objection to this line of questioning. "[T]he district court enjoys

'wide latitude' to impose 'reasonable limits' on cross-examination based on, among other things, 'confusion of the issues' and 'interrogation that is repetitive or only marginally relevant.'" *United States v. Maxwell*, 579 F.3d 1282, 1296 (11th Cir. 2009) (quoting *Delaware v. Van Arsdall*, 475 U.S. 673, 679 (1986)). Dr. Aultman's cross-examination had already established that she had never been board certified in pain management, had a residency or fellowship in pain management, or been peer reviewed in a pain management journal. That she was not licensed in Mississippi as a pain management specialist was repetitive and would have risked confusing the jury, considering that Mississippi's standards did not govern the appellants' Alabama practice and did not go into effect until after the indictment period in this case.

The appellants also contend that the district court erred in limiting the scope of Ruan's cross-examination of Dr. Aultman regarding her previous work for the government. Dr. Aultman testified that she had been paid about $7,600 for her work on the appellants' case and that she had worked for the DEA or the Department of Justice on "five or six cases last year [2016]." Ruan asked her to confirm that between 2000 and 2014, she "had signed government contracts totaling more than $325,000." The government objected that payments for other contracts were irrelevant, and the district court sustained the objection.

The government contends that there was no error here since the jury had already heard of Dr. Aultman's $7,600 fee for this case; the evidence of the additional contract amounts would have been cumulative; and

the district court had discretion to curtail the cross-examination. We disagree. "While the district court has 'discretionary authority to rule on the admissibility of evidence, including the power to limit cross-examination,' this discretion is limited by the guarantee of the Sixth Amendment's Confrontation Clause that a criminal defendant has the right to cross-examine prosecutorial witnesses." *Maxwell*, 579 F.3d at 1295 (quoting *United States v. Garcia*, 13 F.3d 1464, 1468 (11th Cir. 1994)). "In particular, ... 'a presumption favors free cross-examination on possible bias, motive, ability to perceive and remember, and general character for truthfulness.'" *Id.* at 1295–96 (quoting *United States v. Phelps*, 733 F.2d 1464, 1472 (11th Cir. 1984)). "[T]he test for the Confrontation Clause is whether a reasonable jury would have received a significantly different impression of the witness' credibility had counsel pursued the proposed line of cross-examination." *Id.* at 1296 (quoting *Garcia*, 13 F.3d at 1469). Aside from Confrontation Clause concerns, proof of bias or motive to lie is also almost always relevant under Federal Rule of Evidence 402, as "[a] successful showing of bias on the part of a witness would have a tendency to make the facts to which he testified less probable in the eyes of the jury than it would be without such testimony." *United States v. Abel*, 469 U.S. 45, 51–52 (1984).

Applying these principles leads us to the conclusion that the district court abused its discretion by allowing the jury to believe that Dr. Aultman's financial involvement with the government was substantially less than was accurate. All the jury knew is that Dr. Aultman had been paid roughly $7,600 in expert fees for this case, and the appellants

sought to show that she had signed contracts *over 40 times* that much from the government over the years. This evidence was certainly not cumulative and instead would have been probative of Dr. Aultman's credibility in light of her extensive relationship with the government.

This Court held similarly in *United States v. Williams*, 954 F.2d 668 (11th Cir. 1992). There, the district court allowed a government informant to testify regarding the percentage (25%) he received from successful undercover operations and the amount of money he had already been paid in that case. *Id.* at 671–72. However, the district court excluded testimony detailing the total amount of money the informant had received for his work as an informant because the sum was "outrageous" and therefore prejudicial. *Id.* at 671, 672 n.3. That evidence included the fact that the informant had received $450,000 in reward money, including 25% of a $1,258,000 seizure (i.e., $314,500). *Id.* This Court reversed, reasoning that "[t]he jury has the right to know what may be motivating a witness, especially a government paid, regularly employed, informant-witness." *Id.* at 672; *See also Collins v. Wayne Corp.*, 621 F.2d 777, 784 (5th Cir. 1980) ("A showing of a pattern of compensation in past cases raises an inference of the possibility that the witness has slanted his testimony in those cases so he would be hired to testify in future cases.").

Ultimately, however, although we find that the district court abused its discretion in limiting this testimony, we find the error harmless. "[E]videntiary and other nonconstitutional errors do not constitute grounds for reversal unless there is a reasonable

likelihood that they affected the defendant's substantial rights; where an error had no substantial influence on the outcome, and sufficient evidence uninfected by error supports the verdict, reversal is not warranted." *United States v. Arbolaez*, 450 F.3d 1283, 1290 (11th Cir. 2006) (quoting *United States v. Hawkins*, 905 F.2d 1489, 1493 (11th Cir.1990)). As previously detailed, there was ample other evidence aside from Dr. Aultman's testimony to convict the appellants of RICO conspiracy (Count 1), drug distribution conspiracies (Counts 2–4), and health care fraud conspiracy (Count 15). Thus, it is unlikely that Dr. Aultman's testimony affected the outcome on those charges. Couch specifically argues that the error was not harmless because Dr. Aultman was the only expert to review the medical file of undercover DEA agent Officer Kelley, whose treatment by Couch formed the basis of Counts 5–7. Recall that her opinion was that Couch prescribed controlled substances to Officer Kelley outside the usual course of professional practice. However, this Court has held that expert testimony, while helpful, is not required to prove violations of the Controlled Substances Act, and "a jury can find that a doctor prescribed controlled substances not in the usual course of his medical practice and was acting other than for a legitimate medical purpose from evidence received from lay witnesses surrounding the facts and circumstances of the prescriptions." *Joseph*, 709 F.3d at 1103 (quoting *United States v. Rogers*, 609 F.2d 834, 839 (5th Cir. 1980)). In additional support of these counts, Officer Kelley himself testified that he did not need the opioids that Couch prescribed him, and the jury viewed the undercover videos of his visits to PPSA. The jury saw that Officer Kelley touched the floor

without pain and heard him request "Roxy" pills. They heard that a drug test and a PDMP check would have shown that he was neither filling the prescriptions nor taking the drugs. This evidence, which suggests that Couch prescribed controlled substances to Officer Kelley only after a cursory visit with him and without a showing of medical need, was sufficient to convict Couch on Counts 5–7, without Dr. Aultman's additional opinion.

