

## APPENDIX A

RECOMMENDED FOR PUBLICATION  
Pursuant to Sixth Circuit I.O.P. 32.1(b)

File Name: 23a0201p.06

## UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

UNITED STATES OF AMERICA,

*Plaintiff-Appellee,*

v.

SYLVIA HOFSTETTER (20-6245); HOLLI WOMACK  
(20-6426); CYNTHIA CLEMONS (20-6427);  
COURTNEY NEWMAN (20-6428),

*Defendants-Appellants.*

Nos. 20-6245/6426/6427/6428

On Remand from the Supreme Court of the United States.

United States District Court for the Eastern District of Tennessee at Knoxville.

No. 3:15-cr-00027—Thomas A. Varlan, District Judge.

Argued: May 3, 2023

Decided and Filed: August 29, 2023

Before: SILER, COLE, and NALBANDIAN, Circuit Judges.

### COUNSEL

**ARGUED:** Loretta G. Cravens, CRAVENS LEGAL, Knoxville, Tennessee, for Appellant in 20-6245. Karen Savir, OFFICE OF THE FEDERAL PUBLIC DEFENDER, Cincinnati, Ohio, for Appellant in 20-6426. Randall E. Reagan, THE LAW OFFICE OF RANDALL E. REAGAN, Knoxville, Tennessee, for Appellant in 20-6427. Christopher J. Oldham, Knoxville, Tennessee, for Appellant in 20-6428. Brian Samuelson, UNITED STATES ATTORNEY'S OFFICE, Knoxville, Tennessee, for Appellee. **ON SUPPLEMENTAL BRIEF:** Loretta G. Cravens, CRAVENS LEGAL, Knoxville, Tennessee, for Appellant in 20-6245. Kevin M. Schad, OFFICE OF THE FEDERAL PUBLIC DEFENDER, Cincinnati, Ohio, for Appellant in 20-6426. Randall E. Reagan, THE LAW OFFICE OF RANDALL E. REAGAN, Knoxville, Tennessee, for Appellant in 20-6427. Christopher J. Oldham, Knoxville, Tennessee, for Appellant in 20-6428. Brian Samuelson, Tracy L. Stone, UNITED STATES ATTORNEY'S OFFICE, Knoxville, Tennessee, for Appellee.

SILER, J., delivered the opinion of the court in which COLE and NALBANDIAN, JJ., joined. COLE, J. (pp. 9–13), delivered a separate concurring opinion.

Nos. 20-6245/6426/6427/6428 *United States v. Hofstetter, et al.*

Page 2

---

**OPINION**

---

SILER, Circuit Judge. This matter comes before us on remand from the Supreme Court of the United States. All four Defendants were found guilty of maintaining a drug-involved premises. Sylvia Hofstetter was also found guilty of conspiring to distribute controlled substances, distributing controlled substances, and money laundering.

After we affirmed the convictions, the Supreme Court decided *Ruan v. United States*, 142 S. Ct. 2370, 2375 (2022), clarifying the applicable mens rea for an unlawful distribution charge, and remanded the case. Defendants now argue that the district court erred regarding the jury instructions for the maintaining-a-drug-involved-premises charge, and Hofstetter further argues the district court erred as to the instructions for her distribution-of-a-controlled-substance and conspiracy-to-distribute-and-dispense-controlled-substances charges.

Defendants' arguments are unavailing. The district court's instructions were not plainly erroneous regarding the maintaining-a-drug-involved-premises and conspiracy-to-distribute-and-dispense-controlled-substances charges. Moreover, Hofstetter's argument regarding the instruction for the distribution-of-a-controlled-substance charge is foreclosed by *United States v. Anderson*, 67 F.4th 755 (6th Cir. 2023) (per curiam). We affirm.

**I. BACKGROUND**

This case comes on remand from the Supreme Court pursuant to its holding in *Ruan*, 142 S. Ct. 2370. The facts and procedural history are known to the parties so we only include the background relevant to the remaining questions before us.

