In the

Hnited States Court of Appeals for the Seventh Circuit

Nos. 21-3403 & 21-3404

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

v.

LISA HOFSCHULZ and ROBERT HOFSCHULZ,

Defendants-Appellants.

Appeals from the United States District Court for the Eastern District of Wisconsin.No. 18-cr-145-PP — Pamela Pepper, Chief Judge.

Argued September 8, 2023 — Decided June 25, 2024

Before SYKES, *Chief Judge*, and ROVNER and KIRSCH, *Circuit Judges*.

SYKES, *Chief Judge*. A jury convicted Lisa Hofschulz, a nurse practitioner, of conspiracy and 14 counts of distributing drugs in a manner unauthorized by the Controlled Substances Act, including one count of unlawful drug distribution resulting in the death of a patient. *See* 21 U.S.C. § 841(a)(1), (b)(1)(C); *id.* § 846. The charges arose out of her operation of a "pain clinic" as a front for a pill mill from

which she dispensed opioid prescriptions for cash-only payment. Robert Hofschulz, her then ex-husband, was also convicted for his role in helping her run the opioid mill. (The couple have since remarried.)

The Hofschulzes challenge their convictions on three grounds. First, they argue that the jury instructions were inconsistent with the Supreme Court's decision in *Ruan v. United States*, 597 U.S. 450 (2022), issued shortly after they were sentenced. *Ruan* held that in a § 841 case against a medical professional for distributing drugs in an unauthorized manner, the statute's intent requirement applies to the act of distribution *and* lack of authorization. Our circuit has long followed this rule, even before *Ruan*. In accordance with our pre-*Ruan* caselaw, the district judge instructed the jury that the government must prove beyond a reasonable doubt that the Hofschulzes intended to distribute controlled substances *and* intended to do so in an unauthorized manner. There was no instructional error.

The Hofschulzes also argue that the judge wrongly permitted the government's medical expert to testify about the standard of care in the usual course of professional pain management. Circuit precedent says otherwise. Finally, the Hofschulzes challenge the sufficiency of the evidence to support their convictions. This argument is frivolous. We affirm.

I. Background

In June 2018 Lisa Hofschulz, a licensed nurse practitioner, was charged with one count of conspiracy to distribute controlled substances in an unauthorized manner, 21 U.S.C. §§ 841(a)(1), 846; thirteen counts of distributing controlled substances in an unauthorized manner, *id.* § 841(a); and one count of unlawful distribution of controlled substances resulting in death, *id.* § 841(a)(1), (b)(1)(C). The grand jury also indicted Robert Hofschulz, Lisa's then ex-husband and business partner, for conspiracy and aiding and abetting four of the drug-distribution counts.

After significant delay—some necessitated by the pandemic but most instigated by the defense—the case finally proceeded to trial in August 2021. The government introduced a mountain of evidence of the defendants' guilt; a summary will suffice for present purposes. The evidence established that in late 2014 the Hofschulzes opened a "pain management clinic" in Wauwatosa, Wisconsin—a suburban community just west of Milwaukee—as a front for an opioid mill. Over the next two years, Lisa prescribed millions of opioid pills in exchange for cash-only payment. Robert, who is not a medical professional, helped Lisa set up the clinic and served as its registered agent and business manager.

For their first year in operation, the Hofschulzes ran the clinic from a single 8x8-foot room adjacent to a chiropractic office, leasing space from another couple and sometimes giving their landlords large-quantity opioid prescriptions in lieu of rent. The clinic had no exam table or medical equipment. Lisa did not take patients' vital signs, perform physical examinations, review medical records, or order imaging or tests to diagnose illness or injury.

The clinic collected a cash-only fee of \$200 to \$300 per visit from each patient, even though a majority were on Medicaid and thus were entitled to free medical care. Nearly all patients who visited the clinic—99 percent of them—left with a prescription for an opioid drug (sometimes more than

one). Few had conditions that justified treatment with opioids; most patients were suffering from addiction or untreated mental illness rather than seeking legitimate medical care for a confirmed injury or illness.