C. Jury Instructions

The appellants next contend that the district court erred in refusing to give their proposed jury instruction regarding Counts 1–7, 13–15, and 17, which addressed specifically the applicable standard by which to judge a physician's conduct for violations of the Controlled Substances Act. The appellants' proposed "Instruction 18" 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.
>
> If a physician dispenses or distributes a Controlled Substance in good faith while medically treating a patient, then the physician has dispensed or distributed that Controlled Substance for a legitimate medical purpose and within the usual course of professional practice,

and you must return a not guilty verdict for the applicable count. Good faith in this context means good intentions and the honest exercise of professional judgment as to the patient's needs. It means that the Defendant acted in accordance with what he reasonably believed to be proper medical practice. If you find that a 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 Government must prove, beyond a reasonable doubt, that the decision to dispense or distribute a Controlled Substance fell below a standard of medical practice generally recognized and accepted in the United States before you can return a guilty verdict as to that alleged violation of the Controlled Substances Act. But a Defendant's negligence, failure to meet a standard of care, or medical malpractice, on its own is not enough to convict him. An unintentional failure to act how a reasonable doctor would have under similar circumstances is, by itself, insufficient to prove that a Defendant dispensed or distributed a Controlled Substance outside the usual course of professional practice and for no legitimate medical purpose.

To prove a violation of the Controlled Substances Act in this case, the Government must prove, beyond a reasonable doubt, that the physician's decisions to distribute or dispense a Controlled Substance were inconsistent with any accepted method of treating a pain patient – that the physician, in fact, operated as a drug pusher.

The district court refused to give the appellants' proposed instruction for several reasons. The court found too subjective the appellants' request that the court equate subjective "good faith"—acting with "good intentions and the honest exercise of professional judgment as to the patients' needs"—with prescribing "for a legitimate medical purpose and within the usual course of professional practice." The court also found that the language distinguishing the civil standard of care from the criminal standard would unnecessarily confuse the jury, and that the language requiring proof that the physician operated as a "drug pusher" was legally incorrect.

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.
>
> 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 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.

This Court reviews a district court's rejection of a proposed jury instruction for an abuse of discretion. *United States v. Jockisch*, 857 F.3d 1122, 1126 (11th Cir. 2017). A district court commits reversible error if: "(1) the requested instruction was a correct statement of the law, (2) its subject matter was not substantially covered by other instructions, and (3) its subject matter dealt with an issue in the trial court that was so important that failure to give it seriously impaired the defendant's ability to defend himself." *United States v. Carrasco*, 381 F.3d 1237, 1242 (11th Cir. 2004) (quoting *United States v. Paradies*, 98 F.3d 1266, 1286 (11th Cir. 1996)). A district court may properly refuse to give an instruction that fails any one of these prongs. *See Jockisch*, 857 F.3d at 1126.

1. Good Faith Instruction

We first address the appellants' proposed "good faith" instruction, which we find is an incorrect statement of the law. This Court has held 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." *Joseph*, 709 F.3d at 1097; *See also Tobin*, 676 F.3d at 1282–83; *Merrill*, 513 F.3d at 1306; *United States v. Williams*, 445 F.3d 1302, 1309 (11th Cir. 2006),

abrogated on other grounds by United States v. Lewis, 492 F.3d 1219, 1220 (11th Cir. 2007) (en banc). This rule reflects the Supreme Court's decision in *United States v. Moore*, 423 U.S. 122 (1975), the first case by the Supreme Court establishing that physicians can be prosecuted for violating the Controlled Substances Act "when their activities fall outside the usual course of professional practice." *Id.* at 124. Yet under the appellants' proposed instruction, as long as a physician subjectively believes that he is meeting a patient's medical needs by prescribing a controlled substance, then he cannot be convicted of violating the Act no matter how far outside the bounds of professional medical practice his conduct falls. In other words, good faith is a complete defense. This Court has repeatedly rejected good faith instructions nearly identical to that proposed by the appellants here because they failed to include the objective standard by which to judge the physician's conduct. *See Joseph*, 709 F.3d at 1097; *Merrill*, 513 F.3d at 1305; *Williams*, 445 F.3d at 1309. And in these cases, this Court has approved the same instruction that the district court ultimately gave here:

> A controlled substance is prescribed by a physician in the usual course of a 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.

Joseph, 709 F.3d at 1092; *Tobin*, 676 F.3d at 1281; *Merrill*, 513 F.3d at 1306; *Williams*, 445 F.3d at 1309.

The appellants recognize that this Court has rejected nearly identical proposed jury instructions

but argue that this Court should reconsider its prior holdings. However, under the Eleventh Circuit's prior panel precedent rule, this Court is bound by its holdings in *Williams* and *Joseph*. *See United States v. Steele*, 147 F.3d 1316, 1317–18 (11th Cir. 1998) (en banc) ("Under our prior precedent rule, a panel cannot overrule a prior one's holding even though convinced it is wrong."); *See also Smith v. GTE Corp.*, 236 F.3d 1292, 1303 (11th Cir. 2001) ("[W]e categorically reject any exception to the prior panel precedent rule based upon a perceived defect in the prior panel's reasoning or analysis as it relates to the law in existence at that time.").

Nor did the district court's refusal to give the appellants' proposed "good faith" instruction seriously impair the appellants' ability to present an effective defense. The district court's instruction told the jury that good faith was a defense to a Controlled Substances Act violation as long as the appellants' conduct also was in accordance with the standards of medical practice generally recognized and accepted in the United States, and it highlighted that the appellants "maintain[ed] at all times they acted in good faith and in accordance with [that] standard." The jury could have accepted this defense and acquitted based on the good faith instruction that the district court provided. *Cf. United States v. Yeager*, 331 F.3d 1216, 1224 (11th Cir. 2003) ("The jury could have accepted this defense and acquitted Yeager by reference to the instructions, particularly the materiality instruction. Therefore, we can find no error in the refusal of the reasonable reliance instruction.").

2. Drug Pusher Instruction

Next, we find that the proposed "drug pusher" instruction is also an incorrect statement of the law. The appellants argue that the Supreme Court's decisions in *Moore*, 423 U.S. 122, and *Gonzales v. Oregon*, 546 U.S. 243 (2006), taken together, support giving a jury instruction that equates bad physicians to drug pushers. We disagree. Like it or not, the term "drug pusher" connotes imagery of back-alley illicit drug deals, not an established medical practice like PPSA. And while the Supreme Court in *Moore* described the physician-defendant in that case as a "large-scale [drug] 'pusher,'" 423 U.S. at 143, the Supreme Court nowhere suggested that acting as a drug dealer or pusher as conventionally understood is necessary for a Controlled Substances Act conviction, *id.* at 139–42. Rather, as previously noted, the Supreme Court held that a physician violates the Controlled Substances Act if his conduct "fall[s] outside the usual course of professional practice," *id.* at 124, which could occur in a manner of different ways. Additionally, this Court's precedents applying *Moore* do not suggest that acting as a drug pusher is necessary to convict a physician for violations of 21 U.S.C. § 841. *See Joseph*, 709 F.3d at 1096; *Tobin*, 676 F.3d at 1282–83; *Merrill*, 513 F.3d at 1306; *Williams*, 445 F.3d at 1309.