From 2009 to 2015, Hofstetter managed pain clinics in Florida and Tennessee. Hofstetter also co-owned and managed an additional clinic in Tennessee. Cynthia Clemons, Courtney Newman, and Holli Womack were employed as nurse practitioners at these clinics. After suspecting the clinics of illegally prescribing opioids, the government indicted all four Defendants on multiple charges. After a four-month trial, the Defendants were found guilty of

Nos. 20-6245/6426/6427/6428 *United States v. Hofstetter, et al.*

Page 3

maintaining a drug-involved premises. Hofstetter was also found guilty of conspiring to distribute controlled substances, distributing controlled substances, and money laundering.

Hofstetter was sentenced to 400 months in prison, Clemons to 42 months, Newman to 40 months, and Womack to 30 months. We affirmed their convictions and sentences on appeal. *United States v. Hofstetter*, 31 F.4th 396, 410 (6th Cir. 2022).

After our decision, the Supreme Court ruled on the mens rea required to convict a defendant for distributing controlled substances under 21 U.S.C. § 841. *Ruan*, 142 S. Ct. at 2375. The Court then vacated and remanded our decision in *Hofstetter* “for further consideration in light of” the *Ruan* decision. Thus, the only issues now before us concern whether the jury instructions were proper.

## II. ANALYSIS

The district court’s instructions were not plainly erroneous regarding the maintaining-a-drug-involved-premises and conspiracy-to-distribute-and-dispense-controlled-substances charges. Moreover, Hofstetter’s argument regarding the distribution-of-a-controlled-substance instruction is foreclosed under our precedent in *Anderson*, 67 F.4th 755.

### A. *Ruan*

In *Ruan*, the Supreme Court considered the Controlled Substances Act, which makes it unlawful, “[e]xcept as authorized[,] . . . for any person knowingly or intentionally . . . to manufacture, distribute, or dispense . . . a controlled substance[.]” 21 U.S.C. § 841(a)(1). Federal regulations further explain that a prescription is “authorized” only when a practitioner issues the prescription “for a legitimate medical purpose . . . acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04(a). The defendants in *Ruan* argued that the jury instructions were improper because the jury was not required to find that the defendants had knowledge of the illegal acts, i.e., had knowledge that the prescriptions were not authorized. 142 S. Ct. at 2375–76.

The Court held that “§ 841’s ‘knowingly or intentionally’ mens rea applies to the ‘except as authorized’ clause.” *Id.* at 2376 (emphasis omitted). “This means that once a defendant meets

Nos. 20-6245/6426/6427/6428 *United States v. Hofstetter, et al.*

Page 4

the burden of producing evidence that his or her conduct was ‘authorized,’ the [g]overnment must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner.” *Id.* As a result of this holding, it is insufficient for the government to prove that a prescription was “*in fact*” not authorized. *Id.* at 2375. Instead, the government must prove the defendant subjectively knew or intended that the prescription was unauthorized. *Id.*

*B. The Drug-Involved Premises Instruction*

Each Defendant was convicted of maintaining a drug-involved premises in violation of 21 U.S.C. § 856(a)(1). The district court instructed the jury as follows:

Count 13 of the superseding indictment charges that from in or about September 2013 through on or about March 10, 2015 . . . Hofstetter, Newman, Clemons, and Womack, aided and abetted by one another and others, did knowingly and intentionally open, use, and maintain a business . . . for the purpose of illegally distributing Schedule II controlled substances[.]

In order to prove a defendant guilty of opening, using, or maintaining a drug-involved premises, the government must prove each of the following elements beyond a reasonable doubt . . . :

First, that the defendant knowingly opened, used, or maintained a place, whether permanently or temporarily;

And second, that the defendant did so for the purpose of distributing any controlled substance.

The district court also stated that “whether a prescription is made in the usual course of professional practice is to be determined from an objective and not a subjective viewpoint.”

The parties agree that the holding in *Ruan* applies to convictions under § 856(a)(1). Thus, under *Ruan*, the district court must have instructed the jury that knowledge of illegal distribution is an element of offenses under § 856(a). Defendants argue that the instructions given by the district court were erroneous because “the jury was instructed on an objective, not subjective state of mind as to this offense.”

