21-1008

No. 20-

In The
Supreme Court of the United States

ANDRES MENCIA,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

For more than a decade, the civil standard of care established for the practice of medicine has been utilized by federal prosecutors in criminal prosecutions against physicians to create criminal liability resulting in mass incarceration of physicians.

Is the civil definition of standard of care as opined by government hired experts sufficient to create criminal liability against physicians or should a civilized country like the United States clearly spell out what is criminal while the doctor is at his office, in his white uniform, seeing patients in the ordinary course of business?

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RELATED PROCEEDINGS

Petition for Writ of Certiorari: *United States v. Kahn* No 21-5261, United States Court of Appeal for the Tenth Circuit. Judgment entered on February 25, 2021. Petition Granted on November 5, 2021.

Petition for Writ of Certiorari: *United States v. Xiulu Ruan*, No. 19-11508, United States Court of Appeals for the Eleventh Circuit. Judgment entered on Jan 8, 2020. Petition Granted on November 5, 2021 and consolidated with Kahn.

Petition for Writ of Certiorari: *United States v. Nuam* No. 20-1480, United States Court of Appeals for the Fourth Circuit. Judgment entered on October 13, 2020.

PETITION FOR WRIT OF CERTIORARI

Petitioner, Andres Mencia, M.D., respectfully requests the issuance of a writ of certiorari to review the judgment of the United States Court of Appeals for the Eleventh Circuit.

DECISION BELOW

The decision of the United States Court of Appeals for the Eleventh Circuit was released as unpublished on June 9, 2021 at –Fed.Appx.----2021 WL 2351111.

JURISDICTION

The court of appeals' judgment was entered on June 9, 2021. On November 13, 2020, the Court issued guidance reflecting that the 150-day extension "from the date of the lower court judgment, order denying discretionary review, or order denying a timely petition for rehearing," directed by the Chief Justice on March 19, 2020, remains in effect. This Court's jurisdiction is invoked under 28 U.S.C. §1254(1).

RELEVANT STATUTORY AND CONSTITUTIONAL PROVISION

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

> (a) Unlawful acts
> Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally-
> (1) to manufacture, distribute or dispense or possess with intent to manufacture, distribute, or dispense, a controlled substance[.]

21 U.S.C. §822(b), empowers the Attorney General to implement a registration process to authorize medical professionals, referred to as "registrants" to dispense controlled substances. 21 U.S.C. § 829 permits a practitioner to dispense controlled substances by prescription. A physician is a "practitioner" under 21 U.S.C. §802(21) and is therefore authorized to dispense controlled substances by being registered with the Attorney General under the provisions of 21 U.S.C. §822(a)(2).

21 C.F.R. § 1306.04(a) provides for issuance of a lawful prescription.

> (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispending of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription

> issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. §829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Section 846, which is the *only* count that Dr. Mencia was convicted of, provides:

> Any person who attempts or conspires to commit any offense defined in this subchapter shall be subject to the same penalties as those prescribed for the offense, the commission of what was the object the attempt or conspiracy.

A conspiracy conviction requires the government to prove: "(1) [an] agreement between two or more persons to achieve an unlawful objective; (2) knowing and voluntary participation in that agreement by the defendant; and (3) an overt act in furtherance of the agreement". *United States v. Wenxia Man*, 891 F.3d 1253, 1265 (11th Cir.2018).

STATEMENT

When the government is not required to prove *mens rea* in the prosecution against physicians accused of crimes relating to the practice of medicine specifically relating to the issuance of prescription for controlled substances, the

Eleventh Circuit excuses the government from proving the elements of the crime, gaining an unconstitutional advantage in the prosecution. In nearly every one of these cases against physicians, the government builds its case from "bad apple" employees who want to save their own

neck because of their own involvement of dipping into the practice of selling controlled substance prescriptions for a monetary gain, as the did the medical assistants in Dr. Mencia's office.

All three of Dr. Mencia's medical assistants were collecting tips for each prescription they handed out to patients for controlled substances, without the knowledge of Dr. Mencia. The use of vague and what is essentially a civil standard allows the Government a free pass on not having to prove *mens rea*, which indisputably is an element of the crime charged. In the instant case, while the jury instructions are given for 'good faith' defense and knowledge element, the vagueness in statutory language of "outside the scope of professional practice" results in a conviction all day long every time.

Adding to this ambiguity in the statute is the Eleventh Circuit's disregard for the *mens rea* element in these prosecutions against physicians. e of professional practice, Eleventh Circuit's approved jury instructions fall far short from this.

The Eleventh Circuit defines good faith as acting within the scope of professional practice, without any reference to the defendant's beliefs. *United States v. Ruan* 966 F.3d 1101,1167 (11th Cir 2020); *United States v. Joseph* 709 F.3d 1082, 1097 (1th Cir 2013)("The law of this Circuit

is not even clear that [the defendant] was entitled to a "good faith" jury instruction at all"). As such, as was the case in Dr. Mencia's appeal, the review of insufficiency of the evidence does not get afforded the proper appellate inquiry. Where there is no proof established by the government of the knowledge component, irrespective of the jury's verdict, a judgment of acquittal is due to be granted. However, Eleventh Circuit never reaches there because it has written *mens rea* out of existence in connection with prosecutions of physicians accused of prescription or health care fraud.

The Second, Fourth, Sixth and Eighth Circuits define good faith "objectively". In those circuits, a defendant acts in good faith only when he acts within what he *reasonably should have* believed or "reasonably believed" to be the usual course of practice. *United States v. Vamos* 797 F.2d 1146, 1152 (2d Cir. 1986); *Hurwitz,* 459 F.3d at 478(4th); *United States v. Godofsky* 943 F.3d 1011, 1026 (6th Circ. 2019) *United States v. King* 898 F.3d 797, 807-08 (8th Circ. 2018).

The effect of the Eleventh Circuit's instructions is to allow a jury to convict based on a *mens rea* of negligence rather than criminal intent. In the Eleventh Circuit, a defendant who holds a sincere belief about what prescription practices are permissible and writes prescriptions based on that belief can still be convicted under the CSA.

To say that there is a split between the circuits is an understatement. To overcome a good faith defense in the Second Fourth, and Sixth Circuits, the government must prove that the physician did not *reasonably believe* that his prescriptions fell within professional norms. To overcome a

good faith defense in the First, Seventh, and Ninth Circuits, the government must prove that the physician *subjectively intended* a prescription to exceed professional norms. But neither of those 'good faith' defenses are available in the Eleventh Circuit. And all of those standards still improperly criminalize lawful practice of medicine.

All it takes to convict a physician under the CSA in the Eleventh Circuit is a finding that the doctor prescribed controlled substances outside "generally accepted medical standards" . Thus, the Eleventh Circuit invites juries to turn practicing doctors into convicted felons based on nothing than a difference of opinion between the government's paid expert and the physician's expert.

This case, like the recently accepted petitions for writ of certiorari in *Ruan* and *Kahn* is ideal for resolving the question presented. Dr. Mencia filed a motion for new trial in which a comprehensive analysis of controlling federal law and statutes were laid out to show how dangerously vague the jury instructions are regarding 'good faith' and how the government's burden of proof of *mens rea* is completely washed out. *See Appendix E.* The arguments made in the motion for new trial fell on deaf ears in the district court and then again in the Eleventh Circuit.

