No. 17-12653

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

United States of America,

Plaintiff-Appellee,

v.

Dr. Xiulu Ruan,

Defendant-Appellant.

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

SUPPLEMENTAL BRIEF OF APPELLANT ON REMAND

Lawrence S. Robbins
FRIEDMAN KAPLAN SEILER & ADELMAN LLP
7 Times Square
New York, NY 10036
Telephone: (212) 833-1118
lrobbins@fklaw.com

Carolyn M. Forstein
Jeffrey C. Thalhofer
KRAMER LEVIN NAFTALIS & FRANKEL LLP
2000 K Street, NW, 4th Floor
Washington, DC 20006
Telephone: (202) 775-4500
cforstein@kramerlevin.com

Counsel for Appellant

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to 11th Cir. R. 26.1-1, counsel for Appellant certifies that the following persons and entities have an interest in the outcome of this case:

Armstrong, Gordon G. III – Counsel for Appellant

Bivins, Hon. Sonja F. – United States Magistrate Judge

Bodnar, Christopher J. – Assistant United States Attorney

Brinson, Christopher B. – Assistant United States Attorney

*C & R Pharmacy, LLC

Costello, Sean P. – United States Attorney

Couch, John Patrick – Co-Defendant

Darley, Jason B. – Counsel for Appellant

Defense Health Agency

Finlayson, L. Burton – Counsel for Appellant

Forstein, Carolyn M. – Counsel for Appellant

Granade, Hon. Callie V.S. – United States District Court

Gray, Scott Alan – Assistant United States Attorney

Griffin, Deborah A. – Assistant United States Attorney

Knizley, Dennis J. – Counsel for Appellant

Lotito, Nicholas A. – Counsel for Appellant

Martinie, Steve – Counsel for Appellant

Medicare Office of Financial Management – Parts A & B; Part D

Overstreet, Adam W. – Assistant United States Attorney

Pate, Page A. – Counsel for Appellant

* Physician's Pain Specialists of Alabama, P.C.

Ralston, Sonja – Appellate Attorney, U.S. Department of Justice

Robbins, Lawrence S. – Counsel for Appellant

Ruan, Xiulu – Appellant

Thalhofer, Jeffrey – Counsel for Appellant

United Health Group

* No public corporation owns any stock in these entities.

Dated: August 29, 2022

/s/ Lawrence S. Robbins
Lawrence S. Robbins

STATEMENT REGARDING ORAL ARGUMENT

Pursuant to Fed. R. App. P. 34(a) and 11th Cir. R. 28-1, Appellant Dr. Xiulu Ruan respectfully requests oral argument. On remand, this Court will be applying the standard articulated in *Ruan v. United States*, 142 S. Ct. 2370 (2022), for the first time, and assessing the impact of the instructional error on Dr. Ruan's case. This decision implicates all remaining counts of conviction in Dr. Ruan's case. Oral argument will assist the Court in fairly resolving the legal issues raised by this case on remand.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases **Page(s)**

TABLE OF AUTHORITIES—Continued

Page(s)

Statutes

STATEMENT OF JURISDICTION

The Eleventh Circuit Court of Appeals has jurisdiction to consider this case pursuant to 28 U.S.C. § 1291 and 18 U.S.C. § 3742(a). This case involves a direct appeal of a criminal conviction and sentence imposed by the U.S. District Court for the Southern District of Alabama. The district court (Granade, J.) had jurisdiction under 18 U.S.C. § 3231, and entered judgment on May 31, 2017. Dr. Ruan filed a timely notice of appeal on June 13, 2017. The Eleventh Circuit entered judgment on July 10, 2020, and denied rehearing on November 4, 2020. Dr. Ruan filed a timely petition for a writ of certiorari, and on June 27, 2022, the U.S. Supreme Court vacated the Eleventh Circuit's judgment and remanded for further consideration. This Court ordered supplemental briefing on August 8, 2022.

STATEMENT OF THE ISSUES

I. Whether the jury instructions given in Dr. Ruan's trial complied with the standard set forth by the United States Supreme Court in *Ruan v. United States*, 142 S. Ct. 2370 (2022).