Because none of the Defendants objected during trial to the proposed jury instructions relevant to the § 856 charges, we review for plain error. *United States v. Stewart*,

Nos. 20-6245/6426/6427/6428 *United States v. Hofstetter, et al.*

Page 5

729 F.3d 517, 530 (6th Cir. 2013). “To prevail on plain-error review, [a] defendant must show: (1) error, (2) that is clear and obvious, and (3) that affects [her] substantial legal rights.” *Id.* at 528–29. Regarding jury instructions, “plain error requires a finding that, taken as a whole, the jury instructions were so clearly erroneous as to likely produce a grave miscarriage of justice.” *Id.* at 530 (quoting *United States v. Morrison*, 594 F.3d 543, 546 (6th Cir. 2010)).

The jury instructions for the charges under § 856(a)(1) were not plainly erroneous. The district court’s drug-involved premises instruction did not spell out the “knowingly” mens rea standard required under *Ruan*, 142 S. Ct. at 2375, for the second element. But plain error review requires the court to review jury instructions “as a whole,” within context. *Dimora v. United States*, 973 F.3d 496, 502 (6th Cir. 2020) (per curiam); *Stewart*, 729 F.3d at 530. Taken as a whole, the jury instructions made clear that the jury had to find that Defendants knowingly opened the clinics for the purpose of illegally distributing Schedule II controlled substances.

Before giving the instructions regarding the two elements required for the jury to convict under § 856(a)(1), the district court provided an overview of the charge. “Count 13 of the superseding indictment charges that . . . Hofstetter, Newman, Clemons, and Womack, aided and abetted by one another and others, did *knowingly and intentionally*, open, use, and maintain a business . . . *for the purpose of illegally distributing* Schedule II controlled substances[.]” In addition, the district court summarized Count 13 of the indictment for the jury as “charg[ing] defendants with maintaining drug-involved premises, that is, knowingly and intentionally opening, using, and maintaining businesses for the purpose of illegally distributing controlled substances outside the usual course of professional practice and not for a legitimate medical purpose[.]” In context, the instructions make clear that to find Defendants guilty, the jury was tasked with making a subjective inquiry into whether the Defendants purposefully, with knowledge or intent, illegally distributed controlled substances.

Defendants argue that this instruction did not cure the district court’s earlier comment that “whether a prescription is made in the usual course of professional practice is to be determined from an objective and not a subjective viewpoint.” This argument is unavailing. Whether a prescription was unauthorized is an objective question because “the regulation defining the scope of a doctor’s prescribing authority does so by reference to objective

Nos. 20-6245/6426/6427/6428 *United States v. Hofstetter, et al.*

Page 6

criteria[.]” *Ruan*, 142 S. Ct. at 2382. In contrast, as *Ruan* makes clear, the subjective question is whether Defendants knowingly or with intent issued unauthorized prescriptions. The jury instructions, taken as a whole, properly communicate this difference under the lowered plain error standard.

*C. Hofstetter’s Distributing-a-Controlled-Substance Instruction*

Hofstetter argues that the district court erred in its jury instruction related to her deliberate ignorance with respect to the charge for distributing and dispensing controlled substances in violation of 21 U.S.C. § 841(a)(1). Hofstetter’s argument is foreclosed by our precedent. Between the time *Ruan* was decided and oral argument in this case, our court decided *Anderson*, 67 F.4th 755. It explained that a deliberate ignorance instruction “substantially cover[s] the concept of knowledge through the description of deliberate ignorance and the juxtaposition of ‘knowledge’ with ‘[c]arelessness, negligence, or foolishness.’” *Id.* at 766 (citation omitted).

Moreover, the court held that a “deliberate ignorance” instruction “specifically covers the holding of *Ruan*, by referring continuously to the ‘knowledge of the defendant,’ his ‘deliberate ignorance,’ and if he ‘knew’ that the prescriptions were dispensed illegitimately.” *Id.* (citation omitted).

Here, the district court instructed the jury that they had to find two elements to convict under § 841(a)(1):

First, that the defendant knowingly or intentionally distributed or caused to be distributed a controlled substance by writing prescriptions outside the scope of professional medical practice and not for a legitimate medical purpose;

And second, that the defendant knew at the time of distribution that the substance was a controlled substance.

