[DO NOT PUBLISH]

In the

United States Court of Appeals

For the Eleventh Circuit

No. 18-13967

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

versus

ANDRES MENCIA,

Defendant-Appellant.

Appeal from the United States District Court for the Southern District of Florida D.C. Docket No. 0:17-cr-60301-WPD-1

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ON REMAND FROM THE SUPREME COURT OF THE UNITED STATES

Before GRANT and BRASHER, Circuit Judges. 1

PER CURIAM:

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This appeal returns to us on remand from the Supreme Court of the United States. After we affirmed Andres Mencia's conviction for conspiracy to violate the Controlled Substances Act, 21 U.S.C. § 841(a), by dispensing controlled substances without a legitimate medical purpose, in violation of 21 U.S.C. § 846, *United States v. Mencia*, 861 F. App'x 736, 739 (11th Cir. 2021), the Supreme Court issued its decision in *Ruan v. United States*, 597 U.S. ----, 142 S. Ct. 2370, 2374 (2022). The Court granted Mencia's petition for certiorari, vacated our judgment, and remanded his appeal for further consideration in light of *Ruan. See United States v. Mencia*, 142 S. Ct. 2897 (2022).

Mencia, a formerly licensed physician, owned and operated a geriatric specialty clinic where many patients, often younger and addicted to drugs, would pay cash in exchange for narcotic prescriptions. Mencia argues that (1) there was insufficient evidence to support his conviction, (2) the district court abused its discretion in making certain evidentiary rulings, (3) the Controlled Substances Act is unconstitutionally vague as applied to physicians, and (4) the instructions provided to the jury constitute reversible error under

 1 Judge Martin retired from active service to this Court and did not participate in this decision, which is rendered by quorum. 28 U.S.C. § 46(d).

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the Supreme Court's holding in *Ruan*.² We disagree. The government presented overwhelming evidence of Mencia's guilt, the district court did not abuse its discretion, this Court has already held that the Act is not unconstitutional as applied to physicians, and the jury instructions do not constitute reversible error, even in light of *Ruan*. Accordingly, we affirm.

I. BACKGROUND

A. Factual Background

Andres Mencia, a formerly licensed physician, owned and practiced at Adult & Geriatric Institute of Florida, Inc., in Oakland Park, Florida. Although AGI was not a pain clinic and Mencia was not a pain specialist, a significant amount of his business came from prescribing opioids and other controlled substances to certain patients who paid in cash. Mencia called those individuals "Code-G" patients, with the "G" standing for "gypsy," because they did not have insurance. Even though other patients also paid in cash, Code-G patients never paid at the checkout counter. Instead, Mencia assigned certain medical assistants to collect their payments. Mencia often prescribed these Code-G patients a combination of Percocet, Xanax, and Soma, which one of the government's experts, Dr. Sanford Silverman, described as the "holy trinity"—a trio consisting of

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² Mencia's first three arguments were addressed in our now vacated opinion. For the sake of completeness, we address these three arguments again in addition to the fourth argument, which was not raised in Mencia's initial appeal.

an opioid, benzodiazepine, and a muscle relaxant that drug-seeking patients often request.

Between January 1, 2014, and May 31, 2018, Mencia wrote 45,000 controlled substance prescriptions. Around one-third of those prescriptions were for patients who paid in cash. Those patients who were covered by Medicare or commercial insurance often received more prescriptions than just the "holy trinity"; they would also receive Dilaudid, Oxycontin, or amphetamines. And Mencia consistently prescribed the highest possible dose strength of controlled substances, including oxycodone and Xanax.

One patient, JH, returned monthly for controlled substance prescriptions after Mencia initially diagnosed him with back pain without an examination. JH's girlfriend and grandmother each called the front desk at AGI to inform them that JH was an opioid addict, but Mencia continued to prescribe him oxycodone and Soma. In fact, Mencia continually increased JH's doses and even gave him refills when JH claimed that his prescriptions had been stolen. JH eventually fatally overdosed on oxycodone and Xanax.

Oscar Luis Ventura-Rodriguez, one of Mencia's medical assistants, testified that when he first started at AGI, Mencia would spend some time with Code-G patients and then Ventura-Rodriguez would write them prescriptions, which Mencia would sign. The majority of those prescriptions were for Percocet. But Mencia never physically examined those patients, and the consultations usually only lasted around ten minutes.

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Over time, the number of Code-G patients increased, and Mencia stopped entering the room at all when returning patients came in. Instead, medical assistants would look up what prescriptions the patients had previously been given, fill the prescriptions out the same way as before, then take them to Mencia to sign. The patients would receive those controlled substance prescriptions without an examination and without any physician reviewing whether the medications were medically necessary.

The price that AGI charged Code-G patients also increased over time. And Mencia instructed his assistants to get those patients out of the waiting room as soon as they arrived. Although Mencia instructed his medical assistants to ask Code-G patients for MRIs, not having one did not affect their ability to get a prescription for controlled substances.

Ventura-Rodriguez testified that, as the number of Code-G patients increased, Mencia began instructing him and other assistants on which medications and how many pills to prescribe before patients ever arrived. At that point, Ventura-Rodriguez began to suspect that many Code-G patients were not truly in pain. He shared that suspicion with Mencia, but Mencia continued to sign the controlled substance prescriptions. Eventually, Mencia did not even enter the room to see new Code-G patients.

Mencia also instructed the assistants on how to write the charts to justify the prescriptions that he was signing for the new Code-G patients. He instructed them to note the level of a patient's pain, not based on a consultation with the patient, but based on the

level necessary to prescribe the drugs that Mencia had instructed them to give. Toward the end of this operation, Mencia would presign blank prescriptions so that the medical assistants did not even have to bring them to him to sign. The government entered into evidence several text messages between Mencia and Ventura-Rodriguez that confirmed his testimony that Mencia had provided him with pre-signed prescriptions and had allowed him to write prescriptions before the date that another prescription was legally permitted.