A. Statutory Framework

To convict a physician of violating 21 U.S.C. § 841(a)(1), the government must "prove that he dispenses controlled substances for other than legitimate medical purposes in the usual course of professional practice, and that he did so knowingly and intentionally. *United States v. Joseph* 709 F.3d 1082, 1102 (11th Cir. 2013).

To prove that a physician's activities violate the Controlled Substances Act, prosecutors typically present evidence establishing the standard of care, coupled with proof that the doctor's prescriptions departed from it. See, e.g. *United States v. Sabean*, 885 F.3d 27,45 (1st Cir.2018); *United States v. Bourlier,* 518 Fed.Appx. 848, 857 (11th Cir. 2013) (per curiam); *United States v. Wexler*, 522 F.3d 194, 204 (2d Cir. 2008); *United States v. McIver*, 470 f.3d 550, 560-561 (4th Cir. 2006).

While all other circuits permit physicians to present a defense of good faith to counter the prosecution, the Eleventh Circuit has written the good faith defense out of existence for physicians. The Eleventh Circuit has also taken out the *mens rea* element of the crime effectively washing it out by allowing district courts to deny motions for new trial or judgment of acquittal notwithstanding the verdict where juries lose their way in these sensationalized trials with federal prosecutors pointing their fingers at physicians lawfully practicing medicine as if they are drug pushers. *See Appendix E.*

In the final analysis, neither the circuits that are split nor the Eleventh Circuit get it right because in both versions, the net is so broad that nearly all lawfully practicing physicians writing lawful prescriptions are criminalized on the mere difference of opinion between two experts. More is needed in the way of supplementing jury instructions to include "criminal intent" not just intent or knowledge on the part of the physician.

B. Factual Background

1. Dr. Mencia, a licensed physician in the State of Florida authorized to prescribe Schedule II controlled substances, operated a medical practice that predominantly catered to the needs of the elderly. The medical practice was known as Adult Geriatric Institute of Florida, Inc. ("AGI"). AGI was extremely busy, with nice offices and approximately 35 nonphysician employees and 12-16 doctors.

2. A pharmacist working at Publix began to believe that Dr. Mencia was writing excessive controlled substances. Instead of fulfilling her obligations under corresponding responsibility under 21 C.F.R. § 1306.04(a), and picking up the phone to directly speak with Dr. Mencia to fulfill her corresponding responsibility, she stopped filling his prescriptions. The, one day when the DEA came to conduct a visit at her pharmacy, she mentioned Dr. Mencia to them.

3. Subsequently, undercover agents were sent as patients to Dr. Mencia's clinic, which showed only that the medical assistants were accepting tips for prescriptions for controlled substances which they were handing out to patients. In all the videos which were played at trial for the undercover patients, Dr. Mencia either examined or discussed at length the conditions of the patient prior to authorizing a prescription for controlled substances.

4. On December 7, 2017, Dr. Mencia was indicted on two counts along with the three medical assistants who were indicted on multiple counts.

5. However, Dr. Mencia went to trial on the Fifth Superseding Indictment filed on May 3, 2018, charging him with 11 counts related to both prescription and health care fraud.

6. Trial was conducted between June 18, 2018 through June 29, 2018.

7. Dr. Mencia's three co-defendants, who all worked as medical assistants at AGI, testified at trial: Ventura-Rodriguez, a medical doctor in the Dominican Republic but only a medical assistant in the United States, Sampath-Grant, a green card holder with a 15 year old son, and Mensah, a medical assistant at AGI for approximately 13 months.

8. The bulk of the testimony by these co-defendants was that Dr. Mencia was not examining patients who were diagnosed with chronic pain each time they were coming in for a prescription for their pain. No identification was ever made for these patient who were in this chronic pain category receiving prescriptions for controlled substances. Other testimony vaguely established that Dr. Mencia had at some point started not to conduct physical examination on the new patients although these "new" patients were also never identified either by the Government at time of trial.

9. All of these three medical assistants at time of trial were incarcerated as they testified against Dr. Mencia. Soon after the trial, they were all released with time served.

10. Defense expert, Dr. Carol Warfield, who taught pain management at Harvard University, testified on behalf of Dr. Mencia. She was however initially hired by the government as the Government's expert witness. Once the government found out that her opinion was that Dr. Mencia had acted within the scope of his professional practice, she was let go. The defense hired her and she testified at trial that nothing Dr. Mencia did fell outside the scope of his professional practice.. Dr. Warfield further clarified that while some of the practices of Dr. Mencia may not be utilized by her or other physicians, this did not mean that Dr. Mencia was acting outside the scope of his professional practice like a drug pusher. She opined that he was still acting as a doctor. The entirety of Dr. Warfield's testimony has been provided because it is an accurate depiction of the "*The Good, the Bad and the Ugly*" of the world of pain management and opioid crisis. *See Appendix B: Defense turned Government Expert testifying about The Good, the Bad and the Ugly of Pain Management pg 55-128*

11. On June 29, 2018, Dr. Mencia was found guilty only on one out of the eleven counts: Count 2 which was the conspiracy to dispense controlled substances pursuant to 21 U.S.C. §846.

12. On July 20, 2018, Dr. Mencia filed his motion to dismiss or in the alternative motion for new trial underscoring the vagueness of the standard relating to 'good faith' defense and the obvious confusion of the jury. The motion was denied by the district court. *See Appendix E.*

13. On September 10, 2018, the district court sentenced Dr. Mencia to 78 months of incarceration followed by three years of supervised release.

14. Following the affirmance of his timely appeal to the Eleventh Circuit, Dr. Mencia now files this petition for writ of certiorari.

REASONS FOR GRANTING THE PETITION

I. ELEVENTH CIRCUIT HAS WRITTEN *MENS REA* AND 'GOOD FAITH' OUT OF EXISTENCE CREATING A SPLIT AMONG CIRCUITS

The Eleventh Circuit Court of Appeal stands out among all the circuits because it has set the standard which effectively takes *mens rea* out of the equation in government prosecutions against physicians involving either prescription or health care fraud. The Eleventh Circuit's standard allows the government gets a free pass on getting a conviction based on insufficient evidence, relying on inuendo and speculation. Dr. Mencia is just but one of these physicians wrongfully convicted or otherwise ousted from the practice of medicine.

The government should have been required to prove that Dr. Mencia (1) distributed controlled substances, (2) that the distribution of those controlled substances was outside the usual course of professional practice and without a legitimate medical purpose, and (3) that the practitioner acted with *criminal* intent to distribute the drugs outside the course of professional practice. *See United States v. Feingold* 454 F.3d 1001, 10088 (9th Cir.2006). "The jury must make a finding of intent not merely with respect

to distribution, but also with respect to the doctor's intent to act as a pusher rather than a medical professional". *Id.*

Dr. Mencia did not have the intent, knowledge nor awareness of an illegal dispensing of controlled substances. Just because his employees figured out a loophole and were capitalizing on illegally dispensing controlled substances while being employed by Dr. Mencia does not establish *mens rea* on the part of Dr. Mencia. There was no evidence introduced at trial that Dr. Mencia had any knowledge of these illegal activities that were going on behind his back. Dr. Warfield, the government expert turned to being defense expert categorically established that there were many ways ad opinions on how to manage pain for patients who are on chronic pain medications and that differences of opinion between two practicing physicians does not establish a criminal intent. It was established also that Dr. Warfield had written the book on Pain Management. *See Appendix B.* In spite of this powerful testimony, because the jury instructions lacked the specific knowledge element, the jury convicted Dr. Mencia on one out of the eleven counts.