Regarding the knowledge element, the district court instructed that Hofstetter could be found guilty if the jury believed she was deliberately ignorant of the illegal distribution of controlled substances:

Nos. 20-6245/6426/6427/6428 *United States v. Hofstetter, et al.*

Page 7

Although knowledge of the defendant cannot be established merely by demonstrating that she was careless, knowledge may be inferred if the defendant deliberately blinded herself to the existence of a fact. No one can avoid responsibility for a crime by deliberately ignoring the obvious.

If you are convinced that a defendant deliberately ignored a high probability that the controlled substances, as alleged in these counts, were distributed outside the usual course of professional practice and not for a legitimate medical purpose, then you may find that the defendant knew that this was the case.

But you must be convinced beyond a reasonable doubt that the defendant was aware of a high probability that the controlled substances were distributed outside the usual course of professional practice and not for a legitimate medical purpose, and that the defendant deliberately closed her eyes to what was obvious.

Carelessness or negligence or foolishness on her part are not the same as knowledge, and are not enough to find her guilty of any offense charged under this law.

The above jury instruction is almost verbatim the instruction this court approved in *Anderson*. See 67 F.4th at 766. Because of this, we are obliged to affirm. See *Salmi v. Sec'y of Health & Hum. Servs.*, 774 F.2d 685, 689 (6th Cir.1985) (“A panel of this Court cannot overrule the decision of another panel.”); see also 6 Cir. R. 32.1(b) (“Published panel opinions are binding on later panels. A published opinion is overruled only by the court en banc.”).

#### *D. Hofstetter’s Conspiracy-to-Distribute Instruction*

Hofstetter last argues that the district court erred, under *Ruan*, in its jury instructions regarding her conviction for conspiracy to distribute and dispense controlled substances in violation of 21 U.S.C. § 846. This was not objected to at trial nor raised in her initial brief on appeal, so we review for plain error. *Stewart*, 729 F.3d at 530.

The district court’s instructions were not plainly erroneous. The district court instructed the jury they had to find that she “combine[d], conspire[d], confederate[d], and agree[d] . . . to knowingly, intentionally, and without authority distribute, or cause to be distributed, outside the usual course of professional practice and not for a legitimate medical purpose,” a controlled substance. The district court properly instructed the jury. See *United States v. Ruan*, 56 F.4th 1291, 1299 (11th Cir. 2023) (per curiam) (holding that the district court did not err regarding the



Nos. 20-6245/6426/6427/6428 *United States v. Hofstetter, et al.*

Page 8

§ 846 charge “because the conspiracy instructions already required [the jury] to find that the defendant acted with subjective knowledge”).

**AFFIRMED.**

Nos. 20-6245/6426/6427/6428 *United States v. Hofstetter, et al.*

Page 9

---

**CONCURRENCE**

---

COLE, Circuit Judge, concurring. I agree with the majority that we are bound by our court's recent decision in *United States v. Anderson*, 67 F.4th 755 (6th Cir. 2023) (per curiam), and therefore join the opinion in full. But I write separately to highlight how *Anderson* conflicts with the Supreme Court's opinion in *Ruan v. United States*, 142 S. Ct. 2370 (2022).

In *Anderson*, this court held that jury instructions nearly identical to those given on Hofstetter's 21 U.S.C. § 841 charge were proper under *Ruan*. Judge White penned a forceful dissent, explaining why the instruction does not meet the Court's mens rea standard for unauthorized prescription distribution. *Anderson*, 67 F.4th at 771–72 (White, J., concurring in part and dissenting in part). As I agree with her dissent, I will not spend much space reiterating her arguments. But the specifics of the instant case cast further doubt on *Anderson*'s holding.

In the case at hand, this panel ordered supplemental briefing on the issue of *Ruan*'s impact on the jury instructions—briefing that was filed prior to *Anderson*'s publication—in which the government conceded that “the § 841 instructions here likely fell short of conveying the requisite mens rea.” (Appellee Suppl. Br. 6.)

Here, as in *Anderson*, the district court instructed the jury that it had to find two elements to convict Hofstetter under § 841(a)(1):

First, that the defendant knowingly or intentionally distributed or caused to be distributed a controlled substance by writing prescriptions outside the scope of professional medical practice and not for a legitimate medical purpose;

And second, that the defendant knew at the time of distribution that the substance was a controlled substance.