By late 2015 the Hofschulzes had too many "patients" (and a growing waiting list) for the one-room "clinic," so they moved to a somewhat larger temporary location in a nearby office building. They also began to bring on additional nurse practitioners, hiring only newly minted nurses who lacked work experience. Most lasted no more than a few months. Several of these short-term nurses testified at trial, explaining that they raised concerns with the Hofschulzes that the clinic's operations did not conform to standard medical practice. Their efforts to sound the alarm were rebuffed, and many of the nurses either resigned within a few months or were fired after expressing concerns about Lisa's prescribing practices and the clinic's lack of standard medical care.

One patient fatally overdosed on opioids Lisa had prescribed for him. Frank Eberl came to the clinic repeatedly for more than a year, leaving each time with opioid prescriptions in amounts appropriate for end-of-life cancer patients (he was not a cancer patient). Eberl overdosed and died four days after receiving a high-dose opioid prescription from Lisa.

For the two-year period from 2015 through 2016, Lisa wrote prescriptions for more than 2 million opioid pills, collecting over \$2 million in cash from patients, many of whom were repeat customers and obviously addicted. Indeed, during this period Lisa Hofschulz was the leading

prescriber of oxycodone and methadone among all Medicaid prescribers in Wisconsin.

In July 2016 Lisa was called away from Wisconsin to tend to a family matter, so she prewrote and presigned numerous opioid prescriptions and directed two newly hired nurses just out of nursing school—to dispense them to patients while she was gone. They refused, objecting that they had not yet completed their licensing and that dispensing prewritten prescriptions was unsafe and illegal. Robert fired one of the nurses for her refusal to comply with Lisa's instructions, replacing her with a registered nurse from a temporary agency who was willing to distribute the prewritten prescriptions. The temp-agency nurse distributed more than 550 presigned opioid prescriptions while Lisa was away.

The government also presented opinion testimony from Dr. Timothy King, a medical expert who explained the standard of care for legitimate medical practice in pain management. Finally, the government called several of the clinic's patients as witnesses; they confirmed the facts we've just described about the clinic's operations. There was more to the government's case, but further elaboration is unnecessary.

As we've noted, the Hofschulzes were charged with violating the Controlled Substances Act, which makes it a crime to "knowingly or intentionally … manufacture, distribute, or dispense … a controlled substance" "[e]xcept as authorized" by the Act. § 841(a). As relevant here, registered medical professionals may prescribe controlled substances to their patients, but a prescription is "authorized" and thus excepted under the Act only when a registered medical professional issues it "for a legitimate medical purpose … acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a).

Accordingly, the judge instructed the jury on the drugdistribution counts as follows:

> For you to find a defendant guilty of distributing and dispensing a controlled substance, the government must prove the following elements beyond a reasonable doubt as to the defendant and the charge that you are considering:

> First, that that defendant knowingly caused to be distributed or dispensed the controlled substance alleged in the charge you are considering;

> Second, that that defendant *did* so by intentionally distributing or dispensing the controlled substance outside the usual course of professional medical practice, and not for legitimate medical purpose; and

> Third, that that defendant knew that the substance was some kind of a controlled substance. (Emphasis added.)

The judge gave an additional instruction for the charge of unlawful distribution resulting in death: "In order to establish that the oxycodone and morphine distributed by Lisa Hofschulz resulted in the death of Frank Eberl[,] the government must prove that Frank Eberl died as a result of his use of the oxycodone and morphine that Lisa Hofschulz distributed" This instruction also included an explanation of the but-for causation standard adopted in *Burrage v. United States*, 571 U.S. 204 (2014).

The jury found both defendants guilty on all counts. Lisa moved for judgment of acquittal or alternatively, for a new trial. She argued primarily that the evidence was insufficient to prove that she had issued prescriptions without a legitimate medical purpose. The judge denied the motion, ruling that the evidence we've just recounted was easily sufficient for a reasonable jury to find that Lisa had prescribed controlled substances outside the usual course of medical practice and not for legitimate medical purposes. As the judge put it: "[A] reasonable jury could look at these facts and conclude beyond a reasonable doubt that Lisa Hofschulz was issuing prescriptions for other than a legitimate purpose—that she was issuing all of these prescriptions under these circumstances for purposes of making money, and a lot of it."

Lisa also argued that Dr. King, the government's expert, provided impermissible legal conclusions in his testimony. The judge rejected this contention, noting that Dr. King had "offered nothing more than his expert opinion on the standard of care for medical professionals."