In its unpublished opinion, to reach an end that remains consistent with its precedential rulings, the Eleventh Circuit first starts out mischaracterizing the testimony introduced at trial. At trial, the phrase "Code-G" was introduced as label for patients who were traveling from state to state without an insurance. It was described in the following fashion from the medical assistant, Oscar Ventura-Rodriguez, who was the Government's start witness and a co-defendant:

> Q: Did you ever have a discussion with Dr. Mencia about what is a gypsy patient?
> A: Yes.
> Q: And what did he say?
> A: that these were people with different accents when they spoke, and that they lived from one state to another

See Appendix C: Excerpt Trial Transcript: June 19, 2018 pg 401.

This trial evidence is nothing like the description that the Eleventh Circuit uses in its opinion: "a significant amount of his business came from prescribing opioids and other controlled substances to certain patients who paid in cash. Mencia called these individuals "Code-G" patients with the "G" standing for "gypsy" because they did not have insurance". *See Appendix A: Opinion at page 4.*

Next, the Eleventh Circuit Court's decision that plucks out one example, the example of Patient JH, disregards the necessary element of mens rea whether Dr. Mencia actually knew that phone calls to the front desk were made by concerned family members. The Eleventh Circuit uses this as an example of "plenty of evidence for the one count of conspiracy of which Dr. Mencia was convicted. "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. *See Appendix A: Opinion pg 5.*

All the while, not once does the Eleventh Circuit note that there was nothing established at trial that showed that the phone calls from family members of Patient JH to the front desk were actually transmitted to Dr. Mencia himself. Where is the intent for Dr. Mencia if there is no proof that the he ever communicated the information that the front desk received from concerned family members?

There was not a scintilla of evidence presented at trial that Dr. Mencia was ever aware of these concerning phone calls from patient family members. The trial testimony of the family in fact bolstered the fact that these family member never spoke to Dr. Mencia himself. Without establishing this critical nexus, the prosecution was given a free pass from proving *mens rea* which is a necessary element of 21 U.S.C. § 841 (a). The conviction is unjust when the government is excused from this burden of establishing *mens rea.*

Another example the Eleventh Circuit relied on is the testimony of Oscar Ventura-Rodriguez, a foreign trained medical doctor who was working as a medical assistant in the United States, making money out of tips by providing prescriptions for controlled substances to patients who were coming to the clinic.

At the time of his trial testimony, Ventura-Rodriguez was incarcerated and "living in jail". *See Appendix C*: *Trial Testimony pg 131-132.* To say that his testimony was tainted by his self-preservation to save his own neck from the full force of the government's powers to prosecute would be an understatement. But even Ventura-Rodriguez's tainted testimony did not give the

Government the necessary element of *mens rea* in 21 U.S.C. §846:

> Q: I want to draw your attention to 2014 and whether there was a meeting between you and Dr. Mencia. Do you recall such a meeting?
> A: Yes
> Q: Can you please tells us who was at this meeting? This is 2014.
> A: Juan Calle, Homer, myself and Dr. Mencia
> Q: Can you please tell the members of the jury to the best of your recollection what it is that Dr. Mencia said at this meeting?
> A: We were talking about the process in the clinic, and that –about the fact that were already-- ready to see gypsy patients.
> Q: At that time, did Dr. Mencia explain how these gypsy patients were going to pay for their consultation?
> A: Yes
> Q:What did he say?
> A:That they would be paying cash
> Q:And what, if anything, did he say they would get in exchange for cash?
> A: A prescription, a medical prescription
> Q: At that time, was there any explanation about what kind of prescription specifically?
> A: No.

See Appendix C: Trial Transcript: pg 131-132.

One can hardly conclude from this testimony that Dr. Mencia had *mens rea* when he only said that it was a "medical prescription" that were to be given to those patients who were paying cash. If patients do not have insurance, Dr. Mencia has the right to charge case for those patients, and the patients have the same right to pay cash, for whatever medical care they are seeking. Requiring cash payment for non-insurance patients is not a criminal activity under any federal statute. The testimony of Ventura-Rodriguez did not establish any criminal conduct by Dr. Mencia and the Eleventh Circuit's affirmance disregarded the government's burden to establish *mens rea* in order for Dr. Mencia to be constitutionally found guilty of the crime of conspiracy to commit violation of 21 U.S.C. §841.

Remaining testimony of Ventura-Rodriguez merely establishes that on old or returning patients, there was not an examination of the patients each time. No standard of care was established requiring chronically ill patients to be examined each time they came in for their prescription. However, there was plenty of testimony from the government's witnesses that Dr. Mencia was routinely ordering diagnostic tests such as MRI and urinalysis to monitor these chronically ill patients. Lack of a physical examination each time the patient comes in cannot translate into a criminal conviction and loss of an entire career for a physician. But according to the standards set by the Eleventh Circuit, it does.

Next, the opinion of the Eleventh Circuit highlights the testimony of the pharmacist, Dr. Abby Goldstein, describing her involvement as the "beginning of the end" for Dr. Mencia. *See Appendix A: Opinion at pg 30.* The Eleventh Circuit entirely overlooks her corresponding responsibility mandated by statute where she was required to directly communicate with the physician in an attempt to clear up her so-called concerns. No such trial testimony was presented through his Publix pharmacist.

Instead, what came out was that DEA was diverted to Dr. Mencia by this Publix pharmacist during one of the visits to inspect and monitor her own practices at Publix pharmacy. Where the pharmacist does not directly notify the physician of her concerns, how can Eleventh Circuit give a free pass to the government as having met their burden for mens rea on the part of Dr. Mencia?

Nowhere in the entire opinion by the Eleventh Circuit, is there any reference to the fact that the extensive testimony of the government's expert witness turned defense expert, who taught pain management at Harvard University, found no criminal conduct on the part of Dr. Mencia. Yet, the Eleventh Circuit in its opinion paints with a broad brush that there was "plenty" of proof that Dr. Mencia was acting as a drug pusher. The extensive and unchallenged testimony of Dr. Warfield is the very core of why, absent intervention from this Court, there will be a conviction by the jury each and every time the government proceeds in the way it has in Dr. Mencia's case without having to prove *mens rea* and with vague explanations for 'good faith' defense that renders honest mistakes or differences of opinion in medical treatment as criminal.

The Eleventh Circuit has written not just *mens rea* but also 'good faith' defense out of existence. Other circuits have allowed 'good faith' defense while still giving the government a free pass on proving the element of the crime: intent.

The Eleventh Circuit's good faith instruction is consistent with its view that a doctor is strictly liable and takes all consideration of a doctor's mental state out of consideration. The Eleventh Circuit instruction defines good faith as a doctor actually acting in accordance with a standard of medical practice generally recognized in the United States. See *Ruan* 966 f.3d at 1167 ("A controlled substance is prescribed by a physician in the usual course of professional practice and, therefore, lawfully if the substance is prescribed by him in good faith as part of his medical treatment of a patient in accordance with the standard of medical practice generally recognized and accepted in the United States.").