II. Whether any instructional error in Dr. Ruan's trial constitutes harmless error.[1]

[1] These two questions address whether Dr. Ruan should be afforded a new trial governed by the correct scienter standard. In its brief in the Supreme Court, however, the government explained that it is Alabama law that determines the bounds of professional practice, and not a national standard, as the government had suggested at trial. If that is true, then as we contended in our reply brief before the Supreme Court, *see Ruan v. United States*, S. Ct. No. 20-1410, Reply Br. at 11-15, the case should be dismissed outright for want of sufficient Alabama-specific

STATEMENT OF THE CASE

Appellant Dr. Xiulu Ruan practiced medicine as a board-certified interventional pain specialist in Mobile, Alabama. Together with his partner Dr. John Patrick Couch, Dr. Ruan owned and operated a pain clinic (Physicians' Pain Specialists of Alabama (PPSA)) and an affiliated pharmacy (C&R Pharmacy). *See United States v. Ruan*, 966 F.3d 1101, 1121 (11th Cir. 2020), *cert. granted*, 142 S. Ct. 457 (2021), and *vacated and remanded*, 142 S. Ct. 2370 (2022).

In April 2016, a grand jury indicted Appellant and his partner on substantive and conspiracy charges of unlawful distribution of controlled substances under 21 U.S.C. § 841(a)(1), racketeering conspiracy, health care fraud conspiracy, mail and wire fraud conspiracy, and anti-kickback conspiracy. *Id.* at 1120. Dr. Ruan (but not Dr. Couch) was also charged with money laundering and conspiracy to commit money laundering. *Ibid.* The indictment included the Section 841(a)(1) violations as predicate offenses for the majority of these additional charges. *See* Dkt. 269:19-20, 27-28, 39-41 (Second Superseding Indictment (Apr. 28, 2016)).[2] The doctors pleaded not guilty and were tried together.

---

evidence. The Supreme Court did not reach this issue, but it is logically prior to the question of a new trial. We respectfully submit that this Court should request supplemental briefing on that issue before it addresses the two remanded questions.

[2] "Dkt. XX:YY" refers to a district court docket entry, followed by the page number. The trial transcript is numbered as Dkt. 722-[volume]; it is consecutively paginated, and page numbers used herein, cited as "Tr. YY," refer to those numbers.

At trial, the government acknowledged that, "[b]y and large, [defendants'] patients were legitimate patients." *Ruan*, 966 F.3d at 1157. One government witness described PPSA as "one of the best, well-rounded pain centers in this area." Tr. 3177. It was "undisputed" that PPSA was not a "sham practice"; it accepted only patients with insurance (and thus accepted those insurers' oversight), refused cash payments, and used a variety of sophisticated "[d]iagnostic tools" to discover the source of patient pain. *Ruan*, 966 F.3d at 1157.

The government alleged, however, that some of Dr. Ruan's prescriptions fell outside a "usual course of professional practice." To sustain that allegation, the government devoted much of the trial to proof that was indistinguishable from simple negligence. For example, the government presented experts who claimed that Dr. Ruan had prescribed medication "outside [the] standard of care." Tr. 2357; *see also* Tr. 661-1061 (Dr. Greenberg); Tr. 2246-2542 (Dr. Vohra); Tr. 4328-4520 (Dr. Aultman). The government's experts suggested other treatments that Dr. Ruan should have used, and contended that he had engaged in recordkeeping failures, *e.g.*, Tr. 746, and relied unduly on nurse practitioners and other staff, *e.g.*, Tr. 681. Dr. Ruan vigorously contested these allegations, including by calling his own experts who testified that Dr. Ruan complied with and even exceeded relevant professional standards of care. *See* Tr. 6034-6078 (Dr. Gharibo); Tr. 5205-5341 (Dr. Gudin); *see also* Tr. 4763-4914 (Dr. Warfield). Dr. Ruan also testified, explaining that he always

intended to prescribe for a legitimate medical purpose and that his treatment decisions were motivated only by "caring for [his] patients," Tr. 5920-5921, and based on the "need of the patient," Tr. 5828.