(Trial Tr., R. 897, PageID 61805.)

The issues with the instruction begin on its face. Grammatically, the “knowingly or intentionally” mens rea in the first paragraph of the instruction applied directly to the “distributed or caused to be distributed” clause. But it is unclear whether the mens rea phrase also applied to

Nos. 20-6245/6426/6427/6428 *United States v. Hofstetter, et al.*

Page 10

all of the following clauses—the “controlled substance” and “writing prescriptions outside the scope of professional medical practice” clauses—so it is not clear that the district court properly instructed the jury that the knowledge requirement applied through to the “outside the scope of professional medical practice” clause.

But if the mens rea clause should be read as extending to the entirety of the first instructional paragraph, then the second paragraph would be redundant: The first statement would then necessarily indicate that the defendant had to know the substance distributed was a controlled substance, a clause that comes before the “outside the scope of” clause. In this respect, the instruction as written only definitively required a knowledge or intent mens rea as to the “distributed or caused to be distributed” clause and not the subsequent clauses in the first instruction, including the authorization clause. In other words, although the instructions pinpointed key elements of a § 841 offense, they did not make clear that, to be found guilty, Hofstetter had to know that the prescriptions were unauthorized. Yet under *Ruan*, the jury must explicitly be told that knowledge of the prescription’s illegality is an element of the offense. *Ruan*, 142 S. Ct. at 2375–76. The uncertainty in the given instructions does not fulfill the Court’s edict.

Understanding this, the government therefore argued that while the district court likely abused its discretion by providing erroneous instructions, any such instruction was harmless error.

The record supports the government’s concession that the instructions were, in fact, erroneous. Unlike the instructions for the maintaining-a-drug-involved-premises charge, the instructions for the distribution charge did not clarify the requisite mens rea. Elsewhere, the district court instructed the jury that a defendant violates § 841(a)(1) when they “distribute[] a controlled substance without a legitimate medical purpose and while acting outside the usual course of professional practice.” (Trial Tr., R. 897, PageID 61804.) Nowhere does the instruction associate the requisite knowledge mens rea with the lack of authorization or distribution outside of a legitimate medical purpose, nor did the district court clarify that it had to be illegal distribution. In fact, the district court attached *no* mens rea to the authorization element.

Nos. 20-6245/6426/6427/6428 *United States v. Hofstetter, et al.*

Page 11

A review of the jury verdict sheet bolsters the conclusion that the § 841 charge does not comply with the Court's holding in *Ruan*. For the maintaining-a-drug-involved-premises charge, the jury was instructed that to return a guilty verdict, they had to find that the defendants "did knowingly and intentionally open, use, and maintain a business . . . *for the purpose of illegally distributing* Schedule II controlled substances[.]" (Jury Verdict, R. 860, PageID 60529 (emphasis added).) Meanwhile, for the distribution charge, the jury was instructed that they needed to find that Hofstetter "did knowingly and intentionally distribute or cause to be distributed, outside the usual course of professional practice and not for a legitimate medical purpose," a controlled substance. (*Id.* at PageID 60531.)

For the foregoing reasons, then, the district court did not instruct the jury that to find Hofstetter guilty of distributing a controlled substance in violation of § 841(a)(1), the government had to prove beyond a reasonable doubt that Hofstetter subjectively knew the distribution occurred outside a legitimate medical purpose, i.e., illegally.

A closer look at *Anderson* reveals the same flaw. The two elements provided to the jury in this case, distribution and outside the scope of professional conduct, are substantially similar to those provided to the jury in *Anderson*. 67 F.4th at 766. In both cases, as the government conceded here and as Judge White notes in her *Anderson* partial dissent, "[u]nlike the instruction on the first element, the second element's instruction identified no *mens rea* requirement. The Supreme Court's *Ruan* opinion, however, teaches that the second element too must be performed knowingly or intentionally. Without such clarification, this charge by itself does not satisfy *Ruan*." *Id.* at 772 (White, J., concurring in part and dissenting in part) (citation omitted).