Robert likewise moved for judgment of acquittal, challenging the sufficiency of the evidence to prove his guilt on the charges against him. The judge denied his motion too, noting that although Robert was not a medical professional, the government had introduced ample evidence for the jury to find beyond a reasonable doubt that he intentionally conspired with Lisa to unlawfully distribute controlled substances and aided and abetted the commission of the four substantive distribution crimes. Among other datapoints from the trial, the judge emphasized Robert's obvious awareness that the clinic lacked any accoutrements of legitimate medical practice and the testimony from several nurses that they had raised concerns with him about Lisa's unauthorized prescribing practices and the clinic's lack of legitimate medical care.

With the posttrial motions resolved, the judge turned to sentencing. The "death resulting" count against Lisa carried a 20-year minimum prison term; the judge imposed the minimum 20-year term on that count and concurrent sentences of varying lesser lengths on the conspiracy and remaining drug-distribution convictions. Robert was sentenced to concurrent terms of 36 months in prison on each of his five convictions.

II. Discussion

On appeal the Hofschulzes raise several claims of instructional and evidentiary error. They also challenge the sufficiency of the evidence to support their convictions.

A. Jury Instructions

The defendants' primary argument is that the jury instructions did not comply with the Supreme Court's decision in *Ruan*, which as we've noted was issued after they were sentenced. We review the accuracy of the jury instructions de novo. *United States v. Bonin*, 932 F.3d 523, 537–38 (7th Cir. 2019). The trial judge has substantial discretion to formulate the language of the instructions as long as the instructions as a whole "represent a complete and correct statement of the law." *Id.* at 538 (quotation marks omitted). If the instructions correctly stated the law, then we review the judge's phrasing of them for abuse of discretion. *Id*. Section 841(a) makes it unlawful to "knowingly or intentionally ... manufacture, distribute, or dispense ... a controlled substance" "[e]xcept as authorized" by the Controlled Substances Act. In *Ruan* the Supreme Court held that "§ 841's 'knowingly or intentionally' *mens rea* applies to the 'except as authorized' clause." 597 U.S. at 457. Accordingly, to convict a medical professional for violating § 841(a), the government must "prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner." *Id.*

Ruan involved two consolidated cases from the Tenth and Eleventh Circuits raising the same question about the statute's state-of-mind requirement as applied in cases against registered medical prescribers. As noted above, the Controlled Substances Act authorizes certain licensed and registered medical professionals to prescribe controlled substances to patients. See 21 U.S.C. §§ 822(a)(2), 829(a). The prescribed drug must have "a currently accepted medical use," *id.* § 812(b), and the prescription must be "for a medical purpose," id. § 829(c). The Act defines a "valid prescription" as one "issued for a legitimate medical purpose by an individual practitioner," id. § 830(b)(3)(A)(ii); the term "practitioner" includes physicians and other licensed medical professionals who are permitted by their licensing authorities to dispense controlled substances "in the course of professional practice," id. § 802(21).

A regulation pulls these statutory requirements together: A prescription for a controlled substance is "authorized" under the Act when it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). *See also Gonzales v. Oregon,* 546 U.S. 243, 257 (2006) (explaining that this regulation "restate[s] the terms of the statute itself"). We therefore assume, as *Ruan* did, "that a prescription is 'authorized' and therefore lawful if it satisfies [the § 1306.04(a)] standard." 597 U.S. at 455.

Here the district judge carefully crafted the relevant jury instruction to apply the statutory state-of-mind standard to the § 1306.04(a) requirements, as had been the practice in our circuit even prior to *Ruan. See, e.g., United States v. Kohli,* 847 F.3d 483, 489–90 (7th Cir. 2017); *United States v. Chube II,* 538 F.3d 693, 697–98 (7th Cir. 2008). The instruction explained that the government had the burden to prove beyond a reasonable doubt that the defendants "knowingly caused [a controlled substance] to be distributed or dispensed" and that they "did so by *intentionally* distributing or dispensing the controlled substance outside the usual course of professional medical practice, and not for legitimate medical purpose." (Emphases added.) This is an accurate statement of the law and fully compliant with *Ruan*.