To help with his increasing patient load, Mencia contracted with a pain clinic in 2014 to hire Dr. Gabriel Marrero, a pain management specialist, to work one day per week at AGI. Marrero quickly became concerned that many of AGI's patients were not interested in interventional pain, which was his specialty, and only cared about acquiring controlled substances. He also noticed that urine tests, MRIs, and x-rays were missing from patient files. He brought his concerns to Mencia's attention, and Mencia agreed that these issues needed to be addressed. But Marrero continued to see the same issues in patient files, which led him to discharge those patients. Unbeknownst to Marrero, Mencia would often take those patients back.

Mencia took back one such patient after Marrero had discharged him for failing a urine test. That patient testified to having a drug addiction and to selling his prescriptions to buy more heroin. When he asked Mencia for larger quantities of the pills because

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his tolerance had increased, Mencia complied for all but one medication, saying that he had to "stay under the radar."

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The beginning of the end for Mencia came when Dr. Abby Goldstein, a pharmacist at Publix Pharmacy, became concerned about the large number of oxycodone prescriptions that Code-G patients were bringing to the pharmacy. Dr. Goldstein informed the DEA about her concerns, telling them that Mencia "might be overprescribing certain medications," including opioids. Dr. Goldstein testified that Mencia's prescriptions stood out because "[n]inety-five percent of them were for a large quantity immediaterelease narcotics," particularly Percocet and oxycodone. Even though "a lot" of physicians were listed on the prescriptions from Mencia's office, she only received prescriptions from Mencia. She was also concerned because, when she called AGI for the diagnosis codes for these prescriptions, she was told the same diagnosis for most patients. And when she looked Mencia up on the Board of Health license verification website, she discovered that he was not specially certified in pain management despite the large number of pain medications that he was prescribing. Due to her growing concerns, Dr. Goldstein refused to fill approximately eighty percent of Mencia's prescriptions for narcotics.

Also, as a result of Dr. Goldstein's concerns, the government sent confidential informants into AGI to pretend that they were in pain and attempt to obtain controlled substance prescriptions. In the videos captured by those informants, medical assistants can be seen prescribing controlled substances on pre-signed prescription

pads without Mencia ever entering the room or seeing the patients. The videos also show the patients paying in cash and sometimes "tipping" the assistants. The assistants would then pocket that cash. Ventura-Rodriguez testified, however, that he would later give that cash to someone else.

Mencia was originally indicted along with three members of his office staff, Ventura-Rodriguez, Nadira Sampath-Grant, and John Mensah, for conspiracy to commit health care fraud and wire fraud and conspiracy to dispense controlled substances. Ventura-Rodriguez, Sampath-Grant, and Mensah each subsequently entered into plea agreements with the government and agreed to testify against Mencia. Mencia was then charged in a fifth superseding indictment with (1) conspiracy to commit health care fraud and wire fraud in violation of 18 U.S.C. § 1349; (2) conspiracy to dispense oxycodone in violation of 21 U.S.C. § 846; (3) dispensing oxycodone in violation of 21 U.S.C. § 841(a)(1); (4) seven counts of money laundering in violation of 18 U.S.C. § 1957(a); and (5) structuring to avoid reporting requirements in violation of 31 U.S.C. § 5324(a)(3) and (d)(2).

Mencia requested expert disclosures the day after he was indicted. One month later, and thirteen days before trial started, the government disclosed six experts, including Dr. Silverman. The government disclosed two additional experts the next day, including Dr. Jodi Sullivan. The defense filed a motion in limine to exclude the proposed expert testimony on the grounds that the

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government's disclosures were untimely. The district court denied the motion.

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Dr. Silverman is a licensed physician and pain management specialist. He has published around nineteen articles in peer reviewed journals and a textbook on controlled substance management in chronic pain patients. The government presented Dr. Silverman as an expert on pain management and addiction "with the ability to opine on . . . the accepted scope of professional practice and whether medications are issued for a legitimate medical purpose." Mencia objected on the grounds that (1) the term "scope of professional practice" does not appear in the statute under which Mencia was charged and (2) there had not been any testimony as to the methodology that Dr. Silverman used to reach his opinions. The court overruled his objection. Before testifying, Dr. Silverman reviewed Mencia's prescribing history through the Florida Prescription Drug Monitoring Plan, several videos that were taken at AGI by confidential government informants, and a selected number of patient notes.

Based on his review of the evidence, Dr. Silverman opined that the controlled substances that Mencia prescribed in the period between 2014 and 2017 "did not have a medical legitimate need." When asked whether there are Florida statutes that "act as guidance as to what is and is not acceptable practice," Dr. Silverman replied that "[t]hey're law. They're not guidance." And he determined that Mencia had violated those laws by failing to record proper medical examinations prior to prescribing controlled

substances, develop a written treatment plan for assessing patients' apparent drug-seeking behavior, or document an assessment of patients' risk related to that behavior or monitor the behavior on an ongoing basis. He also said that Mencia's failure to refer patients whom he was treating for anxiety to psychiatrists violated the law. He was also concerned by the combination of medications that Mencia was prescribing due to the risk of fatal overdose. And he stated that it is both outside the scope of professional practice and outside Florida law for a physician to re-prescribe opioids after only a very brief check-in with the patient.

Dr. Silverman also testified that it is illegal under Florida law for medical assistants to fill out prescriptions or make diagnoses or treatment plans. Their job, he stated, is to give the physician the facts so that the physician can conduct an informed exam and come up with a plan. And he considered it to be outside the scope of professional practice for a medical assistant to see a patient, brief the doctor, and then for the doctor to sign a prescription for a controlled substance without seeing the patient himself.

The defense asked Dr. Silverman whether there is criminal liability for violating Florida statutes regarding the standard of medical practice. First, the defense tried to ask Dr. Silverman to locate where the statutes provide for jail time. The government objected to that question as irrelevant, and the court sustained the objection. The defense then asked whether a certain statute is enforced by the Board of Medicine. Dr. Silverman responded that "it is my understanding that if you violate [Florida Statute §] 456.44,

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that—it was my understanding there were criminal penalties. I don't know specifically what they were. But since they are law, I believe they (sic) were some penalties." He then explained that "the enforcement of this I believe is through the DOH, Department of Health," and "I don't know if the patient goes before the Board of Medicine when you violate this. I believe this is a law. So, I think this is taken out of the administrative realm of the Board of Medicine. That's my understanding." The defense objected and moved to strike those comments as "an incorrect statement of law."