At the close of evidence, Dr. Ruan requested that the district court give the jury a good faith instruction to explain "the terms 'usual course of professional practice' and 'legitimate medical purpose.'" Dkt. 462:29. The district court refused to do so. Agreeing only to "throw[] a bone to your good faith language," and emphasizing that this was "as far as I'm willing to go" Tr. 6107, the district court instructed the jury, over Dr. Ruan's objection (*see id.;* Dkt. 775:42), that it could convict him if the jury found that Dr. Ruan's prescriptions fell outside professional norms, regardless of what he subjectively believed or intended. *See Ruan*, 966 F.3d at 1166.

Dr. Ruan was convicted on all but two counts in the second superseding indictment. *See Ruan*, 966 F.3d at 1120. He was sentenced to 252 months' imprisonment, to be followed by four years of supervised release, and ordered to pay more than $15 million in restitution and more than $5 million in forfeiture. *Id.* at 1133. Seven of the counts on which he was convicted were controlled substances charges. Every other count of conviction either explicitly relied on the controlled substances offenses as a predicate or implicitly relied on the facts underlying those offenses, together with the allegation that Dr. Ruan did not prescribe for legitimate

medical purposes.[3] Sentencing for all counts relied on the controlled substances offenses to calculate the base level offense range. Dkt. 723:37-38; Dkt. 628:16; *Ruan*, 966 F.3d at 1133, 1135.

Dr. Ruan appealed, raising, among other issues, the district court's erroneous instruction on his good faith defense. *See* 966 F.3d at 1165. "[B]ound by its [prior] holdings," however, this Court affirmed. *Id.* at 1167. Agreeing with the district court, this Court held that 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." *Id.*

On June 27, 2022, the United States Supreme Court vacated Dr. Ruan's judgment of conviction, holding that "in a § 841 prosecution in which a defendant meets his burden of production under § 885, the Government must prove beyond a reasonable doubt that the defendant *knowingly or intentionally acted in an*

[3] *See* Tr. 6330 (racketeering conspiracy); Tr. 6344, Dkt. 269:27-28 (health care fraud conspiracy); Tr. 6349-6351 (money laundering conspiracy and substantive money laundering); Dkt. 269:37-39 (wire and mail fraud conspiracy based on selecting patient prescriptions for reasons other than "the needs of the patient").

Dr. Ruan was also convicted on two anti-kickback conspiracy counts at trial, which were likewise intertwined with the government's theory that Dr. Ruan did not prescribe for a legitimate medical purpose. *See, e.g.*, Dkt. 269:40 (alleging Dr. Ruan was induced to "prescrib[e] high volumes of Subsys," and that "nearly all of [those prescriptions]" were prescribed for off-label). Moreover, one of the Anti-Kickback convictions (Count 16) was reversed on appeal for insufficient evidence, *see Ruan*, 966 F.3d at 1146.

unauthorized manner." *Ruan v. United States*, 142 S. Ct. 2370, 2382 (2022) (emphasis added). The Supreme Court remanded so that this Court could consider in the first instance (1) "whether the instructions complied with the standard we have set forth" and (2) the government's argument that any error was harmless. *Id.* On its own motion, this Court ordered briefing on those questions.

SUMMARY OF ARGUMENT

I. The instructions given to Dr. Ruan's jury did not remotely comply with the standard articulated by the Supreme Court in this case. Indeed, they were the polar opposite: Whereas the Supreme Court required that juries must find that the physician *subjectively intended* to exceed his authorization, Dr. Ruan's jury was told that it could convict him even if all it found was that, as an *objective* matter, Dr. Ruan's prescriptions strayed outside professional norms. That is barely a malpractice standard, much less the kind of scienter the Supreme Court has now required. And far from (somehow) neutralizing that fundamental error, the remaining portions of the instructions *reinforced* the message that any departure from professional norms was enough to convict.

II. By no means was this fundamental instructional error harmless. As the Supreme Court explained in *McDonnell* v. *United States*, 579 U.S. 550 (2016), when an erroneous jury instruction may have led the jury to convict a defendant "for conduct that is not unlawful," the error cannot be harmless. *Id.* at 579-80. That

principle applies with full force here. But even if a further harmless-error inquiry is required, the government cannot possibly carry its heavy burden to show that the instructional errors were harmless "beyond a reasonable doubt." *Chapman v. California*, 386 U.S. 18, 24 (1967). By permitting the jury to convict on nothing more than simple malpractice, the instructions gutted Dr. Ruan's good faith defense and absolved the prosecutors of their duty to prove an element of the offense. And because the case was laden with evidence that was indistinguishable from basic malpractice, the jury, misled by the instructions, could and almost assuredly did convict without regard to scienter.