The Hofschulzes resist this conclusion, arguing that the judge was required to instruct the jury that a prescriber's good-faith belief in the legitimacy of his actions negates intent. *Ruan* does not suggest—much less mandate—that judges give such an instruction. The jury instruction here clearly explained that the government needed to prove beyond a reasonable doubt that the defendants *intentionally* distributed drugs outside the usual course of medical practice and not for a legitimate medical purpose. *Ruan* requires nothing more. Indeed, the judge went further than necessary by using the word "intentionally" alone—rather than the statutory phrase "knowingly or intentionally"—with respect

to the authorization requirement. In that sense, the instruction was subtly more favorable to the defense than it needed to be.

Taking a different tack, the Hofschulzes also suggest that *Ruan* adopted a criminal willfulness standard, which if true would require the government to prove that the prescriber knew that his conduct was illegal. But nothing in *Ruan* even hints at a criminal willfulness standard. The Court reasoned by analogy to several cases in which it had interpreted other criminal statutes to contain, at least implicitly, a "knowledge of status" or "knowledge of nonauthorization" *mens rea. Id.* at 461, 467. The Court did not mention a "knowledge-of-law" requirement (i.e., knowledge that conduct was illegal). The difference between the two standards "is so important ... that the Supreme Court would not have adopted the broader [knowledge-of-law] reading without saying so with unmistakable clarity." *United States v. Maez*, 960 F.3d 949, 954–55 (7th Cir. 2020).

Our conclusion that the judge's instructions complied with *Ruan* aligns with a decision from the Third Circuit involving a similar challenge to materially identical pre-*Ruan* jury instructions. *See United States v. Titus*, 78 F.4th 595, 602 (3d Cir. 2023) (affirming a doctor's conviction in a case involving jury instructions that required the jury to find that he "knowingly or intentionally distributed controlled substances outside 'the usual course of professional practice and not for a legitimate medical purpose'"). The Hofschulzes draw our attention to decisions from the Tenth and Eleventh Circuits on remand from the Supreme Court in *Ruan. See United States v. Kahn*, 58 F.4th 1308 (10th Cir. 2023); *United States v. Ruan*, 56 F.4th 1291 (11th Cir. 2023). But the pre-*Ruan* jury instructions in those cases lacked the intent requirement that was clearly included in the jury instructions here.

The Hofschulzes raise two additional claims of instructional error. First, they argue that the jury instruction on the "death-resulting" count erroneously imposed strict liability. Second, they claim that the judge was wrong to reject their pretrial request for an instruction explaining the difference between the civil-malpractice liability standard and the standard for criminal liability under § 841.

The first argument was not preserved, so we review only for plain error. *United States v. McClellan*, 794 F.3d 743, 753–54 (7th Cir. 2015). Before we will consider exercising our discretion to correct a forfeited error, we must first find "(1) [an] error (2) that is plain, and (3) that affects the defendant's substantial rights." *Id.* at 754 (quotation marks omitted). An error is "plain" only if it is clear or obvious under current law. *United States v. Olano*, 507 U.S. 725, 734 (1993).

There was no error here, let alone a plain error. The instruction on the death-resulting distribution count did not impose strict liability. We've already explained that the jury instructions on the § 841 counts properly applied the "knowingly or intentionally" requirement to the act of distribution *and* lack of authorization, as *Ruan* requires. The steeper penalties in § 841(b) apply "if death or serious bodily injury results from" the use of drugs involved in the underlying § 841(a) violation.

The judge's "death resulting" jury instruction correctly explained the law for this more serious variant of the offense, including the correct causation standard. The instruction also properly explained that this more serious version of the offense "is committed regardless of whether th[e] defendant knew or should have known that death would result." That's an accurate statement of the law for the enhanced penalties in § 841(b). The death-resulting instruction thus imposed strict liability only insofar as the underlying drug-distribution instructions imposed strict liability; in other words, not at all.

The second argument was only partially preserved. The Hofschulzes made a pretrial request for a jury instruction on the difference between the civil-malpractice and criminal liability standards. The judge denied it but left the door open for them to renew the request at the end of trial if the evidence so warranted. They did not do so.