The court asked the government to stipulate that there are no criminal penalties in Section 456.44. The government stated that it was not aware of anything in Section 456.44 stating that it carries criminal penalties. The defense then asked again whether a violation of Section 456.44 is brought before the Board of Medicine and emphasized that Dr. Silverman was brought before the Board of Medicine for a violation of that same statute for wrong-site injections.

In its pretrial disclosures, the government stated that Dr. Sullivan, a licensed pharmacist, would testify regarding how Mencia's unusual patterns of prescribing controlled substances were consistent with a "pill mill" based on her review of Mencia's prescription data from the Florida Department of Health and Prescription Drug Event. Dr. Sullivan reviewed the Medicare Part D and Part B records for Mencia, a date-of-death analysis, and the Florida Prescription Drug Monitoring Program data for Mencia and 54 of his patients before testifying. The defense objected to Dr. Sullivan

being tendered as an expert again at trial on the grounds that the government had not disclosed what methodology she used to reach her conclusions. The defense also requested a *Daubert* hearing. The court overruled the objection and stated that "she's a qualified expert."

Dr. Carol Warfield testified for the defense. She teaches pain management at Harvard Medical School and elsewhere and has written textbooks on the subject. She was originally hired by the government but was dropped as a witness after opining that Mencia was acting as a medical doctor in the usual course of medical practice based on the medical records and videos that they asked her to review. She also informed the government that she "had concerns" about the fact that he was signing blank prescriptions. The defense asked Dr. Warfield whether pre-signing blank prescriptions carries criminal penalties under Florida law, to which the government objected. The court sustained the objection.

During cross-examination, the government asked Dr. Warfield about her concerns over the pre-signing of prescriptions. The prosecutor asked: "I believe what you told me was that under no circumstance would it be within the scope of professional practice to give a medical assistant a presigned prescription for them to fill out at their discretion for controlled two (sic) substances. Do you agree with that?" The defense objected and the court overruled, stating that "what the lawyers say isn't evidence. The answers are evidence. If he wants to pursue this and waive his attorney-client — waive his work product, he can do that." Dr. Warfield

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answered that she "thought those medical assistants were practicing medicine without a license, and they in no way should have been given blank prescriptions to prescribe opiates to these patients."

The government referenced that testimony in closing. It stated that the core of the case was "about a doctor acting outside the scope of professional practice and not for a legitimate medical purpose when he provides medical assistants with presigned prescriptions." The government then stated, "what you heard from both experts that on this matter, there is no dispute. It is outside the scope of professional practice and not for a legitimate purpose to hand out presigned prescriptions for the medical assistants to fill in if the doctor has never seen the patient." The government then reiterated, "[t]here's no dispute about that."

Prior to jury deliberations, the district court gave several jury instructions, two of which Mencia now challenges on appeal. First, Mencia challenges the so called "good faith" instruction—which Mencia requested. That instruction required the jury to "find that the government proved beyond a reasonable doubt that [Mencia's] treatment and prescription of controlled substances were not undertaken with a reasonable good faith belief that he was acting with a legitimate medical purpose and according to the generally recognized and accepted standard of care." Second, Mencia challenges the jury instruction describing the requirements to convict him of conspiracy to dispense oxycodone unlawfully. The instruction stated that Mencia could only be found guilty if the

Government proved beyond a reasonable doubt that (1) he and another person "in some way agreed to try to accomplish a shared and unlawful plan to distribute or dispense a con-trolled substance, outside the scope of professional practice and not for a legitimate medical purpose"; (2) Mencia "knew the un-lawful purpose of the plan and willfully joined in it"; and (3) the purpose of the plan, "was to distribute or dispense a controlled substance, outside the scope of professional practice and not for a legitimate medical purpose."

The jury returned a guilty verdict only as to Count Two: conspiracy to dispense oxycodone unlawfully. Mencia timely appealed.

B. Procedural Background

In his initial appeal, Mencia argued that the government failed to provide sufficient evidence of his guilt, the district court erred by admitting certain expert testimony, and 21 U.S.C. § 841 is not unconstitutionally vague as applied to physicians. We rejected these arguments and affirmed Mencia's conviction on the same grounds explained below. Notably, Mencia did not challenge the sufficiency of the jury instructions at the district court or on appeal.

Following our affirmance of his conviction, Mencia filed a pro se petition for writ of certiorari before the United States Supreme Court. For the first time, Mencia argued, among other things, that the jury instructions at his trial were insufficient. After the filing of his petition, the Supreme Court issued its decision in *Ruan*. The Court then granted Mencia's petition for certiorari,

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vacated our judgment, and remanded his appeal for further consideration in light of *Ruan. Mencia*, 142 S. Ct. 2897 (2022), *vacated, Ruan*, 142 S. Ct. 2370. We asked the parties to file supplemental briefs addressing the impact of *Ruan* on this appeal and they timely did so.

II. STANDARD OF REVIEW

This Court reviews *de novo* whether sufficient evidence exists to support a guilty jury verdict, "reviewing the evidence in the light most favorable to the government and resolving all reasonable inferences and credibility evaluations in favor of the verdict." *United States v. Moran*, 778 F.3d 942, 958 (11th Cir. 2015).

We review the district court's decision whether to admit expert testimony, and the district court's assessment of the reliability of that testimony, for abuse of discretion and will only reverse the district court if its ruling was manifestly erroneous. *United States v. Frazier*, 387 F.3d 1244, 1258 (11th Cir. 2004) (en banc) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997)). We likewise review the district court's decision whether to strike testimony for abuse of discretion. *Mich. Millers Mut. Ins. Corp. v. Benfield*, 140 F.3d 915, 920–21 (11th Cir. 1998). Accordingly, "we must affirm unless we find that the district court has made a clear error of judgment, or has applied the wrong legal standard." *Frazier*, 387 F.3d at 1259.