As for the appellants' reliance on *Gonzales*, that case has no application here. *Gonzales* was not a criminal prosecution. Rather, the Supreme Court applied administrative law to analyze an interpretive rule issued by the Attorney General indicating that physicians who dispense controlled substances for use in physician-assisted suicides of terminally ill

patients would be violating the Controlled Substances Act because assisted suicide was not a "legitimate medical purpose" under the Act. *See* 546 U.S. at 248–49. The Attorney General's judgment conflicted with Oregon law, which permitted the practice. The Supreme Court struck down the interpretive rule because it exceeded the Attorney General's delegated authority under the Controlled Substances Act. *Id.* at 267. In addressing the Act's purpose and design, the Supreme Court stated that "[t]he [Act] and our case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood." *Id.* at 269–70. In describing the Act in such a way, the Supreme Court was referring to its previous decision in *Moore*. But the Supreme Court nowhere displayed the intention to upset or limit its holding in *Moore*; in fact, it cited *Moore* with approval. *See id.* at 269.

Numerous courts have since rejected the argument that those statements in *Gonzales* have any bearing on *Moore*'s holding or that they limit the scope of liability for physicians under § 841 to "drug or street dealer" activity. For example, in *United States v. Volkman*, 797 F.3d 377 (6th Cir.), *cert. denied*, 136 S. Ct. 348 (2015), the Sixth Circuit held that "*Gonzales* did nothing to alter the reality that 'knowingly distributing prescriptions outside the course of professional practice is a sufficient condition to convict a defendant under the criminal statutes relating to controlled substances.'" *Id.* at 386 (quoting *United States v. Kanner*, 603 F.3d 530, 535 (8th Cir. 2010)). In *Volkman*, the defendant proposed the following jury instruction, derived from the Supreme

Court's statements in *Gonzales*: "In other words, in order to find the defendant guilty, you must find that he used his prescription-writing power as a means to engage in the illicit drug-dealing and trafficking as conventionally understood." *Id.* at 385. The Sixth Circuit held that such an instruction was an incorrect statement of the law because it improperly "cabined the scope of what the jury could consider." *Id.* at 386. The court stated, "If Volkman's goal was to conjure up the unsavory specter of 'street' drug dealing—complete with imagery of shady characters conducting quick, suspicious handoffs—then his instruction was not an accurate statement of the law, for 'street' drug dealing is not necessary to prove a violation of the [Controlled Substances Act]." *Id.*

Similarly, in *Kanner*, 603 F.3d at 533–35, the Eighth Circuit rejected the defendant's argument that the indictment should have included the above-quoted language from *Gonzales*, holding that "*Gonzales* did not supplant the standard for violations of the [Controlled Substances Act]." *See id.* at 535 ("Rather, post *Gonzales*, 'knowingly distributing prescriptions outside the course of professional practice is a sufficient condition to convict a defendant under the criminal statutes relating to controlled substances.'" (quoting *United States v. Armstrong*, 550 F.3d 382, 397 (5th Cir. 2008)); *See also United States v. Lovern*, 590 F.3d 1095, 1100 (10th Cir. 2009) ("Unlike *Gonzales*, we have before us no interpretive rule seeking to define a practice as lacking any legitimate medical purpose .... Instead, in this case the government sought to establish that the conduct of the ... physicians was inconsistent with the usual course of professional practice the old-fashioned way: through witnesses and documentary proof at trial

focused on the contemporary norms of the medical profession."). We agree with these courts that *Gonzales* did nothing to disturb the holding of *Moore*, which sets out a standard for violations of the Controlled Substances Act that is based solely on the statutory provisions themselves. To require the jury to find that the appellants acted as drug pushers would violate these principles.

3. Civil Standard of Care Instruction

Finally, we address the appellants' argument that the district court permitted jurors to conflate civil and criminal standards by refusing to give their proposed instruction because it would be too confusing for the jury. While the instruction proposed by the appellants, which stated that "a Defendant's negligence, failure to meet a standard of care, or medical malpractice, on its own is not enough to convict him", is an accurate statement of the law, we do not agree that its exclusion from the instructions impaired the appellants' ability to adequately present their defense.

First, there is no dispute that the district court instructed the jury on the correct criminal standard for Controlled Substances Act violations. This instruction is in keeping with this Court's guidance in *Williams* that an instruction explaining that the government must prove that a doctor dispensed controlled substances "outside the usual course of professional practice ... properly state[d] the standard by which a [doctor's] conduct must be judged." 445 F.3d at 1307–08.

Nonetheless, the appellants argue that an instruction distinguishing the civil standard was

necessary because the government and several of its medical experts confused the two during trial. The appellants point out that the government conflated the terms "standard of care" and "usual course of professional practice" when examining Dr. Greenberg. They also emphasize that Dr. Vohra actually equated those terms in his testimony, and that while Dr. Aultman was never asked to provide a definition of "the usual course of professional practice," the government regularly asked her opinion on whether certain conduct would be within that standard. However, we find that the district court's instruction at the end of trial defining the criminal standard adequately cured any incorrect references to the civil standard of care by experts or the prosecution.

Additionally, the district court instructed the jury that if the appellants acted in good faith, they acted lawfully. Other courts have found that such an instruction sufficiently covered that the jury was not to convict based on a civil standard of care. *See United States v. McIver*, 470 F.3d 550, 560 (4th Cir. 2006) ("The inclusion of a good faith instruction is a plainspoken method of explaining to the jury a critical difference between the two standards."); *United States v. Feingold*, 454 F.3d 1001, 1012 (9th Cir. 2006) (jury instructions that informed the jury that "[a] practitioner may not be convicted of unlawful distribution of controlled substances when he distributes controlled substances in good faith to patients in the regular course of professional practice" and that "the government must prove beyond a reasonable doubt that the defendant prescribed or distributed the controlled substance other than for a legitimate medical purpose and not in the usual

course of professional practice" correctly articulated the standard of liability under § 841(a)(1)).