Other courts of appeal have issued decisions that either implicitly or explicitly required a finding of knowledge on the part of the practitioner. See *Hurwitz* 459 F.3d (4th). ("attorney's statement [admitting that his client acted outside the scope of professional practice] therefore cannot be viewed as a clear and unambiguous admission that [the defendant] knowingly acted outside the bounds of accepted medical practice") *United States v. Jones* 825 F.App'x at 339 (6th Circ 2020)("to have convicted the defendant under §841(a)(1), the jury must have found that Jones filled prescriptions for Schedule II substances knowing that the prescriptions were outside the scope of professional practice and that they were not for a legitimate

medical purpose") (unpublished); *Sabean*, 885 F.3d at 45 (1st) (It stressed that the government had to prove, at a minimum, that the defendant "was aware of a high probability the prescription was not given for a legitimate medical purpose in the usual course of professional practice" and that the defendant " consciously and deliberately avoided learning that fact"; *United States v. Li* 819 F.App'x at 118 (3rd) (" It is settled law that a district court does not abuse its discretion in denying a good faith instruction where the instructions given already contain a specific statements of the government's burden to prove the elements of a 'knowledge' 'crime'. Here the District Court instructed the jury on the requirements to prove knowledge. Thus, it acted within its discretion") (unpublished). *Wexler,* 522 F.3d at 206 (2nd) ("mistake however gross is insufficient" to satisfy knowledge element); *United States v. Smith*, 573 F.3d at 649-50 n.4 (8th Circ. 2009) (instruction conflating civil standard of care with usual course of professional practice was cured, in part, by good faith instruction which noted that unreasonable belief sincerely held is good faith").

While the sister circuit courts' standard of conviction for lawful practice of medicine has some shield, the vagueness in statute still exposes even the most lawfully practicing physicians to convictions with lifelong sentences and permanent loss of entire careers.

The Eleventh Circuit's strict liability standard just catches a wider net of lawfully practicing physicians criminalizing lawful prescriptions based on a mere difference of opinion between the government's expert and

the accused physician's expert without factoring in any burden by the government to prove intent or knowledge by the physician.

This is nothing more than the civil standard of medical malpractice except that for the accused physician, the consequences of two experts having a difference of opinion, are loss of freedom and loss of ability to ever practice medicine again.

II. STANDARD IN ALL CIRCUITS IS CIVIL EVINCING THE NEED TO CLEARLY SPELL OUT 'CRIMINAL INTENT' RATHER THAN 'INTENT' AS WELL AS SPELLING OUT 'CRIMINAL CONDUCT OUTSIDE THE SCOPE OF PRACTICE'

Even with the standard adopted by circuits other than the Eleventh Circuit, where the jury instruction references to "intent" or "knowledge", it still falls short because the jury starts contemplating that the physician who is in the same office must have intent and knowledge. The intent and knowledge must be clarified as to being a "criminal intent" a "knowledge to act criminally".

Dr. Mencia's case is a poster child example of how mere instructions on 'good faith' and requirement of 'intent' does not suffice. While it was sufficient enough to acquit Dr. Mencia of the 11 counts, it was insufficient to acquit him on Count II which was the Count of Conspiracy to dispense controlled substances. In cases like the instant case, this Court should clarify the vagueness in the statute sufficiently so that district court judges can feel comfortable entering a judgment of acquittal in cases like Dr. Mencia's case.

Unless the "intent" element is clearly spelled as "criminal intent" with explanation of what facts constitute criminal intent on a case by case basis, we will continue to be in the eye of the epidemic of incarcerating innocent physicians in this country. Explanations of facts could be along the lines of "it could be construed as criminal intent if the physician was at a party and took $300 from an individual in exchange for a prescription for controlled substance. The same goes for "scope of practice" as well. What falls inside a scope of practice and what falls outside scope of practice has to be criminally defined. Right now, it is defined by standard of civil medical malpractice cases. An example clarifying explanation could be if the doctor was not at his office, wearing his white robe, and seeing patients, he was likely outside of the scope. In the extensive testimony provided by Dr. Warfield, Dr. Warfield, a Harvard graduate who wrote the book on pain management, specifically touches on this issue stating that Dr. Mencia was still within the scope of practice because he was seeing patients, he was rendering medical care, he was at his medical office during the commission of the acts alleged even though some of those acts may not have been carried out the same way by all physicians. *See Appendix D: pg 54-128.*

Unless the split as well as the Eleventh Circuit's draconian standard to criminalize physicians' writing prescriptions for controlled substances is clarified, US will remain as the number one country mass incarcerating physicians. This is not because all criminal doctors happen to reside here in the US, but rather this is because statutory language of 'scope of practice' and 'for a legitimate medical purpose' are vaguely and poorly defined for the jury instructions relying on a standard that is used in civil cases. Jury instructions given in this case

speak volumes as to the ambiguity that will result in a conviction time and time again by the mere presence of a differing opinion.

> To convict the Defendant of unlawfully dispensing or distributing controlled substances, the Government must prove beyond a reasonable doubt that the Defendant was not acting "for legitimate medical purposes in the usual course of his professional medical purpose" or "beyond
> the bounds of medical purpose." This requires you to measure the Defendant's conduct against
> the prevailing standard of care or practice within the Defendant's professional community. Such a standard of care is determined from the laws, rules, and guidelines which govern the Defendant's medical practice where he works.

See Appendix D: Jury Instructions pg. 154.

There should be little persuading that this Court needs that prescription writing has been criminalized at the whim of prosecutors who decide what is standard of care by hiring the expert who is going to sing to the sound of their drum.

CONCLUSION

For all the foregoing reasons, the petition for writ of certiorari should be granted.

DATED: January 11, 2022.

Respectfully submitted,

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APPENDIX A

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 18-13967

D.C. Docket No. 0:17-cr-60301-WPD-1

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

versus

ANDRES MENCIA,

Defendant-Appellant.

Appeal from the United States District Court
for the Southern District of Florida

(June 9, 2021)

Before MARTIN, GRANT, and BRASHER, Circuit Judges.
BRASHER, Circuit Judge:

This is Andres Mencia's direct appeal of his 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 the usual course of professional practice, in violation of 21 U.S.C. § 846. Mencia, a 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, and (3) the Controlled Substances Act is unconstitutionally vague as applied to physicians. We disagree. The government presented overwhelming evidence of Mencia's guilt, the district court did not abuse its discretion, and this Court has already held that the Act is not unconstitutional as applied to physicians. Accordingly, we affirm.

I. 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 an opioid, benzodiazepine, and a muscle relaxant that drug-seeking patients often request. Between January 1, 2014, and May 31, 2018, Mencia prescribed controlled substances to around 45,000 patients. Around one-third of those patients 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.

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 pre-sign 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 xrays 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 his tolerance had increased, Mencia complied for all but one medication, saying that he had to "stay under the radar." 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 immediate-release 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 government's disclosures were
untimely. The district court denied the motion. 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, 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 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." The jury returned a guilty verdict only as to Count Two: conspiracy to dispense oxycodone unlawfully. Mencia timely appealed.