We review a challenge to a statute's constitutionality *de novo. United States v. Knight*, 490 F.3d 1268, 1270 (11th Cir. 2007).

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Finally, "[w]e review the legal correctness of jury instructions de novo." *United States v. Cooper*, 926 F.3d 718, 736 (11th Cir. 2019). Jury instructions objected to before the district court are subject to harmless error review, meaning this Court will not reverse if it finds beyond a reasonable doubt that an erroneous instruction did not affect the verdict. *United States v. House*, 684 F.3d 1173, 1196-97 (11th Cir. 2012). However, "jury instructions that are challenged for the first time on appeal are reviewed for plain error." *United States v. Felts*, 579 F.3d 1341, 1343 (11th Cir. 2009).

III. DISCUSSION

In his initial appeal, Mencia raised three arguments, each of which we rejected in *Mencia*, 861 Fed. Appx 736. Mencia now also challenges the sufficiency of the jury instructions in light of *Ruan*. We address each argument in turn.

A. Sufficiency of the Evidence

Mencia argues that there was insufficient evidence to support his conviction for conspiracy to violate Section 841(a). Specifically, on remand, he argues that there was insufficient evidence elicited at trial to prove beyond a reasonable doubt that he knowingly or willingly distributed oxycontin in an unauthorized manner. We disagree.

The Controlled Substances Act makes it illegal for anyone to "knowingly or intentionally distribute . . . a controlled substance." 21 U.S.C. § 841(a)(1). But there is an exception for licensed

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health care professionals—they may prescribe Schedule II, III, and IV controlled substances so long as the prescription is for a "legitimate medical purpose[] in the usual course of professional practice." *United States v. Joseph*, 709 F.3d 1082, 1102 (11th Cir. 2013) (quoting United States v. Ignasiak, 667 F.3d 1217, 1228 (11th Cir. 2012)). To convict a physician of violating Section 841(a)(1), the government must "prove that he dispensed controlled substances for other than legitimate medical purposes in the usual course of professional practice, and that he did so knowingly and intentionally." *Joseph*, 709 F.3d at 1102 (quoting *Ignasiak*, 667 F.3d at 1228). "Because the Act prohibits the distribution of prescription drugs that is *not* authorized, a distribution is unlawful if 1) the prescription was not for a 'legitimate medical purpose' or 2) the prescription was not made in the 'usual course of professional practice." Id. (cleaned up) (quoting United States v. Tobin, 676 F.3d 1264, 1282 (11th Cir. 2012), abrogated on other grounds by United States v. Davila, 569 U.S. 597, 610 (2013)). In Ruan, the Court held that, in a 21 U.S.C. § 841(a) prosecution of a licensed physician for dispensing unauthorized controlled substance prescriptions, the government must prove beyond a reasonable doubt that the physician knew that the prescriptions were unauthorized. 142 S. Ct. at 2374.

Section 846 makes it illegal to conspire to violate Section 841(a)(1). See 21 U.S.C. § 846. To convict a defendant of violating Section 846, the government must prove that "(1) there was an agreement between two or more people to unlawfully distribute . . . controlled substances in violation of § 841(a)(1); (2) the defendant

dence. Id.

knew about the agreement; and (3) the defendant 'voluntarily joined' the agreement." *United States v. Iriele*, 977 F.3d 1155, 1169 (11th Cir. 2020) (quoting *United States v. Azmat*, 805 F.3d 1018, 1035 (11th Cir. 2015)). The government may prove the first element, the existence of an agreement, "by proof of an understanding between the participants to engage in illicit conduct[.]" *United States v. Achey*, 943 F.3d 909, 916 (11th Cir. 2019). And the government may prove that understanding through circumstantial evi-

"[R]esolving all reasonable inferences and credibility evaluations in favor of the verdict," *Moran*, 778 F.3d at 958, we conclude that sufficient evidence supports the jury's verdict. Indeed, the evidence in this case is comparable to the evidence in in similar cases where we have affirmed guilty verdicts. Mencia set aside a class of patients known as "Code-G" patients and, even though he is a geriatric specialist, prescribed them the "holy trinity" of controlled substances for cash. Eventually, as in *Joseph*, Mencia distributed these drugs by pre-signing and pre-dating prescriptions and instructing his medical assistants to give out those prescriptions. See Joseph, 709 F.3d at 1102. And he prescribed these controlled substances "without conducting any physical examination of the patient," which "provides strong evidence to support a conviction under the Act." Id. Moreover, Mencia continued to prescribe the "holy trinity" to various patients despite obvious signs of drugseeking behavior that led Dr. Marrero to reject them. Ventura-Rodriguez testified that, as the number of Code-G patients increased,

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Mencia stopped entering the examination rooms at all—let alone physically examining the patients—before the medical assistants gave the patients prescriptions. And the video evidence gathered by confidential informants supports that testimony.

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This Court has found sufficient evidence that a physician distributed a prescription without a legitimate medical purpose and outside the usual course of professional conduct where, among other factors: "(1) An inordinately large quantity of controlled substances was prescribed[,] . . . (2) [l]arge numbers of prescriptions were issued[,]" (3) "[t]he physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment[,]" and (4) "[t]here was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing." *United States v.* Rosen, 582 F.2d 1032, 1036 (5th Cir. 1978). Here, Mencia regularly prescribed the maximum lawful dose of controlled substances and combined them with high doses of other controlled substances. And he wrote over 45,000 controlled substance prescriptions in less than four years. He refilled at least one patient's prescriptions early based on claims that the prescriptions had been stolen and authorized Ventura-Rodriguez to write prescriptions before the date that they were allowed. And several witnesses testified that there was no logical connection between the opioids that Mencia prescribed and the medical conditions that he was purporting to treat. Each of these pieces of evidence is "strong evidence to support a conviction under the Act." *Joseph*, 709 F.3d at 1102.