Finally, the appellants presented an expert to provide an explanation of the "usual course of professional practice." Dr. Warfield's definition was that medical malpractice is not outside the usual course of professional practice. At closing, the appellants argued that malpractice is not enough to convict. Thus, the jury was able to consider these standards in determining whether the appellants' conduct was criminal. *See Joseph*, 709 F.3d at 1097 (highlighting the fact that "[e]xperts for both the prosecution and the defense testified about the accepted standard of medical practice").

D. Ruan's Sentence

Ruan also challenges the sentence imposed by the district court. First, he argues that the district court clearly erred in finding that at least 10.6% of the prescriptions written were illegal. Next, he argues that the district court clearly erred when it applied an obstruction-of-justice enhancement based on his testimony that he was unaware that one of his employees was forging prescriptions. Then, he argues that the district court plainly erred by applying an enhancement under U.S.S.G. § 2S1.1(b)(2)(B) because he was convicted under § 1956(h). He also argues that the district court clearly erred in calculating the restitution amount based on the number of off-label prescriptions for TIRFs and overmedicated patients. Finally, he argues that the district court erred in ordering forfeiture for the RICO Act violation because the evidence was insufficient to support his conviction. The government argues that any error in calculating the guideline range was harmless because

the district court said that it would have imposed the same sentence, regardless of any errors in calculating the guidelines range.

1. Harmless Error

We first address the government's harmless-error argument. Where a defendant preserves a challenge to the guidelines calculations, we have held that any error is harmless if (1) the district court stated it would impose the same sentence even if it decided the guidelines issue in the defendant's favor, and (2) assuming an error occurred and the lower guideline range argued for by the defendant applied, "the final sentence resulting from consideration of the § 3553(a) factors would still be reasonable." *United States v. Keene*, 470 F.3d 1347, 1349 (11th Cir. 2006). This is because "[t]he Supreme Court and this Court have long recognized that it is not necessary to decide guidelines issues or remand cases for new sentence proceedings where the guidelines error, if any, did not affect the sentence." *Id.* (alteration in original). We need not reach the substantive reasonableness issue where a district court's decision is based on a clearly erroneous fact. *United States v. Slaton*, 801 F.3d 1308, 1320 (11th Cir. 2015).

We examine "whether the sentence is substantively reasonable under the totality of the circumstances." *United States v. Tome*, 611 F.3d 1371, 1378 (11th Cir. 2010). The party who is challenging the sentence bears the burden of showing that it is "unreasonable in light of the record and the § 3553(a) factors." *Id.*

The district court must impose a sentence that is "sufficient, but not greater than necessary, to comply

with the purposes" set forth in 18 U.S.C. § 3553(a)(2), including the need to reflect the seriousness of the offense, promote respect for the law, provide just punishment for the offense, deter criminal conduct, and protect the public from the defendant's future criminal conduct. 18 U.S.C. § 3553(a)(2). Additionally, the court must consider: (1) the nature and circumstances of the offense; (2) the history and characteristics of the defendant; (3) the kinds of sentences available; (4) the guideline sentencing range; (5) any pertinent policy statements; (6) the need to avoid unwarranted sentencing disparities among defendants with similar records who have been convicted of similar conduct; and (7) the need to provide restitution to any victims. 18 U.S.C. § 3553(a)(1), (3)–(7).

In determining whether to sentence a defendant outside the guidelines, a district court must "consider the extent of the deviation and ensure that the justification is sufficiently compelling to support the degree of the variance." *Gall v. United States*, 552 U.S. 38, 50 (2007). "[A] major departure should be supported by a more significant justification than a minor one," and the district court "must adequately explain the chosen sentence to allow for meaningful appellate review and to promote the perception of fair sentencing." *Id.*

Here, the district court's statement that it would have imposed the same sentence did not render the alleged Guidelines errors harmless. If Ruan succeeded on his Guideline challenges, the offense level would be 25, which, with a criminal history score of I, results in a lower guideline range of 57 to 71 months. The district court did not provide sufficient fact-finding or

explanation to support an upward variance from 71 to 252 months. *See Gall*, 552 U.S. at 50. Thus, the sentence would have been substantively unreasonable, so the alleged Guidelines errors were not harmless. *See Keene*, 470 F.3d at 1349.

2. Drug Quantity Calculation

Next, we address each of Ruan's arguments in turn. First, Ruan argues that the district court clearly erred in finding that at least 10.6% of the prescriptions written were illegal. When reviewing for procedural reasonableness, we consider legal issues *de novo*, review factual findings for clear error, and apply the guidelines to the facts with due deference, which is akin to clear error review. *United States v. Rothenberg*, 610 F.3d 621, 624 (11th Cir. 2010). The district court's determination of the quantity of drugs used to establish a base offense level for sentencing purposes is reviewed for clear error. *United States v. Reeves*, 742 F.3d 487, 506 (11th Cir. 2014). We may affirm for any reason supported by the record, even if not relied upon by the district court. *United States v. Chitwood*, 676 F.3d 971, 975 (11th Cir. 2012).

To be clearly erroneous, a finding must leave us with a "definite and firm conviction that a mistake has been committed." *Rothenberg*, 610 F.3d at 624 (quoting *United States v. Rodriguez-Lopez*, 363 F.3d 1134, 1137 (11th Cir. 2004)). A factual finding cannot be clearly erroneous when the factfinder is choosing between two permissible views of the evidence. *United States v. Saingerard*, 621 F.3d 1341, 1343 (11th Cir. 2010) (per curiam). "'We accord great deference to the district court's credibility determinations' of drug-quantity witnesses." *United States v. Barsoum*, 763

F.3d 1321, 1333 (11th Cir. 2014) (quoting *United States v. Gregg*, 179 F.3d 1312, 1316 (11th Cir. 1999)).

The government bears the burden of establishing drug quantity by a preponderance of the evidence. *United States v. Rodriguez*, 398 F.3d 1291, 1296 (11th Cir. 2005). The district court must ensure that the government "carries this burden by presenting reliable and specific evidence." *United States v. Lawrence*, 47 F.3d 1559, 1566 (11th Cir. 1995). In the medical context, drug distribution requires proof that either: (a) the prescription was not for a legitimate medical purpose; or (b) the prescription was not made in the "usual course of professional practice." *Joseph*, 709 F.3d at 1102.