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

III. DISCUSSION

A. Sufficiency of the Evidence

Mencia argues that there was insufficient evidence to support his conviction for conspiracy to violate Section 841(a). 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 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)) ; *United States v. Ruan*, 966 F.3d 1101, 1122 (11th Cir. 2020). 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)). 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 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 evidence. *Id.*

"[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 drug-seeking behavior that led Dr. Marrero to reject them. Ventura-Rodriguez testified that, as the number of Code-G patients increased, 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. 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 prescribed over 45,000 controlled substances 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. 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 pre-signed 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 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 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 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 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, Qualifications, 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.

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] textbooks" 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, 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. 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 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 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.

C. Constitutionality

Finally, Mencia 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." 1 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. 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.

CONCLUSION

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

APPENDIX B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
FORT LAUDERDALE DIVISION

CASE NO. 17-60301-CR-WPD

UNITED STATES OF AMERICA,

Plaintiff,

v.

ANDRES MENCIA,
Defendant.

Fort Lauderdale, Florida
June 22, 2018
8:58 a.m.

Transcript of Trial Proceedings had
before the Honorable William P. Dimitrouleas,
United States District Judge, and a Jury.

VOLUME 5

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THE COURT: Then he'll probably stay.
(Laughter)

MR. BEATON: So, at this time, the defense would call Carol Warfield to the stand.

THE COURT REPORTER: Please raise your right hand.

(CAROL WARFIELD, DEFENDANT'S WITNESS, WAS SWORN)

THE COURT REPORTER: Please sit down. Please get right behind that microphone and state your full name for the record, spelling your last name.

THE WITNESS: Carol Warfield, W-A-R-F-I-E-L-D.

DIRECT EXAMINATION
BY MR. BEATON:

Q. Dr. Warfield, good morning.

A. Good morning.

Q. Can you please introduce yourself to the ladies and gentlemen of the jury.

A. Yes. I'm Carol Warfield.

Q. And what do you do for a living, Dr. Warfield?

A. I'm a professor at -- an endowed professor at Harvard Medical School. I teach pain management nationally, internationally, and I run the Harvard Medical School pain management course and teach -- do a lot of teaching and have written textbooks on pain medicine.

Q. And so, before we get further into your background, was I -- was the defense the first party to hire you in this case?

A. Uhm, no, Mr. Gilfarb called me and hired me.

Q. Okay. And as part of the work that you were doing without telling me what you all discussed, but as part of the work that you were doing for the prosecution team, did you review certain records?

A. Yes. Mr. Gilfarb asked me to review medical records regarding Dr. Mencia's practice. And I did.

Q. And did you also review some videos?

A. Yes, I did.

Q. Okay. And did you then render an opinion?

A. Yes. I spoke with Mr. Gilfarb and his colleague over the phone and told them what my opinion was based on those medical records and videos that I had reviewed.

Q. Dr. Warfield, when did you first learn that you would not be called as a witness by the government?

A. Uhm, I think it was last week. And I think -- yeah, I think it was last week when I heard from you.

Q. So, did you learn from me that you weren't being called as a witness by the government?

A. Well, I -- as I said, I had several conversations with Mr. Gilfarb and his colleagues, and I thought I was coming to testify for the government.talk? And, uhm, then Mr. Beaton emailed me and said, Can we And I emailed him back, and I said, you know, I'm testifying for the pros -- for the government, so I'm not sure we should be talking. And I emailed Mr. Gilfarb, and I said, you know,
What's going on? Defense just tried to contact me.
And he called me, and he said, you know, You can speak to the defense, if you want to. If you don't want to, you don't have to. And I said -- I said, you know, Am I testifying for you or not? And he said, Well, you know, at this point, I'm not sure. And I said, Well, you know, what is it? And he said, No, I don't think we're gonna call you.

So, I said, Okay. He said, You can talk to Mr. Beaton, but -- you can discuss with him what the opinion you had of the review of the medical records, but you can't discuss with him anything that we talked about with respect to my plans for the prosecution or for work product, they call it. But he said, If you want to talk to Mr. Beaton, you can talk to him and tell him what you told me. You can tell him what records you reviewed and what your opinion was. So, I did that.

Q. And you and I have never spoken about what Mr. Gilfarb asked you to do, or what the prosecution plan was, or what any of his theories were.

A. No. The only thing we talked about was what records I had reviewed and what my opinion was based on those records and videos that I had reviewed.

Q. Okay. So, Doctor, tell us a little bit about your education.

A. Uhm, I have undergraduate degrees in mathematics and mechanical engineering and an M.D. degree from Tufts University in Boston. I then trained in medicine and surgery doing an internship. And I did an anesthesia residency at Massachusetts General Hospital in Boston. And did a fellowship at the Beth Israel Hospital in Boston. And in 1980, I started the Pain Management Center at Harvard Medical School at Beth Israel Hospital. And subsequently was a pain specialist and ran the pain management center. I was the director of the Pain Management Center there for a number of years. And in 2000 became chairman of the Department of Anesthesia, Critical Care, and Pain Medicine at Beth Israel at Harvard, which encompassed not only pain medicine, but also the operating room and all of the intensive care units.

And during that time, I continued to see patients in the pain center. And subsequently stepped down from that, continued to see patients in the pain center until a few years ago when I stopped seeing patients, but I have continued on as a full professor at Harvard. I have an endowed professorship, the Lowenstein Distinguished Professor of Anesthesia at Harvard Medical School. And I continue in that capacity to teach, to write textbooks, to lecture, and I'm involved administratively in a number of committees and such at Harvard Medical School. I just stopped seeing patients in the Pain Management Center a few years ago.

Q. What is the name of the Pain Management Center at Harvard
Medical School?

A. It's the Arnold Warfield Pain Management Center.

Q. Is it named in part after you?

A. Yes.

Q. You said that you have written -- you've authored some textbooks. Tell the jury what textbooks you have authored.

A. I've authored a number of textbooks on pain medicine, which are widely used by residents and fellows who are in training to become pain doctors. I think the first one was called – the pain -- just *Pain Management,* and that was published by Lippincott, I believe, and that came out in two or three editions, was translated into several languages. The second one is *Principles and Practice of Pain Medicine,* which is a large textbook -- the first one was meant mainly for internal medicine doctors and doctors who weren't pain specialists. The second one was more of a textbook for doctors who wanted to be pain specialists called *Principles and Practice*

THE COURT REPORTER: I'm sorry.

A. I'm sorry. I'm from Boston. I talk too fast. *Principles and Practice of Pain Medicine,* published by McGraw-Hill. And that was translated into many languages, I think Spanish, Chinese, Italian, and is in the third edition this past year. And has we just published is very widely used by doctors training to be pain doctors today.

Q. So, you literally wrote the book on pain management.

A. You could say that.

Q. And the textbook that you have authored is being used to teach students who are aspiring to be physicians how pain management should be done.

A. Correct. And doctors in training -- I mean and doctors who are practicing pain medicine often have a copy of that textbook to refer to.

Q. Okay. How long have you practiced and taught pain medicine?

A. Over 40 years.

Q. And have you testified before in court?

A. Yes.

Q. And have you been admitted as an expert in courts in the Southern District of Florida?

A. Yes.

MR. BEATON: Your Honor, at this time, we would tender Dr. Warfield as an expert in the area of pain management and the standards of care associated with that practice.

MR. GILFARB: I object. The standards of care are not relevant. It's to opine on the opinion of whether something is or is not within the scope of professional practice.