The government also provided sufficient evidence that an agreement existed between Mencia and his medical assistants to unlawfully distribute controlled substances and Mencia knew that this distribution was not authorized. An "agreement may be inferred when the evidence shows a continuing relationship that results in the repeated transfer of illegal drugs to the purchaser." *United States v. Mercer*, 165 F.3d 1331, 1335 (11th Cir. 1999). Here, Mencia's medical assistants testified at length about the understanding between them and Mencia that they could fill in presigned prescriptions for controlled substances without a physician ever examining the patients. Mencia instructed the assistants to fill in patient charts, not based on a patient's actual data, but based on the "data that would justify the reason why the patient would be prescribed the drugs." And the medical assistants did so. Through this testimony, the government demonstrated that Mencia and his medical assistants had an agreement that he would instruct them on what controlled substances to prescribe, for no legitimate medical reason and outside the usual course of professional practice, and that they would unlawfully write those prescriptions in exchange for patients' cash payments. Accordingly, there was sufficient evidence to support Mencia's conviction.

B. Expert Witnesses

Mencia next argues that the district court abused its discretion in allowing certain expert testimony. He challenges the district court's resolution of in-trial objections to specific portions of Dr. Silverman's and Dr. Warfield's testimony. And he argues that

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neither Dr. Silverman nor Dr. Sullivan should have been allowed to testify as experts at all.

1. In-trial Objections to Expert Testimony

First, Mencia argues that the district court abused its discretion in allowing Dr. Silverman to testify that, in his opinion, Mencia acted outside the scope of professional practice in treating certain patients. We disagree. An expert witness may testify about an opinion that "embraces an ultimate issue," Fed. R. Evid. 704(a), but may not "merely tell the jury what result to reach" or "testify to the legal implications of conduct[.]" *Montgomery v. Aetna Cas. & Sur. Co.*, 898 F.2d 1537, 1541 (11th Cir. 1990). "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." Fed. R. Evid. 704(b). In other words, "the expert cannot expressly state a conclusion that the defendant did or did not have the requisite intent," *United* States v. Alvarez, 837 F.2d 1024, 1031 (11th Cir. 1988), but he can provide an opinion as to facts that support such a conclusion, *United States v. Augustin*, 661 F.3d 1105, 1123 (11th Cir. 2011).

Dr. Silverman opined that the controlled substances that Mencia prescribed to certain patients "did not have a medical legitimate need." And he stated that Florida law defines what is and is not within the scope of professional practice for physicians licensed in the state. Based on those laws, he opined that Mencia was acting outside the scope of professional practice when he failed to (1) record proper medical examinations prior to prescribing controlled

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substances, (2) develop a written treatment plan for assessing patients' apparent drug-seeking behavior, or (3) document an assessment of patients' risk related to that behavior or monitor the behavior on an ongoing basis. He further testified that allowing medical assistants to fill out prescriptions or make diagnoses or treatment plans violates Florida law.

The district court did not abuse its discretion in admitting this testimony. To prove that Mencia was guilty of conspiracy to unlawfully distribute controlled substances, the government had to prove that he knowingly and intentionally dispensed those substances for other than legitimate medical purposes in the usual course of professional practice. *See Joseph*, 709 F.3d at 1094. But Dr. Silverman did not testify that Mencia knowingly and intentionally acted outside the usual course of professional practice. Instead, he testified that, in his opinion, because Mencia's actions violated Florida law, Mencia was acting outside the usual course of professional practice. Whether Mencia *knew* that he was doing so or *intended* to do so is another question.

That intent question, whether a physician knowingly and intentionally prescribed a medication for other than a legitimate medical purpose outside the usual course of professional practice, is for the jury. *See United States v. Guerrero*, 650 F.2d 728, 734 (5th Cir. 1981 Unit A). But what practices fall within the usual course of professional practice is precisely what an expert witness is needed to define. Based on that definition and Dr. Silverman's opinions, the jury was free to infer whether or not Mencia knew he was

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acting or intended to act outside of the usual course of professional practice or whether he knew he was prescribing or intended to prescribe medications without a legitimate medical purpose. *See United States v. Greenfield*, 554 F.2d 179, 184–86 (5th Cir. 1977). Because Dr. Silverman did not state that Mencia had the requisite intent to commit the crime alleged, but instead offered his opinion that Mencia was acting outside the usual course of professional practice and without a legitimate medical justification, the district court did not err in allowing his testimony.

Second, Mencia argues that the district court abused its discretion in declining to strike Dr. Silverman's statement during cross-examination that violating Section 456.44 carries criminal penalties. We disagree. When defense counsel asked, "where the statute provides for a criminal penalty, any sort of jail time," the district court sustained the government's objection on relevance grounds. When defense counsel continued and asked whether the statute is "enforced by the Board of Medicine," Dr. Silverman responded that "it was my understanding there were criminal penalties. I don't know specifically what they were." The defense then objected to Dr. Silverman's answer and moved to strike because it was "an incorrect statement of the law." Instead of sustaining the objection, the court asked the government to stipulate that there are no criminal penalties and the government responded that it was not aware of anything in Section 456.44 that defines a violation as a misdemeanor, felony, or anything else.

The district court did not err in resolving Mencia's objection to his own question. Although the government argues that the invited error doctrine prevents Mencia from raising this issue on appeal, *see United States v. Sarras*, 575 F.3d 1191, 1216 (11th Cir. 2009), we need not decide that point here. Even if the district court erred by declining to strike this allegedly erroneous portion of Dr. Silverman's testimony, that error was harmless. *See United States v. Frediani*, 790 F.3d 1196, 1202 (11th Cir. 2015). Under the harmless error standard, we need not reverse a conviction because of evidentiary error when "the error had no substantial influence on the outcome and sufficient evidence uninfected by error supports the verdict." *Id.* (quoting *United States v. Hands*, 184 F.3d 1322, 1329 (11th Cir. 1999)).