ARGUMENT

I. THE INSTRUCTION GIVEN DID NOT COMPLY WITH THE *MENS REA* STANDARD ANNOUNCED BY THE SUPREME COURT.

The Supreme Court remanded to permit this Court to determine "*whether the instructions complied with the standard* we have set forth today." 142 S. Ct. at 2382 (emphasis added). That question is subject to *de novo* review. *United States v. Mayweather*, 991 F.3d 1163, 1174 (11th Cir. 2021). A correct instruction "must define the offense charged and its elements to enable the jury to apply the law to the facts." *United States v. Silverman*, 745 F.2d 1386, 1395–96 (11th Cir. 1984). Absent a harmless error claim (which we address in Point II below), this Court "will reverse a conviction due to an erroneous jury instruction" if "the issues of law were presented inaccurately, or the charge improperly guided the jury in such a substantial

way as to violate due process." *United States v. Abovyan*, 988 F.3d 1288, 1308 (11th Cir. 2021).

1. The instructions given, taken as a whole, came nowhere close to the standard set forth by the Supreme Court. Indeed, they were the polar opposite: Whereas the Supreme Court required a showing that the prescribing doctor subjectively knew and intended that his prescriptions were unauthorized, Dr. Ruan's jury was invited to convict him if it found, merely, that his prescriptions fell outside professional norms, regardless of his *mens rea*. In particular, the district court told the jury:

> 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.

Tr. 6333 (emphasis added).

This was the "bone" the district court was willing to throw to defendants (Tr. 6107). The trial court told the jury that it was entitled to accept Dr. Ruan's good faith defense, but *only* if his prescriptions fell within "the usual course of professional practice." Put another way, Dr. Ruan could advance a good faith defense only if his prescriptions were already lawful.

Lest the jury miss the point, the district court reiterated that position when it summarized its Section 841(a)(1) instructions:

> The defendant can be found guilty of each offense only if all of the following facts are proved beyond a reasonable doubt as to that offense: One, on or about the date charged, the defendant dispensed by prescription the identified controlled substance to the identified individual; two, the defendant did so knowingly and intentionally; and, three, the defendant did not have a legitimate medical purpose to do so or did not do so in the usual course of professional practice.

Tr. 6339. The district court thereby reinforced the point that "knowingly and intentionally" applied *only* to the act of dispensing a controlled substance. As to the crucial third element—whether Dr. Ruan issued an *unauthorized* prescription (because it lacked a legitimate medical purpose and fell outside professional norms)—the district court refused to give *any* scienter instruction. Yet "it is the fact that the doctor issued an *unauthorized* prescription that renders his or her conduct wrongful, not the fact of the dispensation itself." *Ruan*, 142 S. Ct. at 2377. For that reason, as the Supreme Court held, the "unauthorized" element *must* carry a *mens rea* requirement. *See id.*; *id*. at 2381-82.

Nor does the balance of the district court's instructions somehow compensate for the flatly misleading good faith instruction. To be sure, the district court adverted to the statute's "knowingly or intentionally" language, but (as noted above) it applied that scienter requirement only to the act of distribution, not to the "except as authorized" element. Thus, for example, the district court instructed on the distribution-conspiracy charges that:

> Counts two, three, and four of the indictment each allege that the defendants conspired with each other and with others to violate the Controlled Substances Act, Title 21, United States Code, Section 846.
>
> That statute makes it a separate federal crime or offense for anyone to conspire or agree with someone else to do something which, if actually carried out, would be a violation of section 841(a)(1). That section makes it a crime for anyone to knowingly or intentionally distribute or dispense a controlled substance, *unless* it was prescribed by a practitioner within the usual course of professional practice and for a legitimate medical purpose.