When the drug amount that is seized does not reflect the scale of the offense, the district court must approximate the drug quantity. *United States v. Frazier*, 89 F.3d 1501, 1506 (11th Cir. 1996). In estimating the drug quantity attributable to the defendant, the court may rely on evidence demonstrating the average frequency and amount of a defendant's drug sales over a given period. *Id.* This determination "may be based on fair, accurate, and conservative estimates of the quantity of drugs attributable to a defendant ... [but] cannot be based on calculations of drug quantities that are merely speculative." *United States v. Zapata*, 139 F.3d 1355, 1359 (11th Cir. 1998) (per curiam).

The drug guideline, § 2D1.1(a)(1), calculates a base offense level based on the total "marihuana equivalent" of all drugs involved in all the defendants' offenses. U.S.S.G. § 2D1.1 cmt. nn.7, 8(B). The highest base offense level (38) applies for quantities over 90,000 kilograms; that is what the PSR applied here.

PSR ¶ 65; U.S.S.G. § 2D1.1(c)(1). The marijuana equivalent of all the morphine, oxycodone, methadone, hydromorphone, oxymorphone, and fentanyl defendants prescribed over the course of the conspiracy was almost 855,000 kilograms. Here, the district court did not clearly err in concluding that at least 10.6% of the prescriptions were illegal. Testimony from two nurse practitioners, Palmer and Parker, suggested that half of the clinic's patients were overmedicated, and given those nurses' qualifications and length of employment at the clinic, the district court was entitled to credit that testimony. *Barsoum*, 763 F.3d at 1333. Moreover, the evidence at trial indicated that significant amounts of Ruan and Couch's practice occurred outside the usual course of professional practice, including: altering prescription habits to further their financial interests; allowing a nurse practitioner to forge prescriptions for his and other nurses' patients; leaving presigned prescription pads for nurses to use when the doctors were out of the office; insufficiently safeguarding high-risk patients; ignoring signs of potential drug diversion; failing to adequately get informed consent for prescriptions, especially for off-label prescriptions; not conducting adequate examinations to diagnose patients; and not first attempting more conservative care. The sheer breadth of improper conduct at the clinic means that the district court did not clearly err in concluding that at least 10.6% of the prescriptions were illegal.

3. Obstruction-of-Justice Enhancement

Ruan next argues that the district court clearly erred in finding that he obstructed justice. In

reviewing the district court's imposition of the obstruction-of-justice enhancement under U.S.S.G. § 3C1.1, we review the district court's factual findings for clear error and its application of those findings to the Guidelines *de novo*. *United States v. Doe*, 661 F.3d 550, 565 (11th Cir. 2011). We accord great deference to a district court's credibility determinations when applying the obstruction-of-justice enhancement based on perjury. *United States v. Banks*, 347 F.3d 1266, 1269 (11th Cir. 2003).

Pursuant to § 3C1.1, a defendant's offense level is increased by two levels if the defendant "willfully obstructed or impeded ... the administration of justice with respect to the investigation, prosecution, or sentencing of the instant offense of conviction," such as by committing perjury. U.S.S.G. § 3C1.1 & cmt. n.4(B). Perjury occurs where a witness gives deliberately false testimony regarding a material matter, which is not caused by confusion, mistake, or faulty memory. *United States v. Dunnigan*, 507 U.S. 87, 94 (1993).

"[I]f a defendant objects to a sentence enhancement resulting from [his] trial testimony, a district court must review the evidence and make independent findings necessary to establish a willful impediment to or obstruction of justice ...." *Id.* at 95. To apply the enhancement, the district court must make a factual finding that the defendant gave perjured testimony on a material matter. *United States v. Vallejo*, 297 F.3d 1154, 1168 (11th Cir. 2002).

Here, the district court's finding that Ruan testified falsely about knowing about Palmer's forgery is not clearly erroneous. In his email to Couch, Ruan directed him to "talk to [Palmer] on cutting down" on

the use of red flag drugs. This email can reasonably be read to demonstrate that Ruan knew Palmer was illicitly prescribing medication, especially when considered with the testimony that others, who worked both in and outside the office, were aware that Palmer was writing prescriptions. Because the district court was entitled to choose between two reasonable constructions of the evidence, it did not clearly err in finding that Ruan testified falsely. *See Saingerard*, 621 F.3d at 1343. Accordingly, we affirm as to this issue.

4. Money Laundering Conviction Enhancement

Next, Ruan argues for the first time on appeal that the district court erred in applying a § 2S1.1(b)(2)(B) enhancement because he was convicted under § 1956(h). A failure to preserve a procedural objection at sentencing means that we only review for plain error. *United States v. Vandergrift*, 754 F.3d 1303, 1307 (11th Cir. 2014). Under plain error review, we consider whether (1) an error occurred, (2) the error was plain, and (3) the error affects substantial rights. *United States v. Olano*, 507 U.S. 725, 732–36 (1993). When these factors are met, we may exercise discretion and correct the error if it "seriously affects the fairness, integrity or public reputation of judicial proceedings." *Id.* at 736.

Under U.S.S.G. § 2S1.1(b)(2)(B), a two-level sentencing enhancement applies if a defendant was convicted under 18 U.S.C. § 1956. U.S.S.G. § 2S1.1(b)(2)(B). However, that enhancement does not apply "if the defendant was convicted of a conspiracy under 18 U.S.C. § 1956(h) and the sole object of that conspiracy was to commit an offense set forth in 18

U.S.C. § 1957." U.S.S.G. § 2S1.1 cmt. n.3(C). If a defendant is convicted under § 1957, a one-level enhancement applies. U.S.S.G. § 2S1.1(b)(2)(A).

Here, the district court erred in applying the two-level sentencing enhancement under § 2S1.1(b)(2)(B), and it should have applied the one-level enhancement under § 2S1.1(b)(2)(A). However, this error did not affect Ruan's substantial rights. Ruan's original offense level was 44, which was treated as 43 because that is the maximum offense level used by the Guidelines. Because applying the correct enhancement would only reduce his offense level to 43, it would not have changed the calculation of the guideline range. Accordingly, the district court's error did not affect Ruan's substantial rights, so we affirm as to this issue.

5. Restitution Calculation

Next, Ruan argues that the district court's restitution calculation was clearly erroneous. "The district court's factual finding as to the specific amount of restitution is reviewed for clear error." *United States v. Futrell*, 209 F.3d 1286, 1289 (11th Cir. 2000) (per curiam). "The district court's decision to allow an estimate of the victim's loss in a particular case" is reviewed for "abuse of discretion." *Id.*

The Mandatory Victims Restitution Act ("MVRA") provides that, in the case of certain offenses, a defendant must make restitution to the victim of the offense. 18 U.S.C. § 3663A(a)(1). In particular, the MVRA applies where a defendant has been adjudicated guilty of: (1) a crime of violence; (2) an offense against property or under 21 U.S.C. § 856(a), including offenses committed by fraud or

deceit; (3) an offense under 18 U.S.C. § 1365; or (4) an offense under 18 U.S.C. § 670. *Id.* § 3663A(c)(1)(A)(i)–(iv).