That is the case here. To convict Mencia under Section 846, the government needed to prove that Mencia conspired to distribute a controlled substance in violation of Section 841(a)(1)—that is, for "other than legitimate medical purposes" or outside "the usual course of professional practice." *Joseph*, 709 F.3d at 1102 (quoting *Ignasiak*, 667 F.3d at 1228). To do so, the government called Dr. Silverman to testify. Although Dr. Silverman testified that he believed a state law defining the standard of medical practice carried criminal penalties, the existence of criminal penalties under that law is immaterial to whether Mencia's actions comport with the standard that law sets. On top of that, Dr. Silverman's testimony was not necessary to establish whether Mencia's actions were consistent with "accepted standards of professional practice"—lay

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testimony and other evidence work just as well. See id. at 1103. And on that front, the government introduced overwhelming evidence that Mencia conspired to distribute controlled substances for "other than legitimate medical purposes" or outside "the usual course of professional practice." Id. at 1102 (quoting Ignasiak, 667 F.3d at 1228). For example, several witnesses testified that there was no logical connection between the medical conditions Mencia treated and the opioids he prescribed; three of Mencia's co-conspirators testified at length that he instructed them to sell medically unnecessary, pre-signed prescriptions for cash; Marrero testified that many of Mencia's patients displayed obvious signs of drugseeking behavior and that their patient files were incomplete, often missing standard urine tests, MRIs, and x-rays; and the government introduced undercover DEA recordings in which Mencia prescribed controlled substances without conducting physical examinations of patients. Taken together, any error in failing to strike the allegedly erroneous portion of Dr. Silverman's testimony was harmless; it "had no substantial influence on the outcome and sufficient evidence uninfected by error supports the verdict." *Frediani*, 790 F.3d at 1202 (quoting *Hands*, 184 F.3d at 1329).

Third, Mencia argues that the government improperly implied the existence of additional evidence not before the jury by asking Dr. Warfield about a previous inconsistent statement. Again, we disagree. Specifically, the prosecutor asked: "I believe what you told me was that under no circumstance would it be within the scope of professional practice to give a medical assistant

with a presigned prescription for them to fill out at their discretion for controlled two (sic) substances. Do you agree with that?" "It is hornbook law that evidence of prior inconsistent statements of a witness may be admitted to impeach that witness." United States v. Sisto, 534 F.2d 616, 622 (5th Cir. 1976). "The prior statements may have been oral and unsworn, and the making of the previous statements may be drawn out in cross-examination of the witness himself." *Id.* (quotation marks and citation omitted). For her part, Dr. Warfield had an opportunity to answer—she responded that she had said only that she "thought those medical assistants were practicing medicine without a license, and they in no way should have been given blank prescriptions to prescribe opiates to these patients." And the court correctly instructed the jury in response to Mencia's objection to this question that "what the lawyers say isn't evidence. The answers are evidence." The district court did not abuse its discretion in ruling on Mencia's objection.

2. Dr. Silverman's and Dr. Sullivan's Methodologies, Qualification, and Disclosures

Mencia next argues that the court abused its discretion in allowing Drs. Silverman and Sullivan to testify as experts because (1) the court should have conducted Daubert hearings before qualifying them as experts, and Dr. Silverman's methodology was not sufficiently reliable; and (2) Dr. Silverman's disclosures were insufficient, and the untimeliness of the government's disclosures prejudiced the defense. We address each argument in turn.

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First, the district court did not abuse its discretion in declining to conduct Daubert hearings. In Daubert v. Merrell Dow Pharmaceuticals, Inc., and its progeny, the Supreme Court explained the requirements for expert testimony to be admissible under Federal Rule of Evidence 702. 509 U.S. 579, 589-94 (1993). Such testimony is admissible if the expert is qualified, the expert's methodology is reliable, and the testimony assists the trier of fact. City of Tuscaloosa v. Harcros Chems., Inc., 158 F.3d 548, 562 (11th Cir. 1998) (citation omitted). When assessing methodology, courts should consider, where applicable, "whether it can be (and has been) tested," "whether the theory or technique has been subjected to peer review and publication," "the known or potential rate of error, . . . and the existence and maintenance of standards controlling the technique's operation," and "general acceptance." Daubert, 509 U.S. at 593–94 (citation omitted). But that inquiry is "a flexible one." *Id.* at 594. If an expert's methodology is based "solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." Fed. R. Evid. 702 advisory committee's note to 2000 amends.

In *Azmat*, we held that the district court did not abuse its discretion in allowing expert testimony where the government detailed the "federal and state medical guidelines, literature from national organizations, published journal articles, and [medical] text-books" that the expert relied on in reaching his conclusions. 805

F.3d at 1042. The government had also explained the expert's "method of reviewing patient files, which involved [the expert] weighing [the defendant's] decisions against the standards articulated in the" medical texts that the expert relied on and the expert "exercising his judgment as an experienced medical practitioner to reach conclusions" as to the defendant's conduct. *Id.* Because the expert "relied on published sources generally accepted by the medical community in defining the applicable standard of care," the district court did not abuse its discretion in admitting the testimony. *Id.*

To determine whether an expert's methodology meets *Daubert*'s standards, a district court can, but is not required to, conduct a *Daubert* hearing. *See City of Tuscaloosa*, 158 F.3d at 564 n.21. *Daubert* hearings are particularly helpful "in complicated cases involving multiple expert witnesses[.]" *Id.* "A district court should conduct a *Daubert* inquiry when the opposing party's motion for a hearing is supported by 'conflicting medical literature and expert testimony." *United States v. Hansen*, 262 F.3d 1217, 1234 (11th Cir. 2001) (quoting *Tanner v. Westbrook*, 174 F.3d 542, 546 (5th Cir. 1999)).

Here, Dr. Silverman's experience includes a medical degree, board certifications in pain management and addiction, more than twenty years of pain management in Florida, authorship of numerous peer-reviewed articles and a textbook on pain management, and a history of assisting state and federal investigations into the opioid crisis in Florida. He testified that his practice, training,

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experience, and education have made him familiar with the "accepted scope of professional practice when it comes to pain management and opioid prescriptions." Based on those qualifications, the government tendered him as an expert in pain management and addiction "with the ability to opine on what is and what is not, in his opinion, within the accepted scope of professional practice and whether medications are issued for a legitimate medical purpose."

Dr. Silverman applied that experience to the evidence to form his opinions. He reviewed patient files that the government selected for him, a list of the controlled substances that were prescribed to Dr. Mencia's patients, applicable Florida statutes, applicable federal regulations, and the confidential informant videos and transcripts. He then applied his experience and knowledge to that data to determine that Mencia was acting outside the scope of professional practice in prescribing certain controlled substances without a legitimate medical purpose.