Tr. 6331-32 (emphasis added). *See also* Tr. 6332-33 (similar), 6336 (similar); 6337-38. Here, again, the district court decoupled the scienter element ("knowingly or intentionally") from the "except as authorized" element, and applied it only to the act of distributing.[4]

[4] If one strains to read part of the CSA-conspiracy charge in just the right light, it might suggest to the jury that, because knowledge of the conspiracy's aims and intent to join the conspiracy are necessary to convict, so too the government must prove knowledge or intention as to lack of authorization in the substantive offense:

> Each defendant can be found guilty of the conspiracy alleged in one or more of counts two, three, and four only if all of the following facts are

These instructions, taken as a whole, fail to require any *mens rea* as to whether a physician's prescription is authorized. That failure cannot be squared with the Supreme Court's holding. As that Court emphasized, the "authorization" element "plays a crucial role in separating innocent conduct—and, in the case of doctors, socially beneficial conduct—from wrongful conduct." *Ruan*, 142 S. Ct. at 2377. *Cf. Mayweather*, 991 F.3d at 1185 ("The concerns highlighted in *McDonnell* [*i.e.*, "lawful interactions between state officials and constituents, vagueness, and federalism"] are only heightened when, as here, no definition *at all* for 'official act'

> proved beyond a reasonable doubt as to the count in question: One, two or more people in some way agreed to try and accomplish a shared and unlawful plan to distribute or dispense outside the usual course of professional practice and not for a legitimate medical purpose the alleged controlled substance or substances; and, two, the defendant knew the unlawful purpose of the plan and willfully joined in it.

Tr. 6334-35. But "a single instruction to a jury may not be judged in artificial isolation," *United States v. Park*, 421 U.S. 658, 674 (1975), and this conspiracy instruction, which came after both the crucial, erroneous instruction on Section 841(a)(1) and the conspiracy instruction just quoted above the line, cannot set those wayward instructions right. For one, it does not specify that the "agree[ment] to try" and "kn[owledge of] the unlawful purpose of the plan" include knowledge or intent as to authorization, rather than simply as to distribution. What is more, the instruction immediately following the above omits any language of scienter in describing the trial evidence on "the schedule II and III controlled substances alleged to have been prescribed either not for a legitimate medical purpose or outside the usual course of professional practice." Tr. 6335. And, as described *supra* at 9 (quoting Tr. 6339), the court several transcript pages later gave a substantive CSA instruction that plainly divorced knowledge and intent from authorization. Further, the jury was instructed that "[e]ach count of the indictment charges a separate crime" and "[y]ou must consider each crime and the evidence relating to it separately." Tr. 6354.

is given.") Mis-defining the scienter requirement for this "crucial" element is clearly wrong.

Nor, as the government has argued, is the error abated because the jury would "naturally understand 'professional' 'medical' practice as including some reasonable degree of individualized physician judgment as to how such practice would translate into individualized treatment of specific patients." U.S. BIO at 14, *Ruan*, No. 20-1410 (July 7, 2021). Even if the jury could have intuited a statutory *mens rea* from a bare recitation of the regulatory language—and it's hard to see how it could have divined that *mens rea*, especially given the district court's explicit instruction that a departure from professional norms is enough to convict—any standard that turned on a "reasonable degree" of judgment would "turn a defendant's criminal liability on the mental state of a hypothetical 'reasonable' doctor, not on the mental state of the defendant himself or herself." *Ruan*, 142 S. Ct. at 2381.[5] Neither did the district court's passing references to "good faith" somehow neutralize its errors. According to the government, these remarks "would naturally [be] understood as encompassing a sincere belief at which Ruan had *reasonably*

[5] The government has also suggested that defense counsel's arguments to the jury cured any error in the jury instructions. But it is the *instructions* that constitute the "definitive and binding statements of the law," and juries are presumed to follow them. *Boyde* v. *California,* 494 U.S. 370, 384 (1990). And here, the court reminded the jury that it must "follow the law as [the court] explain[s] it," Tr. 6322; that "anything the lawyers say . . . is not binding on you," Tr. 6323; and that "arguments . . . by the lawyers are not evidence," Tr. 9.

arrived." U.S. Br. at 45, *Ruan*, No. 20-1410 (Jan. 19, 2022) (emphasis added). But even if the jury were actually that clairvoyant, an invitation to decide on Dr. Ruan's "reasonable arrival" on a prescription "reduces culpability on the all-important element of the crime to negligence." *Ruan*, 142 S. Ct. at 2381. And negligence, the Supreme Court was at pains to emphasize, *is not* the correct standard. *Id.*