THE COURT: Well, I'll allow her to testify. You may proceed.

BY MR. BEATON:

Q. Dr. Warfield, based on your review of the videos in this case and the records that you reviewed, what was your opinion about whether what you saw led you to the opinion of whether Dr. Mencia was acting as a medical doctor?

A. I felt that Dr. Mencia was acting as a medical doctor in his practice.

Q. And is that the finding that you communicated to the prosecution team?

A. Yes. I communicated to Mr. Gilfarb and his colleagues that, uhm, I felt -- you know, and there were many different pieces of this, but basically felt that this was a medical practice, and that what he was doing was in the usual course of medical practice, and that I had concerns about his – his signing the blank prescriptions.

Q. And explain to the members of the jury your view on treating pain patients without a physical examination.

A. Well, you know, I think just to preface this by saying that -- that there within medicine, and when we look at a doctor's practice, we try and determine if what the

doctor is doing is within the standard of care. And there are lots of different practices that are within the standard of care when it comes to pain medicine. There are some doctors who say, you know, I think these are the best pain relievers we have. I'm not gonna deny my patients these drugs, and I'm gonna provide them for a lot of my patients who have severe pain that can't be treated otherwise. And there are other doctors who say, I'm never gonna prescribe these drugs, because I think they're dangerous, and I'm afraid that I'm gonna end up in jail if I provide these drugs; I'm afraid of sanctions. Lots of doctors have ended up in jail by prescribing these drugs, and they won't prescribe them. And I think all of that's within the standard of care. And in medicine today, there's a lot of controversy still about the right way to do this. Should you prescribe these drugs to people who don't have cancer? Should you not? Is it legal? Is it illegal? What's the right way to do it? And there are lots and lots of different ways of doing it. There's my way of doing it, there's Dr. Silverman's way of doing it, and then there are millions of other ways of doing it, many of which are within the standard of care. There are -- easily are some that are outside of the standard of care. But there's still -- there's really no consensus as to how to do this. And, you know, within the standard of care, there's the best possible practice, that's, you know

MR. GILFARB: Objection, your Honor. Based upon the memorandum that we submitted to the Court, this is irrelevant.

THE COURT: Overrule.

A. But, you know, the -- within the standard of care, there's the best possible practice. You know, you dot every I, you cross every T, you do every exact thing that you're told to do. And everybody aspires to that, but, you

know, not everybody does that. Then there's kind of your average practice, which your average doctor does. You know, they maybe don't do everything perfectly. And then there's, you know, not so great practice doctor, probably makes some mistakes, but maybe you still consider it within the standard of care. Then there's outside of the standard of care. That's a doctor who makes a mistake. That's what malpractice is. It's outside of the standard of care.

MR. GILFARB: Objection. She is not a legal expert, your Honor, and I object to her drawing legal conclusions.

THE COURT: Okay. **I'll** allow some latitude. Overrule.

A. So, something that's considered outside of the standard of care that's negligent and, you know, something that -- or a patient gets injured. That's considered malpractice. So, things like, you know, if a surgeon leaves a sponge in somebody's abdomen, that's outside of the standard of care, but that doctor is still practicing medicine. That's not outside the usual course of medical practice. That surgeon was practicing medicine when he did the surgery. He wasn't selling drugs, he wasn't doing something illegal, but he made a mistake.

I mean a doctor who does an injection on a wrong side, he makes a mistake. That's outside of the standard of care, but it's not outside the usual course of medical practice. He doesn't go to jail for that. He may get sanctioned by the Board of Registration in Medicine, he may get a finding in a malpractice case, but doctors don't go to jail because they weren't practicing within the standard of care, they were doing something wrong. And, you know, sometimes doctors do something wrong

because they just plain made a mistake. Sometimes they do

something wrong because they just didn't have the right information. Maybe they didn't go to the lecture, or maybe they didn't read the book, or maybe they didn't read the instructions, or whatever, and they do something wrong. Sometimes it's just a lack of knowledge. You know, sometimes it's a mistake where, you know, instead of prescribing ten milligrams of something, they add a zero and prescribe a hundred milligrams, and somebody dies. I mean those are all mistakes, but those doctors are all practicing medicine. They don't go to jail for that. They may get sanctioned, there may be malpractice, there may be Board of Registration may sanction them by fining them or the making them do community service or something like that, or even taking their license away.
Outside the usual course of medical practice means the doctor is no longer practicing medicine. They're -- they're selling drugs. They're doing something illegal. They're criminals. So

MR. GILFARB: Your Honor, I would just like the Court to note my continuing objection to the use of the term "drug dealing," "criminal," or anything like that.

THE COURT: Overruled.

A. So, that's what outside the usual course of medical practice is. You know, if someone came up to me at a cocktail party and said, "Hey, Doctor, would you write me a prescription for some opiates," and I said, "Oh, sure, here's a prescription," I'm not practicing medicine there. Or if a patient comes into my office and says, "You know, I don't really have any pain, but if I slip you a couple of thousand dollar bills will you write me a prescription for oxycodone, because I like it to get high," that's outside the usual course.

Or if I -- you know, if I trade sex for drugs, or something like -- I'm no longer practicing medicine. I'm not writing these prescriptions because I think I'm doing the patient some good by providing them pain treatment. Those things are all outside the usual course of medical practice.

Q. And, Doctor, can you explain to the jury the difficulty in treating the population that makes up patients in the pain management area?

A. Well, they're very, very difficult to treat. Especially the patients who aren't insured, especially the patients for whom there isn't a good, easy way to treat pain. Remember, if you have back pain, and you go to your internist, and they do an MRI, and it shows a big bulge, they're gonna send you to a surgeon and fix it, and that will be that. You'll never end up in a pain clinic. It's the patients who go and have that MRI, and the MRI shows nothing, and they still have this severe pain. And the internist tries some things, and they don't work. Those are the people who end up in our pain clinics. The easy ones never make it to a pain clinic. They get treated
by other doctors. So, the ones who end up in pain clinics often are patients who have pain that's intractable. There's no nothing we can do to treat that pain. There's no surgery that's indicated to take care of that back pain. There's nothing -- there's nothing else that's gonna treat it. The pain is intractable. So, we are asked what we can do to treat the patient. And there are a number of things that we might do, depending on the pain clinic. There are some pain clinics that just do injections. There are some pain clinics that just prescribe opioids. There are some pain clinics that just do acupuncture, and some of them just do massage therapy. You know, all of those are within the standard of care. You can do that in different pain clinics. But we often have these patients who are very, very difficult to treat and, you know,

very little -- very little treats them. The other problem is that in the current climate of you know, there are lots of people out there overdosing, and there are lots of doctors being sanctioned and doctors ending up in jail for prescribing drugs that a patient takes home and shoots up and dies. Lots of doctors have just said -- and I think Dr. Silverman mentioned this too -- they're just not gonna do this. They're not gonna prescribe opiates anymore. Even a lot of pain clinics won't prescribe opiates anymore. They just say, you know, We don't want -- this isn't worth it to us. We're not gonna prescribe these drugs. And, of course, what's gonna happen is people who really need these drugs aren't gonna be able to get them eventually, because the doctors aren't gonna be willing to prescribe them. And so, it becomes harder and harder and harder for these patients who truly need drugs to get them. I mean, are there patients who are bad actors and who are faking the pain and selling the drugs and taking the drugs to get high? Sure. I've had patients like that. Anyone who does this enough gets fooled, because these fakers get really, really good at what they do. Because they make -- you know, they make a lot of money selling these drugs, and they have a lot of incentive to get really good at lying. So, you know, yes, we all understand that, you know, if you're a pain doctor, and you do this long enough, you're gonna have patients who lie to you and fool you, and they're gonna end up getting drugs from you. But the alternative is, you never prescribe these drugs. And so, there are patients left in horrible pain who can't get these drugs.