The amount of restitution ordered by a district court "must be based on the amount of loss actually caused by the defendant's conduct." *United States v. Liss*, 265 F.3d 1220, 1231 (11th Cir. 2001). The government must establish the loss amount by a preponderance of the evidence. 18 U.S.C. § 3664(e); *United States v. Valladares*, 544 F.3d 1257, 1269 (11th Cir. 2008) (per curiam). This burden "simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence." *United States v. Trainor*, 376 F.3d 1325, 1331 (11th Cir. 2004) (quoting *Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Tr. for So. Cal.*, 508 U.S. 602, 622 (1993)). Additionally, because "criminals rarely keep detailed records of their lawless dealings, totaling up every column and accounting for every misbegotten dollar ... the preponderance standard must be applied in a practical, common-sense way." *Futrell*, 209 F.3d at 1292 (quoting *United States v. Savoie*, 985 F.2d 612, 617 (1st Cir. 1993)). As the determination of the restitution amount is an "inexact science," the government "need not calculate the victim's actual loss with laser-like precision, but may instead provide a 'reasonable estimate' of that amount." *United States v. Martin*, 803 F.3d 581, 595 (11th Cir. 2015) (first quoting *United States v. Huff*, 609 F.3d 1240, 1248 (11th Cir. 2010); then quoting *Futrell*, 209 F.3d at 1290). Notwithstanding the government's burden to prove the restitution amount, "[t]he defendant bears the burden to prove the value of any goods or services he provided that he claims should not be included in the restitution amount." *United States v. Foster*, 878

F.3d 1297, 1308 (11th Cir. 2018) (ellipsis omitted) (quoting *United States v. Bane*, 720 F.3d 818, 829 n.10 (11th Cir. 2013)).

When a district court orders restitution, it "must explain its findings with sufficient clarity to enable this [C]ourt to adequately perform its function on appellate review." *Huff*, 609 F.3d at 1248. To that end, the district court must specifically find "whether the victim suffered a loss and the amount of those actual losses." *Id.* at 1249 (emphasis omitted).

Here, the district court ordered restitution to insurers BCBS, United Healthcare, Medicare, and TriCare for 85% of the payments each insurer made for TIRF medications that Ruan and Couch prescribed during the indictment period. This percentage was based on evidence that no more than 15% of PPSA patients had active cancer and that TIRF medications were indicated only for cancer-related pain. Ruan argues that the 85% figure is overstated.

At sentencing, Ruan and Couch objected to the 85% figure, pointing out that Dr. Aultman had opined that it was not inherently illegal to prescribe medications off-label and that there was testimony from a BCBS representative that BCBS sometimes approved TIRFs for a non-cancer diagnosis. The government responded that even if non-cancer patients needed some kind of medication to control their pain, there was ample evidence that Ruan and Couch prescribed Abstral and Subsys to enrich themselves because they had a financial interest, not for appropriate patient care, and that such conduct was also outside the usual course of professional practice. Ruan now adds to his argument for the first time that deducting only 15% for cancer patients is

not enough because the government's charts showed that out of the 25 patients to whom each doctor was prescribing the most TIRF medications, 44% of those patients, or 11 for each doctor, *did* have cancer.

The evidence at trial does not point to any precise number of TIRF prescriptions that were illegal. There is a possibility that PPSA's few cancer patients were prescribed TIRF medications at higher rates than its patients who did not have cancer. There may also have been some patients without a cancer diagnosis who were legitimately prescribed TIRFs off-label to control extreme pain. However, in light of the impracticality of determining which of the thousands of TIRF prescriptions were illegal,[27] and when one also considers the abundant evidence that the appellants prescribed millions of doses of TIRFs for their own financial gain (i.e., their investments in Galena stock and their payments as Insys speakers) rather than for the legitimate needs of their patients—a practice that made them some of the top TIRF prescribers nationwide—we find that 85% of all TIRF medications paid for by each insurer is a "reasonable estimate" of the actual loss to those insurers. *See Martin*, 803 F.3d at 595.

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[27] We imagine that the only way to compute the exact losses that each insurer incurred by paying for TIRF prescriptions written at PPSA would be to present testimony from all of the patients who were prescribed TIRFs (over 1,000 during the indictment period) or opinions from medical experts who have reviewed their files. A consideration of each patient's medical needs would be necessary to determine whether the prescriptions written were illegal or legitimate. The MVRA does not require such "laser-like precision." *Martin*, 803 F.3d at 595.

Moreover, it was Ruan's burden "to prove the value of any goods or services he provided that he claims should not be included in the restitution amount." *Foster*, 878 F.3d at 1308 (quoting *Bane*, 720 F.3d at 829 n.10). But when asked by the district court at Couch's sentencing, which was held first and in which Ruan participated and adopted Couch's counsel's arguments, "What do you think is a more appropriate figure?", Couch's counsel stated: "Your honor, I don't have an alternative figure." It was not enough for Ruan to assert that the government's estimate of the insurers' loss amount was improper, when that estimate was reasonable based on the facts presented at trial. Ruan had to show the value of the TIRF prescriptions he wrote that he claims were medically necessary, in order to enable the district court to offset them against the restitution amount. *See Foster*, 878 F.3d at 1308; *United States v. Bryant*, 655 F.3d 232, 254 (3d Cir. 2011) (emphasizing that the defendant has the burden of establishing offsets to restitution because he is in the best position to know the value of the legitimate goods or services provided to his victims). Ruan failed to carry that burden.

Ruan also separately argues that it was error for the district court to have ordered restitution to be paid to insurers BCBS, United Healthcare, Medicare, and TriCare for 50% of each insurer's payments for the remaining Schedule II prescriptions dispensed by PPSA during the relevant period. This percentage was based on trial testimony from Palmer and Parker that at least half of PPSA's patients were overmedicated or had received prescriptions for larger doses of drugs than they needed.