II. THE INSTRUCTIONAL ERROR WAS NOT HARMLESS.

A. The instructional error was prejudicial because Dr. Ruan may have been convicted for conduct that is not unlawful.

This Court need not parse the trial record to assess the harmfulness of Dr. Ruan's erroneous jury instruction. In *McDonnell* v. *United States*, 579 U.S. 550 (2016), the Supreme Court explained that when an erroneous jury instruction may have led the jury to convict a defendant "for conduct that is not unlawful," the error cannot be harmless. *Id.* at 579-80. In *McDonnell*, the Court concluded that the jury was improperly instructed to apply an overly broad definition of a statutory element under the Hobbs Act. Because "the jury was not correctly instructed on the meaning of [the required element], it may have convicted Governor McDonnell for conduct that is not unlawful." *Id.* Accordingly, the Court "c[ould] not conclude that the errors in the jury instructions were 'harmless beyond a reasonable doubt.'" *Ibid*. (quoting *Neder v. United States*, 527 U.S. 1, 16 (1999)).

The same rule applies here. The district court incorrectly instructed Dr. Ruan's jury that the *mens rea* requirement applied only to the act of dispensing, and

not to the question of whether Dr. Ruan acted outside "the usual course of professional practice" or without a "legitimate medical purpose." *See supra* at 8-9. The Supreme Court has now clarified that Dr. Ruan's jury instruction was wrong, as the *mens rea* requirement under Section 841(a) extends to *both* dispensation and authorization. Dr. Ruan's jury instructions thus "lacked important qualifications, rendering them significantly overinclusive." *McDonnell*, 579 U.S. at 577.

Because Dr. Ruan's jury "was not correctly instructed on the meaning of [*mens rea* requirement], it may have convicted [Dr. Ruan] for conduct that is not unlawful." *McDonnell*, 579 U.S. at 579. As in *McDonnell*, that precludes any finding that Dr. Ruan's erroneous jury instruction was "harmless beyond a reasonable doubt." *Id*. at 580; *see also United States* v. *Williams*, 836 F.3d 1, 20 (D.C. Cir. 2016) (Kavanaugh, J., concurring) ("In a criminal appeal where a mens rea-related jury instruction issue may have made a difference to the conviction and sentence, it is critically important to ensure that the jury had a correct understanding of the relevant law.").

B. Assuming a further harmless-error inquiry is warranted, the instructional error was highly prejudicial.

While *McDonnell* should pretermit a further harmless error inquiry, the trial record confirms that the government cannot carry its heavy burden to show harmless error.

1. As the Supreme Court has repeatedly held, an instruction that omits or misdescribes a required element of an offense is "unconstitutional." *Pope v. Illinois*, 481 U.S. 497, 501 (1987); see also *Neder*, 527 U.S. at 12 ("an improper instruction on an element of the offense violates the Sixth Amendment's jury trial guarantee"). By stripping *mens rea* out of its instructions, the district court relieved Dr. Ruan's prosecutors of their traditional "burden of proving beyond a reasonable doubt all elements of the crime charged"—"an error of constitutional dimension." *United States v. Rogers*, 94 F.3d 1519, 1523-24 (11th Cir. 1996). In that circumstance—involving an error of constitutional magnitude—*Chapman v. California*, 386 U.S. 18 (1967), requires the government to prove the error "harmless beyond a reasonable doubt." *Id*. at 24; *see, e.g., Neder*, 527 U.S. at 10 (explaining that jury instructions containing "misdescriptions and omissions" of elements "preclude[] the jury from making a finding on the actual element of the offense"); *see also United States v. Himmelberger*, No. 21-11284, 2022 WL 351961, at *3 (11th Cir. Feb. 7, 2022) (per curiam).