Q. And so -- tell the jury a little bit more about that last subject that you were talking about in terms of, you know, who is faking, who isn't a real patient.

A. You know, there have actually been scientific professional studies looking at this, where they've brought in fakers and they've brought in real patients to see if they

can -- if there really are doctors who can tell the difference. You can't. You can't tell. Remember, anybody who's getting these drugs to sell, they can get, you know, $80 for an 80 milligram Oxycontin tablet. It's big, big money. And, you know, some of these drug -- drug lords, or whatever you want to call them, you know, train people in how to go in, how to fake, what to say to the doctor, how to fake the physical exam, how to fake a urine drug screen and there are lots of ways to do that -- how to get the drugs, you know, the whole nine yards. And so, most of the doctors I know who have been doing this for long enough have been fooled by these patients. And as I said, the scientific studies show there's absolutely no foolproof way to tell if a patient is faking or not.

Q. And -- so, if you can, talk a little bit about what in the practice is referred to as the "continuum of care." And let the ladies and gentlemen of the jury know what that is.

A. Well, "continuum of care" just means you continue to care for those patients with -- you know, with what they need. I mean you may start with a dose of medication, or you may start with a different medication, or whatever, and you continue to treat them and change the medication up or down, or add medications, or whatever, or add different treatments, depending on the patient and depending on what's needed.

Q. What I'm let me see if I can perhaps ask it a little bit differently. I mean some physicians never prescribe opioids?

A. Right.

Q. And some choose alternatives to opioid therapy.

A. Oh, okay.

Q. So, that's kind of what I was getting at in terms of the continuum of care.

A. Within the standard of care. Yeah, and I think I

mentioned, there are doctors who never prescribe opiates. There are doctors who prescribe opiates to almost all of their severe pain patients who come to see them. And then there's everybody in between. So, in the middle, there are lots of doctors who prescribe for some patients, but they don't prescribe for other patients. Again, there are some people who just use acupuncture. There are some people who just use injections. There are lots of pain clinics now that will just do injection treatments, and they refuse to prescribe any of these medications because of the sanctions that have been going on. So, there are lots and lots of different ways of doing this. You know, medicine's an art. And, you know, as Dr. Silverman said, there are, you know, different ways that doctors might do it. You might be asked for a second opinion. And, you know, it's not you're saying that doctor was wrong, he shouldn't have done that. You're saying, Well, you know, here's another way we could do this, here's another way of looking at this. You know, maybe instead of using this injection, we could try the opiates. Or, you know, maybe instead of thinking that he has a bulging disc, maybe we think it's the joints in his back that's causing the problem. You know, we're not saying that other doctor was wrong, or outside of the standard of care, or, God forbid, you know, a criminal. We're saying there are different ways of doing this. And if you look in the guidelines that are out there, the guidelines are specifically purposely loose to include all of these things. They don't say you have to do an exam that includes this, this, this, and this. You have to do this. If a urine drug screen shows cocaine, you can never -- you can never prescribe again. If a patient says they bought drugs off the street, you must never prescribe. You'll never find a guideline that says that. Because there are lots of different ways of doing this. And as long as the doctor is well intentioned in doing this, the

doctor is not doing something that's outside the usual course of medical practice. As long as what they're trying to do is treat these patients in their way, that's not -- it's not something that's criminal.

Q. I think you were in the courtroom when I asked – I discussed with Dr. Silverman the patient Bill of Rights and that patients were entitled to integrity no matter what form of payment they had. Talk to the jury about the role that cash payments play in pain management practices and why those type of patients often pay with cash.

A. And this -- and this often comes up. You'll never see in a guideline saying if a patient pays by cash, you shouldn't give them opiates. I mean it's nuts. You'll never see that. No matter how a patient pays, they should be treated the same. Whether they have insurance, whether they have great insurance, whether they have lousy insurance, or they have no insurance at all, they are they're -- they're all treated the same. And, of course, many of these patients who have severe pain, you know, have been to their internist and nothing has helped, oftentimes they're out of work, oftentimes they're -or they have some sort of job that doesn't provide them with insurance, and so a lot of these patients end up with no insurance and end up paying cash. And, again, you'll never find anything that says if a patient pays cash, they're a bad person, and they're a drug addict. It's ridiculous.

Q. Do these patients often pay cash because of a lack of insurance?

A. Exactly.

Q. Do you understand Workers' Compensation to be a form of insurance?

A. Yes.

Q. So, there's an interesting term in your field called "pseudoaddiction." What does that mean?

A. Well, it is an interesting term. "Pseudoaddiction" means if a patient exhibits behaviors that used to be thought to be indicative of addiction, they may not be addicted at all. They may just be in pain. And I'll give you an example. It used to be that we thought that if a patient said -- you know, you've had some surgery or whatever, and the patient said, "You know, Doctor, I had -- you know, I had five knee surgeries before, and the only thing that helped me for the fourth and fifth surgery was Percocet. You know, they tried different things with me. Nothing else helped except Percocet." They used to say, Oh, this guy must be addicted, because he's asking for Percocet. Or if the patient says, "You know, you gave me the five milligram Percocet tablets, and they're just not doing anything at all, I think I need a higher dose." People would say, Oh, this person must be addicted, because they're asking for twice the dose. No. We now call that pseudoaddiction. What that means is the patient is just in pain. And the patient is right. Maybe the drug they got before didn't work for them. Because, you know, there are a lot of individual variation among people in terms of what drugs work, what doses work. And the patient could actually -- you know, the patient probably is telling you the truth. The Motrin or whatever they gave them for their first, second, and third surgeries didn't help them, but the Percocet did. And he didn't do well with five milligrams. He really needs ten milligrams. So, that patient's not addicted. They're not asking for those extra doses or extra drugs or that particular drug because they're a drug addict; they're asking them for them because they're in pain, and they need more pain medicine. And, remember -- you probably talked about pain in general over the course of this trial, but there's a big difference in how much pain medicine you all here – sitting here will require. I mean I might need 20

milligrams of oxycodone to help my knee pain. You may only need five. There's a big difference whether you're opioid naive or not, there's a big difference in what people need and what their opiate needs are. And so, you know, if a patient says, "What I needed in the past was ten milligrams of Percocet to help this pain," you know, we believe them. They're probably right. That's probably exactly what they needed. And that helped them during the last knee surgery, so that's what we're gonna give them.

Q. And so, questions about what a patient has used in the past and what has worked in the past are important questions for a doctor to ask.

A. Yes, certainly.

Q. And that brings me to the subject of dosing and something called "dose escalation." Can you talk to the jury about that?