The district court did not abuse its discretion in admitting that testimony. The district court was required to assess Dr. Silverman's methodology before admitting his testimony and the government provided ample evidence of his qualifications and the resources that he relied on in coming to his opinions. Like in *Azmat*, those resources included applicable law and "published sources generally accepted by the medical community in defining the applicable standard of care." 805 F.3d at 1042.

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The court was not required to conduct a Daubert hearing, and the defense did not support its objection with conflicting medical literature or expert testimony. *See Hansen*, 262 F.3d at 1234. Mencia argues that Dr. Warfield's conflicting opinions should have necessitated a Daubert hearing, but he did not make that argument in his motion to exclude Dr. Silverman's expert testimony or in his objection. Instead, he merely argued that Dr. Silverman's methodology was insufficiently reliable. Under such a deferential standard of review, that is insufficient reasoning for this Court to reverse the district court's decision. Because the district court's decision not to hold a Daubert hearing was based on the implicit decision that Dr. Silverman's methodology was reliable, the district court did not abuse its discretion in making that determination, either.

Second, the district court did not abuse its discretion in overruling Mencia's objection to the government's pre-trial disclosures as incomplete or untimely. At the defendant's request, the government must give a defendant a written summary of any expert testimony it intends to use, which "must describe the witness's opinions, the bases and reasons for those opinions, and the witness's qualifications." Fed. R. Crim. P. 16(a)(1)(G). In the absence of a scheduling order, this Court has not stated a bright-line rule for how far in advance of trial the government should provide a summary. But this Court has held that a summary provided "almost one month before trial" was sufficient, even when the identity of the proposed expert changed weeks later. See United States v. Chalker, 966 F.3d 1177, 1193 (11th Cir. 2020). In any event, this

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Court "will not reverse a conviction based on a Rule 16 expert disclosure violation unless the violation prejudiced the defendant's substantial rights." *Id.* (quoting *United States v. Stahlman*, 934 F.3d 1199, 1222 n.10 (11th Cir. 2019)). A defendant must establish that the violation of Rule 16 "adversely affected their ability to present a defense." *United States v. Chastain*, 198 F.3d 1338, 1348 (11th Cir. 1999).

There is no reversible error in this case. The government disclosed Drs. Silverman and Sullivan about one month after Mencia requested its disclosures, thirteen and twelve days before trial, respectively. Even assuming for the sake of argument that those disclosures came too close to trial, we cannot say the timing adversely affected Mencia's ability to present a defense. The government agreed to a trial continuance to allow Mencia more time to prepare, but he did not ask for one. *See United States v. Rivera*, 944 F.2d 1563, 1566 (11th Cir. 1991) ("if Rivera had, in fact, been prejudiced by the delayed disclosure . . . he should have moved for a continuance"). And Mencia presented a rebuttal expert witness, Dr. Warfield, whose opinions directly conflicted with Dr. Silverman's opinions. He also had time to acquire Dr. Silverman's Florida Department of Health disciplinary records to use during cross-examination.

The disclosures were also sufficient. In its disclosures, the government summarized Dr. Silverman's testimony as opining "that the defendant prescribed or caused to be prescribed Schedule II substances outside the course of professional practice and not for

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a legitimate medical purpose." He would additionally opine on Mencia's conduct in the undercover recordings, concluding that the conduct was "outside the scope of professional practice." Mencia argues that this description did not encompass Dr. Silverman's testimony that Mencia's conduct in pre-signing prescriptions and allowing medical assistants to see patients alone before merely signing a prescription fell outside the scope of professional practice. But those opinions were encompassed by the government's summary. Whether Mencia prescribed or caused to be prescribed controlled substances outside the course of professional practice encompasses pre-signing prescriptions and signing them without seeing patients. And the undercover recordings included medical assistants seeing patients alone and giving them prescriptions without consulting with Mencia. But even if the government's summary was too vague, it again did not impair Mencia's substantial rights because he was able to present Dr. Warfield's conflicting testimony on the same issues.³

³ Mencia argues for the first time on appeal that Dr. Sullivan was not qualified to testify as an expert. Mencia did not object to Dr. Sullivan's testimony on that ground—the defense argued only that her methodology had not been sufficiently vetted by the district court. Accordingly, we review that argument for plain error, Fed. R. Crim. P. 52(b), and conclude that the district court did not plainly err in allowing Dr. Sullivan's testimony.

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C. Constitutionality

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Mencia also argues that the Controlled Substances Act is unconstitutionally vague as applied to physicians. He contends that, because no statute or regulation defines the standard of care against which his conduct can be compared, that standard was defined by "unqualified government experts" and Mencia was convicted "based on this nebulous definition of standard of care."

When "a vagueness challenge does not involve the First Amendment, the analysis must be as applied to the facts of the case." *United States v. Wayerski*, 624 F.3d 1342, 1347 (11th Cir. 2010). Mencia has not raised a First Amendment challenge. Accordingly, the question for this Court is whether the Act "fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits' or 'it authorizes or even encourages arbitrary and discriminatory enforcement." *Id.* (quoting *Hill v. Colorado*, 530 U.S. 703, 732 (2000)). To establish that the Act is unconstitutionally vague, Mencia must overcome the "strong presumption that statutes passed by Congress are valid." *Id.*

In *United States v. Collier*, a physician appealed his conviction under Section 841(a)(1) for distribution of methadone while acting outside the usual course of professional practice. 478 F.2d 268, 270 (5th Cir. 1973). This Court rejected the physician's argument that the phrase "in the course of his professional practice" did not give physicians notice as to what conduct violates the statute. *Id.* at 270–72. We held that the statute necessarily gave physicians

"a certain latitude of available options," because "the physician must make a professional judgment as to whether a patient's condition is such that a certain drug should be prescribed." *Id.* at 272. And that judgment is what physicians must routinely exercise in prescribing controlled substances. *Id.* Accordingly, the Act's prohibition of distributing controlled substances outside the course of professional practice is not unconstitutionally vague; it is a clear reference to the judgment calls that physicians routinely make. *Id.*

Here, Mencia makes an argument nearly identical to the defendant's argument in *Collier*. He argues that the lack of a statute or regulation defining the baseline standard of care renders the Act unconstitutionally vague as applied to physicians. But this Court already held that the phrase "in the course of his professional practice" is not unconstitutionally vague and does not require a statutory or regulatory definition because it is a necessarily fact-intensive inquiry in which physicians must exercise their professional judgment. Id. And Mencia fails to distinguish his argument from the defendant's argument in *Collier*. Instead, he argues that his case is different because he was not acting as a drug pusher. But that is exactly the question that the Act seeks to answer—when does a physician stop acting as a doctor and start acting as a "drug pusher." The answer under the Act is when he prescribes controlled substances outside the course of his professional practice or without a legitimate medical purpose. Because this Court has already rejected the exact argument that Mencia raises, we affirm.