At sentencing, the government stated that some of the victim insurers felt they were entitled to more than 50%—for instance, United Healthcare felt it was entitled to 80%—but all four insurers ultimately agreed with the government that 50% was a fair and accurate calculation based on the trial testimony. The government argued that it would be impossible to calculate which particular Schedule II prescriptions were illegal and that 50% was a reasonable estimate based on the evidence. Ruan and Couch disagreed, arguing that restitution should only be ordered for the value of specific prescriptions experts had testified were written outside the usual course of professional practice or not for a legitimate medical purpose, describing those amounts as "miniscule."

As with the TIRF prescriptions, the evidence at trial did not point to any precise number of the remaining Schedule II prescriptions as being illegal. Calculating the exact amount of loss to each of the four insurers would be impractical, if not impossible. The MVRA justifies the use of approximation in cases like this, provided the estimate is reasonable and based on a preponderance of the evidence. Here, two different nurse practitioners, who had firsthand knowledge of PPSA's patients for years, each testified that at least half of the patients were overmedicated or had received prescriptions for larger quantities of drugs than they needed. This testimony was bolstered by the abundant evidence that Ruan and Couch's prescribing habits were consistently outside the usual course of professional practice during the indictment period, as evidenced by their allowing Palmer to forge prescriptions; leaving pre-signed prescriptions for nurses to use; failing to obtain informed consent from patients before writing multiple prescriptions for high

doses of Schedule II drugs; and ignoring signs of drug diversion. Additionally, the 50% estimate was conservative because all of the illegal prescriptions were not included in calculating the restitution amount—only those for Schedule II drugs, which does not include drugs like benzodiazepines and Soma, the other two components of the dangerous "Holy Trinity" cocktail that the appellants prescribed so often. *See Futrell*, 209 F.3d at 1292 ("So long as the basis for reasonable approximation is at hand, difficulties in achieving exact measurements will not preclude a trial court from ordering restitution."). We thus cannot say that the district court's estimate that the insurers were each owed 50% of payments they made for Schedule II drugs was speculative to the point of being clearly erroneous.

Additionally, we find that the district court explained its findings with sufficient clarity to enable us to perform our duty on appellate review. Ruan's judgment of conviction breaks down the amount of restitution that is owed individually by Ruan to each insurer and the amount that Ruan owes jointly and severally with Couch to each insurer. Ruan never objected to the actual losses sustained by any insurer, instead objecting only generally to the method of calculating the losses.

For these reasons, the district court did not abuse its discretion in determining that the government had proven the restitution amount by a preponderance of the evidence.[28]

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[28] Ruan also argues that the district court erred in ordering forfeiture because insufficient evidence established a RICO Act violation. The government responds that Ruan's forfeiture

III. CONCLUSION

For the foregoing reasons, we vacate Ruan and Couch's convictions on Count 16 of the Superseding Indictment, and we remand the cases to the district court for resentencing. We affirm Ruan and Couch's remaining convictions and sentences.

AFFIRMED IN PART, VACATED AND REMANDED IN PART.

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argument is waived because it was raised in a perfunctory manner without supporting arguments or citations, and that, in any event, the RICO conviction was valid. A party seeking to raise a claim or issue on appeal must raise it "plainly and prominently" or otherwise the issue is deemed abandoned. *United States v. Jernigan*, 341 F.3d 1273, 1283 n.8 (11th Cir. 2003). Ruan's argument regarding forfeiture does not appear to be an independent claim that his forfeiture was illegal. Rather, his claim appears to be derivative of his claim that insufficient evidence supports his RICO conviction. Because we affirm the RICO conviction, we uphold the forfeiture order regarding the RICO violation.

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 17-12653

UNITED STATES OF AMERICA,

Plaintiff–Appellee,

v.

XIULU RUAN, JOHN PATRICK COUCH,

Defendants–Appellants.

Filed: Nov. 4, 2020

ON PETITION(S) FOR REHEARING AND PETITION(S) FOR REHEARING EN BANC

Before: WILSON and NEWSOM, Circuit Judges, and COOGLER,* District Judge.

PER CURIAM:

The Petitions for Rehearing En Banc are DENIED, no judge in regular active service on the Court having requested that the Court be polled on rehearing en banc. (FRAP 35) The Petitions for Panel Rehearing are also denied. (FRAP 40)

* Honorable L. Scott Coogler, United States District Judge for the Northern District of Alabama, sitting by designation.

APPENDIX C

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ALABAMA

UNITED STATES OF AMERICA,

v.

JOHN PATRICK COUCH, M.D., ET AL.,

Defendants.

CASE NO. 1:15-CR-88-CG
FEB. 6, 2017

DEFENDANTS' PROPOSED JURY INSTRUCTIONS

Defendants John Patrick Couch, M.D., and Xiulu Ruan, M.D., [1] respectfully request that, at the close of all evidence, the Court instruct the jury as outlined in Exhibit A.

* * *

Defendants' Requested Instruction Number 18

* * *

If a physician dispenses or distributes a Controlled Substance in good faith while medically treating a patient, then the physician has dispensed or distributed that Controlled Substance for a

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[1] The parties have conferred, and Dr. Ruan joins in these requests.

legitimate medical purpose and within the usual course of professional practice, and you must return a not guilty verdict for the applicable count. Good faith in this context means good intentions and the honest exercise of professional judgment as to the patient's needs. It means that the Defendant acted in accordance with what he reasonably believed to be proper medical practice. If you find that a 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.

* * *

Source: United States v. Moore, 423 U.S. 122 (1975); United States v. Smith, 573 F.3d 639 (8th Cir. 2009); United States v. Merrill, 513 F.3d 1293 (11th Cir. 2008); United States v. Feingold, 454 F.3d 1001 (9th Cir. 2006); United States v. McIver, Case No. 8:04-CR-745, Doc. #27 (D.S.C. Apr. 18, 2005) (final jury instructions), affirmed by United States v. McIver, 470 F.3d 550 (4th Cir. 2006).

* * *

APPENDIX D

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ALABAMA

UNITED STATES OF AMERICA,

v.

JOHN PATRICK COUCH, M.D., AND XIULU RUAN, M.D.,

Defendants.

CASE NO. CR15-00088
COURTROOM 2B
MOBILE, ALABAMA
FRIDAY, FEBRUARY 16, 2017

DAY 27 OF TRIAL BEFORE
THE HONORABLE CALLIE V. S. GRANADE,
UNITED STATES DISTRICT JUDGE, AND JURY

* * *

MR. ESSIG: Next, Your Honor, the second aspect of it is that the Court's proposed instructions do not contain a definition of "usual course of medical practice or legitimate medical purpose."

We think there needs to be one in this case and it's sort of a two-part issue, is that, one, those terms wholly undefined are, I think, difficult for the jury to determine.