Given the importance of the *mens rea* requirement in delineating lawful from unlawful conduct under the Controlled Substances Act—and the centrality of good faith to Dr. Ruan's defense—the government cannot meet this very heavy burden. The trial was heavily consumed by "standard of care" and simple malpractice proof, which openly invited the jury to convict based on the *mens-rea*-free instruction. The

government presented medical experts who testified at length that Dr. Ruan and his partner had prescribed medication "outside [the] standard of care." Tr. 2357; *see also* Tr. 661-1061 (Dr. Greenberg); Tr. 2246-2542 (Dr. Vohra); Tr. 4328-4520 (Dr. Aultman). Free to disregard Dr. Ruan's core defense—that he neither knew nor intended that his prescriptions fell outside the bounds of medicine—the jury could, and almost surely did, latch on to this evidence to convict Appellant of simple negligence.

So too for the expert testimony. At *best* for the government, the competing experts confirmed that professional medical providers can and do reasonably disagree about the bounds of professional practice. *Compare, e.g.*, Tr. 2483 (Dr. Vohra) (a physician's "do[ing] an exam to assess the patient's clinical condition" before prescribing is "certainly standard of care"), *with* Tr. 4844 (Dr. Warfield) (it is "common practice across the country for someone else to be able to give the patient informed consent"); Tr. 6052 (Dr. Gharibo) ("Most of us use nurse practitioners or physician extenders. It's very common.").

Nor do the various statistics touted by the government carry its *Chapman* burden. Although the government showed that Dr. Ruan's clinic prescribed a sizeable amount of medication, *see* U.S. Br. at 5, the trial record places that proof in context. For example, trial testimony describes how Dr. Ruan's clinic took patients only by referral, Tr. 70, 977; how Dr. Ruan took only patients with insurance,

accepting insurers' oversight, *Ruan*, 966 F.3d at 1157; and how more than 90% of these patients already had active opioid prescriptions when they came to the clinic, Tr. 70, 5843 ("That's when people come to the interventional pain practice[.]"). And the trial record contains testimony from medical experts, former clinic employees, and Dr. Ruan himself concerning Dr. Ruan's treatment approach and intent. *See* Tr. 5227-5231, 5282 (Dr. Gudin) (describing review of patient charts and concluding that "the prescribing seemed appropriate and certainly within the course of legitimate medical practice"); Tr. 6035, 6042-6056 (Dr. Gharibo) (describing review of patient charts and confirming that "each of the prescriptions were proper"); Tr. 5512-5513 (Harville) (describing how Dr. Ruan "developed an opioid risk tool" for the clinic); Tr. 5787 (Dr. Ruan) (prescription decisions were based on "[p]atient need, that's all there is"); Tr. 5821-5822 (Dr. Ruan) (describing use of an "abuse-deterrent formulation drug" when he "see[s] the indication [for abuse] in [a] patient"); Tr. 5920-5921 (Dr. Ruan) (treatment decisions were always motivated by "caring for [his] patients").

This was a hard-fought case, and medical experts could (as they did at trial) reasonably disagree about the standard of care. But contradictory evidence about the standard of care does not suggest, let alone show beyond a reasonable doubt, that a rational jury would have convicted Dr. Ruan of *intentionally* prescribing outside the usual course of professional practice. Indeed, as reflected in the trial record, the

government *itself* conceded at trial that Dr. Ruan's clinic was not a "pill mill," *see Ruan*, 966 F.3d at 1131 n.6, and that "[b]y and large, their patients were legitimate patients," *id.* at 1157. Moreover, the trial record is not silent about Dr. Ruan's mental state. A properly-instructed jury would have been able to consider the evidence regarding Dr. Ruan's good faith efforts to treat patients and to proactively prevent addiction and reduce the risk of opioid abuse. Where "the defendant contested the omitted element and raised evidence sufficient to support a contrary finding," the reviewing court "should not find the error harmless." *Neder*, 527 U.S. at 19.[6]

2. Even if analyzed under the lower standard governing *non*-constitutional errors, *see Kotteakos v. United States*, 328 U.S. 750, 776 (1946); *Brecht v. Abrahamson*, 507 U.S. 619, 637-38 (1993), the government must still show that the instructional error did not have a "substantial and injurious effect or influence in determining the jury's verdict." *Kotteakos*, 328 U.S. at 776; *Brecht*, 507 U.S. at 637. The government cannot meet that standard.