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D. Jury Instructions

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Finally, Mencia argues that the "good faith defense" instruction given by the district court does not comply with *Ruan*. However, Mencia omits from his supplemental brief the fact that he requested the jury instructions and the district court granted his request. And "where a party expressly accepts," or in this case requests, "a jury instruction, such action constitutes invited error" and "serve[s] to waive [his] right to challenge the accepted instruction on appeal." *United States v. Silvestri*, 409 F.3d 1311, 1337 (11th Cir. 2005). Regardless, the instructions given by the district court do not constitute reversible error even viewed in light of *Ruan*. As Mencia failed to object to the sufficiency of the challenged jury instructions at the district court, we review for plain error.

1. Mencia waived his right to challenge the good faith instruction as he requested it

Mencia's argument is based principally on his contention that in *Ruan*, "the Supreme Court [ruled] the 'good faith' jury instruction to be error." This is a misstatement of the Court's holding and is irrelevant in any event because any error associated with the instruction was invited.

In *Ruan*, the defendants were physicians convicted of violating 21 U.S.C. § 841(a)(1) by unlawfully dispensing opioid prescriptions. 142 S. Ct. at 2375. Section 841(a) makes it a federal crime, "[e]xcept as authorized[,] . . . for any person knowingly or intentionally . . . to manufacture, distribute, or dispense . . . a con-trolled

substance." 21 U.S.C. § 841(a) (emphasis added). A licensed physician is authorized to prescribe certain controlled substances if she issues that prescription "for a legitimate medical purpose . . . acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a).

One of the *Ruan* defendants requested a jury instruction requiring the government to prove that he knew that his prescriptions fell outside the scope of his prescribing authority. Ruan, 142 S. Ct. at 2375. The district court rejected that instruction, and this Court affirmed, determining that the requested good faith instruction was an incorrect statement of the law because a doctor's "subjectiv[e] belie[f] that he is meeting a patient's medical needs by prescribing a controlled substance" is not a "complete defense" to a Section 841 prosecution. *Id.* at 2376; *United States v. Ruan*, 966 F.3d 1101, 1166 (11th Cir. 2020) ("Whether the defendant acts in the usual course of his professional practice must be evaluated based on an objective standard, not a subjective standard"). The Supreme Court, however, disagreed.

Instead, the Supreme Court held that Section 841(a)'s "knowingly or intentionally" mens rea applies to the "except as authorized" clause of that statute, meaning a defendant physician's subjective intent could be a complete defense to the crime. Ruan, 142 S. Ct. at 2375. The Court did not evaluate whether the district court's jury instructions substantially covered that subjective intent requirement or whether any instructional error was harmless, leaving those determinations for this Court on remand. Id. at 2382.

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The Court in *Ruan* did not hold, as Mencia claims, that reversal was warranted there because of the inclusion of the good faith instruction. Instead, the failure to include the instruction—as well as our holding that a doctor's subjective belief that he is meeting a patient's medical needs by prescribing a controlled substance is not a complete defense to a Section 841 prosecution—formed the basis of the Court's reversal. Consistent with the Court's holding in *Ruan*, the good faith instruction in this case required the jury to consider Mencia's subjective intent in determining whether he had a "good faith reasonable belief" that the distribution of controlled substances was unauthorized. Regardless, as Mencia himself requested that instruction, it cannot serve as the basis for a reversal of his conviction as he "waive[d] [his] right to challenge the accepted instruction on appeal." *Silvestri*, 409 F.3d 1311, 1337 (11th Cir.2005).

2. The jury instructions for the conspiracy count sufficiently conveyed the mens rea requirement for unauthorized distribution

Similarly, the jury instruction for the conspiracy count was not erroneous under *Ruan* or, at least, not plain error under that decision. The instruction communicated that the government must prove beyond a reasonable doubt that the physician knew that the prescriptions were not "authorized."

The instruction stated that Mencia could be found guilty only if the Government proved beyond a reasonable doubt that (1) he and another person "in some way agreed to try to accomplish a

shared and unlawful plan to distribute or dispense a con-trolled substance, outside the scope of professional practice and not for a legitimate medical purpose"; (2) Mencia "knew the unlawful purpose of the plan and willfully joined in it"; and (3) the purpose of the plan, "was to distribute or dispense a controlled substance, outside the scope of professional practice and not for a legitimate medical purpose." This instruction thus required the government to prove that Mencia knew that the prescriptions he had written were unauthorized or, in other words, that they were outside the scope of professional practice and not for a legitimate medical purpose. Had he not known that the prescriptions were unauthorized, he could not have known the "unlawful purpose of the plan" and the second element would not have been satisfied.

The conspiracy charge was the sole count for which Mencia was ultimately convicted. Further, as explained above, the argument relating to the sufficiency of the good faith instruction cannot be the basis for reversible error, and he does not challenge the language of any other jury instructions. Accordingly, Mencia's argument that the jury instructions at his trial require us to vacate his conviction fails.

IV. CONCLUSION

The government provided sufficient evidence of Mencia's guilt, the district court properly admitted the expert testimony, the Act is not unconstitutionally vague as applied to physicians, and the

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jury instructions are acceptable in light of *Ruan*. Accordingly, we affirm.