Setting that misstep aside, the claim of error is meritless. The Hofschulzes argue that the judge was required to instruct the jury on the difference between the criminal and civil liability standards because Dr. King testified that the two standards are identical. He did no such thing: as explained in more detail below, he did not offer an opinion about liability standards, criminal or civil; rather, he explained the standard of care in the usual course of professional medical practice in this context. Accordingly, the instruction was at best unnecessary and at worst potentially confusing. The judge was well within her discretion to reject it.

B. Expert Testimony

The Hofschulzes next argue that Dr. King, the government's medical expert, should not have been permitted to offer opinion testimony about whether Lisa's conduct was outside the usual course of professional practice and not for a legitimate medical purpose. This argument rests on a misunderstanding of the rules for admission of expert testimony.

Rule 704 of the Rules of Evidence expressly provides that "[a]n opinion is not objectionable just because it embraces an ultimate issue." FED. R. EVID. 704(a). There is a qualifier: "In a criminal case, an expert witness must not state an opinion about whether the defendant did or did not have a mental state or condition that constitutes an element of the crime charged or of a defense." *Id.* R. 704(b).

In United States v. Kohli we explained how Rule 704 applies in this specific context. 847 F.3d 483 (7th Cir. 2017). *Kohli* involved a medical expert who, like Dr. King, provided opinion testimony that the defendant's prescribing practices "were inconsistent with the usual course of professional practice and lacked a legitimate medical purpose." *Id.* at 491. We explained that this testimony "falls squarely within the parameters of Rule 704." Id. We noted first that Rule 704(a) explicitly permits experts to testify "about ultimate or dispositive issues in the case." Id. And the expert in Kohli did not violate the qualifier in Rule 704(b): he did not offer an opinion about the defendant's subjective mental state but instead gave his opinion about the defendant's prescribing practices "in light of his own experience and training." Id. The same is true here. Dr. King's testimony stayed well within the bounds of Rule 704.

In a slightly different twist on the same argument, the Hofschulzes insist that the judge wrongly permitted Dr. King to testify about the medical standard of care in relation to the "usual course of professional practice" and "legitimate medical purposes." *Kohli* forecloses this variant of the argu-

ment too. We explained there that expert testimony on the medical standard of care is not tantamount to an impermissible expert opinion on the governing legal standard "just because the two standards overlap." *Id.* at 492. "If that were the case, physicians could virtually never offer meaningful expert opinions in prosecutions under § 841(a)." *Id.*

In their final challenge to the government's expert, the Hofschulzes argue that Dr. King's testimony was at odds with the standard for guilt under § 841 and was wrong as a matter of law, effectively usurping the judge's prerogative to instruct the jury on the law. This argument is way off the mark. Like the expert in *Kohli*, Dr. King did not testify about the *legal* standard but instead gave expert testimony about the "applicable standard of care among medical professionals." *Id.* Though the medical standard of care is "no doubt closely linked to § 841(a)'s prohibition on prescribing outside the 'usual course of professional medical practice,'" *id.*, Dr. King's testimony did not invade the judge's province as the sole explainer of the law.

C. Sufficiency of the Evidence

Finally, the Hofschulzes argue that the evidence was insufficient to establish their guilt. Great deference is owed to the jury's verdict. *United States v. Beechler*, 68 F.4th 358, 368 (7th Cir. 2023). "We view the evidence in the light most favorable to the government and will overturn a conviction only if the record contains no evidence from which a reasonable juror could have found the defendant guilty." *United States v. Longstreet*, 567 F.3d 911, 918 (7th Cir. 2009). This highly demanding standard is rightly characterized as imposing "a nearly insurmountable burden." *Beechler*, 68 F.4th at 368 (quotation marks omitted).

The Hofschulzes have not come remotely close to satisfying this demanding standard. They continue to insist, as they did in their posttrial motions, that the government failed to prove that they knew their opioid prescriptions were "unauthorized." This argument is frivolous. As our summary of the trial record shows, the government presented plentiful evidence of their intent to prescribe opioids outside the usual course of professional practice and not for legitimate medical purposes. The Hofschulzes point to evidence on the other side of the ledger-mostly their own testimony claiming that they were operating a legitimate pain clinic. But the jury was entitled to reject their testimony and had ample basis to do so. In any event, we cannot "supplant the jury's credibility findings on appeal." Kohli, 847 F.3d at 490. Abundant evidence supports the guilty verdicts.

Affirmed