Second, Your Honor, is that there is sort of a -- the Eleventh Circuit certainly doesn't have a pattern jury instruction on this issue. But through United States v. Moore, which is sort of the beginning case, the Supreme Court case from the '70s that kind of starts the juris prudence on the Controlled Substances Act as applied to physicians, it's sort of developed an accepted jury instruction that the Eleventh Circuit has given.

Now, we have proposed in Couch instruction 18 various aspects of the concept of usual course for the jury to be instructed on and we think those are appropriate. All of the requested instructions that we provide, most of them are taken from Eleventh Circuit case law, some of them are taken from the Fourth Circuit -- a Fourth Circuit case as well. But, Your Honor, particularly we think the Court included a good faith instruction as it was related to the fraud counts in this case. But we think some sort of good faith or honest faith, honest effort language or instruction should be included along with the -- with the usual course instruction, the Controlled Substances Act portion of the Court's instructions to the jury.

MS. GRIFFIN: Your Honor, excuse me. Are you finished?

MR. ESSIG: Yes.

MS. GRIFFIN: Are you finished? We would be opposed to that. I don't think there is a definition by the Eleventh Circuit about "outside the usual course of professional care" and I think to charge them anything would invite confusion. Further, I don't think there's been any argument or any suggestion

about good faith or honest effort through the testimony of the defense.

MR. BODNAR: As it applies to the drugs. For the fraud --

MS. GRIFFIN: As to the drugs.

MR. BODNAR: -- of course, it is our burden to show that it wasn't done in good faith, as instructed.

MR. ESSIG: Judge, we would disagree with the notion there's been no good faith. Both Dr. Ruan and Dr. Couch in their testimony stated that they did everything with their patients that they believed was appropriate, based on their medical training and experience as board certified pain management doctors. So that's certainly sufficient.

THE COURT: Well, the problem with your requested instruction, as I understand it -- and having looked at some, although I looked at not all of the case law in this regard -- is what you are proposing is a subjective view of what is the usual course of professional practice. And the standard should be an objective one, not a subjective one. I understand that good faith is a subjective aspect, although the Eleventh Circuit has approved the language from the Williams case that included good faith.

MR. ESSIG: Yes, ma'am. Yes, ma'am. And that's -- the Williams case, I mean, that instruction has kind of emerged from the case law as kind of the standard Eleventh Circuit instruction that's been given repeatedly in these cases. I mean, it's Williams, it's Merrill, I think the most recent Eleventh Circuit case that applies that is the case of Joseph, which is at --

THE COURT: Yeah, I read the Joseph case.

MR. ESSIG: And that case sort of gives -- that case gives an analysis of the jury instructions there.

THE COURT: But that was not national versus -- not a national standard of care. I mean, it was more of a jurisdictional-type argument.

MR. ESSIG: Yes, ma'am. I think it was. And I think that's right. And one of the challenges, of course, with the Eleventh Circuit case law on this is it's muddled, it is not clear. The Eleventh Circuit's gone both ways on this issue. I mean, I think they rejected a more robust request for a good faith instruction from the defense but defaulted to this instruction which incorporates -- which incorporates good faith while recognizing that their position that a more robust good faith instruction was not required. We think it is. Again, our position is that we think that defense instruction 18 should be given. However, if the Court --

THE COURT: Portions of instruction 18 are not what the law is in that regard, at least as I understand it, in that regard. And so that's why I rejected 18. The government didn't propose any definition on that.

MR. BODNAR: For the reason being there's not a defined --

THE COURT: No. But, I mean, there have been cases where they say the giving of such instruction was not plain error. Although we're not -- you know, you're talking about this now, and so it wouldn't be plain error. It would be whether or not it's error not to give the instruction. So I am willing to give the instruction that was in the Williams case.

MR. ESSIG: Yes, ma'am.

THE COURT: That would say: "The defendants in this case maintain at all times they acted in good faith and in accordance with the standard of medical practice generally recognized and accepted in treating patients. Thus a medical doctor has violated the Controlled Substances Act when the government has proved beyond a reasonable doubt that the doctor's actions were not for legitimate medical purpose in the usual course of professional practice or were beyond the bounds of professional medical practice." But that's as far as I'm willing to go, given the state of the law on this issue. But it throws a bone to your good faith language while still being fairly general.

MR. BODNAR: We would have no problem with that instruction.

MR. ESSIG: Judge, without waiving our objection that we would like to see instruction 18 --

THE COURT: You would rather see that than nothing at all?

MR. ESSIG: -- we will accept the Court's -- no, we will accept the Court's position.

THE COURT: All right. Okay. Then I'll stick that in there. And that would be -- where I will stick that would be -- there are two places where I describe that. One is on page 15 and --

MR. ESSIG: It becomes a little bit cumbersome because it relates to multiple parts.

THE COURT: Yeah. And then the other place I discuss it is on page 23. 15 is under the conspiracy charge, the substantive portion of the conspiracy charge. And page 23 is concerning the -- no. Well, it's --

MR. ESSIG: The substantive offenses.

THE COURT: -- the substantive offenses. It starts over on page 22. So I would be inclined to stick it in there where the substantive offenses are. And actually I'll just append it to after "issued," the period and "issued," then start with: "The defendants maintain at all times they acted in good faith," blah, blah, blah, blah, blah.

* * *

APPENDIX E

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ALABAMA

UNITED STATES OF AMERICA,

v.

JOHN PATRICK COUCH, M.D., AND XIULU RUAN, M.D.,

Defendants.

CASE NO. CR15-00088
COURTROOM 2B
MOBILE, ALABAMA
FRIDAY, FEBRUARY 17, 2017

DAY 28 OF TRIAL BEFORE
THE HONORABLE CALLIE V. S. GRANADE,
UNITED STATES DISTRICT JUDGE, AND JURY

* * *

THE COURT:

Members of the jury, it is now my duty to instruct you on the rules of law that you must use in deciding this case. After I have completed these instructions, you will go to the jury room and begin your discussions -- or what we call your deliberations.

* * *

Title 21, United States Code, Section 841(a)(1) makes it a crime for a physician to knowingly or

intentionally distribute or dispense a controlled substance unless it was done within the usual course of professional practice and for a legitimate medical purpose. Dispense can mean to prescribe a controlled substance. Distribute can mean to deliver other than by dispensing a controlled substance. 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.

A controlled substance is prescribed by a physician in the usual course of a 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 defendants in this case maintain at all times they acted in good faith and in accordance with standard 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.

* * *