[6] Additionally, the defense would certainly have submitted further evidence if the district court had recognized the correct standard for scienter under § 841(a)(1). The district court's incorrect belief that subjective intent was irrelevant to culpability under § 841(a)(1) led to both an erroneous jury instruction and the wrongful exclusion of evidence at trial. Because the district court did not believe that Dr. Ruan's intent was relevant, the district court excluded "good patient" testimony, as well as videos of undercover agents who sought and failed to obtain opioids from Dr. Ruan. *See Ruan*, 966 F.3d at 1153. The jury was thus deprived of relevant – and potentially exculpatory – facts as a result of the district court's incorrect understanding of § 841(a)(1)'s scienter requirement.

The erroneous jury instruction permitted the jury to convict Dr. Ruan *without regard* to his mental state. Although the record contains substantial evidence showing Dr. Ruan's abundant good faith, the jury was wrongly instructed that such subjective beliefs were *irrelevant as a matter of law*. That instruction gutted Dr. Ruan's core defense. Time and again, this Court and others have declined to find harmlessness in such circumstances. *See, e.g.*, *United States v. Mayweather*, 991 F.3d 1163, 1181 (11th Cir. 2021) (failure to give jury instruction on entrapment defense was not harmless error where the "absence of the entrapment instruction seriously impaired their ability to present their defense"); *Caldwell v. Bell*, 288 F.3d 838, 844 (6th Cir. 2002) (instructional error was not harmless under *Kotteakos/Brecht* standard where "once the instruction was given, jurors were unable fairly to consider the defense's theory of provocation"); *Dick v. Kemp*, 833 F.2d 1448, 1451 (11th Cir. 1987) (jury instruction that "unacceptably shifted the burden of proof" was not harmless error under *Chapman* where sole defense was lack of intent).

C. The instructional error affected all of Dr. Ruan's convictions.

Dr. Ruan was convicted on seven counts of controlled substances violations. For the reasons described above, the erroneous jury instruction clearly prejudiced those counts, and requires vacatur of Dr. Ruan's CSA convictions. Additionally, the other counts of conviction were either explicitly predicated on the controlled

substances offenses or implicitly relied on the allegation that Dr. Ruan did not prescribe for legitimate medical purposes. Where the "convictions are inextricably intertwined," the Court should review the evidence for these convictions together. *United States v. Ignasiak*, 667 F.3d 1217, 1227 (11th Cir. 2012) (assessing substantive fraud counts and dispensing controlled substances counts "together" "because the manner and means in which the fraudulent scheme was carried out directly related to whether Ignasiak's prescriptions for controlled substances were legitimate and within the usual course of professional practice."). The prejudicial instructional error likewise requires vacatur of Dr. Ruan's conviction on these related counts.

Finally, Dr. Ruan's sentencing for all counts relied on the controlled substances offenses to calculate the base level offense range. His sentence should thus likewise be vacated.

CONCLUSION

This Court should vacate all of Dr. Ruan's remaining convictions, and vacate his sentence.

Dated: August 29, 2022

Respectfully submitted,

/s/ Lawrence S. Robbins
Lawrence S. Robbins
FRIEDMAN KAPLAN SEILER
& ADELMAN LLP
7 Times Square
New York, NY 10036
Telephone: (212) 833-1118
lrobbins@fklaw.com

Carolyn M. Forstein
Jeffrey C. Thalhofer
KRAMER LEVIN NAFTALIS
& FRANKEL LLP
2000 K Street, NW, 4th Floor
Washington, DC 20006
Telephone: (202) 775-4500
cforstein@kramerlevin.com

Counsel for Appellant

CERTIFICATE OF COMPLIANCE

1. This brief complies with the page limitation set by the Eleventh Circuit Court of Appeals in its August 8, 2022, order on supplemental briefing in this case, because it is not longer than 20 pages, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2. This brief complies with the typeface requirements of Fed. R. App. P. (32)(a)(5) and type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in Times New Roman 14-point font, a proportionally spaced typeface, using Microsoft Office 365.

Dated: August 29, 2022

/s/ Lawrence S. Robbins
Lawrence S. Robbins

CERTIFICATE OF SERVICE

I hereby certify that on August 29, 2022, this brief was filed and served on all parties by CM/ECF.

/s/ Lawrence S. Robbins
Lawrence S. Robbins