*Anderson* instead holds that the deliberate indifference instruction ensures the charge's correctness under the abuse-of-discretion standard. The explanation is that the instructions "substantially cover the concept of knowledge through the description of deliberate ignorance and the juxtaposition of knowledge with carelessness, negligence, or foolishness." *Id.* at 766 (cleaned up).

But that is not what the deliberate indifference instruction accomplishes nor what *Ruan* dictates. This instruction tells the jury that it may "infer[]" knowledge if it finds that a defendant

Nos. 20-6245/6426/6427/6428 *United States v. Hofstetter, et al.*

Page 12

“deliberately ignor[ed] the obvious,” and so the defendant “was aware of a high probability that the controlled substances were distributed” outside authorized practice. (Trial Tr., R. 897, PageID 61806–07.) Importantly, though, the second element of the offense, knowledge of unauthorized distribution, “does not depend on perceiving or ignoring probabilities. [The defendant] either understood and intended to prescribe[] controlled substances without a legitimate medical purpose in the usual course of professional practice, or he did not.” *Anderson*, 67 F.4th at 772 (White, J., concurring in part and dissenting in part). In this way, a deliberate indifference instruction does not inform the jury that both elements of the § 841 offense—distribution and outside the course of professional conduct—must be done with knowledge or intent. *Id.* Per *Ruan*, “the [g]overnment must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner.” *Ruan*, 142 S. Ct. at 2376. As the deliberate indifference instruction does not hold the government to that burden, it is inadequate, on its own, under *Ruan*.

And beyond that, *Anderson* does not cite any caselaw, within or outside of our circuit, providing that a deliberate indifference instruction makes up for or imposes a missing knowledge requirement. Instead, it cites a case concerning a good-faith instruction in a tax evasion case where instructions stating that the jury had to find that the defendant acted willfully, meaning “voluntarily and deliberately, and intending to violate a known legal duty,” covered the defendant’s requested but omitted good-faith instruction. *United States v. Damra*, 621 F.3d 474, 502 (6th Cir. 2010). This principle does not resolve the issue with Hofstetter’s jury instructions for two reasons: A good-faith instruction is not identical to a deliberate indifference instruction, nor did we hold in *Damra* that a good-faith instruction cures otherwise defective instructions because the main elements in *Damra* were not defective.

In § 841(a) prosecutions, what commonly separates lawful acts from unlawful ones is whether or not the distribution was authorized: “In § 841 prosecutions, then, 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. In other words, authorization plays a ‘crucial’ role in separating innocent conduct . . . from wrongful conduct.” *Ruan*, 142 S. Ct. at 2377 (citation omitted). Here, the jury was never instructed that Hofstetter had to have the knowledge or intent to

Nos. 20-6245/6426/6427/6428 *United States v. Hofstetter, et al.*

Page 13

illegally distribute controlled substances in an unauthorized manner, and a deliberate indifference instruction cannot cure that initial error.

The government, prior to *Anderson*'s publication, agreed that the deliberate indifference instruction did not remedy the error in the jury instruction, and I agree. But bound as we are by *Anderson*, I concur in the judgment's affirmance.

UNITED STATES COURT OF APPEALS  
FOR THE SIXTH CIRCUIT

Nos. 20-6245/6426/6427/6428

UNITED STATES OF AMERICA,

Plaintiff - Appellee,

v.

SYLVIA HOFSTETTER (20-6245); HOLLI WOMACK (20-6426); CYNTHIA CLEMONS (20-6427); COURTNEY NEWMAN (20-6428),

Defendants - Appellants.

**FILED**  
Aug 29, 2023  
DEBORAH S. HUNT, Clerk

Before: SILER, COLE, and NALBANDIAN, Circuit Judges.

**JUDGMENT**

On Remand from the Supreme Court of the United States.

PURSUANT TO the Supreme Court's opinion in *Ruan v. United States*, 142 S. Ct. 2370, 2375 (2022), and

UPON CONSIDERATION of the supplemental briefs and arguments of counsel,

IT IS ORDERED that the judgment of the district court is again AFFIRMED on all issues.

**ENTERED BY ORDER OF THE COURT**



---

Deborah S. Hunt, Clerk