A. Well, again, we start with a dose of a drug, and it may be the dose the patient said worked for them in the past, it may be a dose the doctor picks because the doctor has had good success with that dose, but you try that, and the patient may come back and say, "You know, that didn't help me at all. In fact, I had to take two of them." Or, "It didn't help me at all. Can I get more this time?" And the doctor -- and that's what the doctor does. The doctor's job is to determine what the right dose is. So, maybe they go up. Maybe the patient comes back and says, "You know, that dose you gave me, it helped the pain, but I was throwing up all day, and I couldn't even get out of bed." Well, then, maybe the doctor goes down on the dose. Or the patient says, "You know, so I tried taking half of the Percocet, and that seemed to work really well." It's called "titration." You increase the dose or decrease the dose depending on whether the medicine helps the pain and whether the patient is having side effects. So, you may increase the dose

and sometimes the patients increase these doses themselves. They're not supposed to do that, but it's not uncommon.

Q. Did you reach an opinion about whether it's appropriate for a doctor to -- without first suggesting alternative treatments and without first prescribing medications less potent than oxycodone, to prescribe oxycodone?

A. It very much depends on the individual's situation. If a patient had been taking the oxycodone, and that's what helped them, then it's perfectly reasonable to prescribe the
oxycodone. It's like the patient comes in and says, "You know, I tried Motrin in the past. It didn't help me. I'm not gonna try that again." They say, "The thing that helps me is the oxycodone in this particular number of milligrams." Then that's probably the appropriate treatment to use. And, again, all -- many, many doctors would do it differently. Some doctor might say, "Well, you know, before I write you this oxycodone, I'm gonna suggest you go try acupuncture." That's fine. But it's also fine not to do that. Some doctor might say, "You know, before I prescribe this, I'm gonna suggest that you go get massage therapy, or you try some over the counter, you know, rub or something." There may be different things that you can try. But -- and that's okay, but it's also okay for the doctor not to suggest those and to prescribe the drug that had helped the patient.

Q. Is it always the case, sometimes the case, never the case that a doctor can continue to prescribe oxycodone or a similar drug to folks that may even be addicted to the prescription?

A. It's sometimes the case, for a couple of reasons. And there are actually many reasons. First of all, when

somebody says "addicted," it's very, very confusing. Uhm, addiction is a psychiatric diagnosis. It's the insatiable craving that these drug addicts have to get the drug. The drug is interfering with their lives. That's addiction. Drug dependence is a very different thing. That means that if I give any of you enough opiate for a long enough period of time, and I suddenly stop it, you're gonna go through a withdrawal phenomenon. You're dependent on that opiate. You're not necessarily addicted, but you're dependent. Your body depends on it. Oftentimes, when people say, "I'm addicted," what they mean is they're dependent. What they mean is they've been on it, they have to keep taking it, or they're gonna withdraw. They're not addicted. I'll gave you some examples. We've had patients who've come in, for example, who've been on these opiates for years even, because they have some horrible pain, and they're sent to the pain clinic in the hopes that we can do some kind of injection to take the pain away. So, we do an injection, and the pain goes away, and we say, "Now, Mrs. Jones, when you go home today, don't stop taking that morphine, because if you stop taking it, you're gonna have a withdrawal." And Mrs. Jones is so happy not to have to take this awful medicine that was making her throw up every night, she stops it, and she withdraws. She's not addicted; she's dependent. You can be addicted after one dose of heroin. You're not dependent. You're not gonna withdraw if you don't have the second dose of heroin. But you are addicted. It's a psychological craving. So, these two terms are very often misinterpreted or mis -- or confused. So, when you say is it okay to prescribe to someone who's addicted, first of all, that person may not be addicted; they may be dependent. Secondly, someone who is addicted can

also have severe pain and need pain medication. You will not see any guidelines that say if a patient is addicted, you may never give them opiates. Because, again, someone who's a drug addict may need these medications. We see patients who are heroin addicts, who are in car accidents, who end up in the emergency room and have to come to the operating room, what do we do stop the heroin? Of course not. We give them more, because they're tolerant. They need more. So, we give them more medication. And if that person has had a terrible accident and terrible pain, we'll probably continue to treat them with those drugs, maybe for many, many months, maybe for years. You know, are they drug addicts? Yes. Do they need those medications? Probably. So, there's no rule or law that says if you're addicted, you must never get these drugs. Now, again, I said sometimes it's okay. Because, you know, typically, you know, you think of someone who's an addict, and they're just taking the medication to get high. Well, no, then you don't prescribe in those situations. But remember, people who are addicted -and there are a lot of them out there these days -- have pain too. So, sometimes it is appropriate to give these drugs to people who are addicted.

Q. And what about, for example, the presence of -- let me say marijuana in somebody's urine?

A. Yep.

Q. How does that affect the decision-making process or what needs to be done?

A. Well, again, lots of doctors do it differently. And it's all -- you know, it's all -- it all can be okay. There are some doctors who won't do urine tests for marijuana, because they don't want to know. Don't ask, don't tell. They don't want to know. Because they think it's okay if a patient has terrible nausea from the opiates that they're taking and that they need for their pain, and they need some

marijuana to take away the nausea. Sure, let them have it. And there are others who say, No -- you know, before it was legal, before it was even medically legal, doctors would say, No, you know, that's against the law. If someone has it in their urine, I'm not gonna ever give it to them again.
So, again, I think there are many, many different ways of doing it. There's very little out there to indicate that it's dangerous in terms of -- in terms of combining it with the opiates, compared to other drugs that get combined with opiates to treat -- you know, to sedate people, to treat nausea, and such. So, it very much depends on the doctor's practice. And I would not say it's outside the usual course of medical practice to continue opiates in patients -- someone who tested positive for marijuana.

Q. Doctor, what is your opinion about whether a doctor can who's initially consulted with a patient, can delegate some of his or her seeing of the patient, provided that there's been an initial visit?

A. You're talking about delegating to a nurse or –

Q. Medical assistant.

A. A medical assistant. Again, medical assistants are a perfectly reasonable group to use for gathering information. They -- they shouldn't be making decisions about patients' care. They're not qualified to do that.
So, for example, if a doctor in a busy office wants to have a medical assistant ask the patient, you know, how's your pain, can you rate your pain on a scale of zero to ten, have you had any side effects, are you nauseated, is the pain going away, are there any problems? That's fine. They can ask those questions, and then they can go back and report to the doctor what the -- what the issues were. And it's up to the doctor ultimately to make -- to make a medical decision about the patient. So, I mean to use them as

practice extenders or whatever you want to call them -- they're not licensed, they're not -- they're not able to make decisions like nurse practitioners or physicians' assistants, but their job really is to gather information, you know, what's the blood pressure, what's -- that sort of thing.

Q. So, as long as the physician exercises some measure of judgment, what is your opinion as to delegating some of the information gathering and duties regarding patient care in pain management?

A. Again, it's okay as an information gatherer. It's okay -you know, I'm sure you've looked at the guidelines. There's no regulation saying that every time a patient comes for opiate prescription, they have to see the doctor. There's no regulation for that. The regulations basically say periodically -- and, again, nobody generally defines that -- you know, periodically, at given intervals or whatever, the doctor should see the patient. But, you know, you can't prescribe refills for opiates. So, you know, sometimes what happens is the patient comes back to the office every month to pick up a prescription, doesn't necessarily see the doctor, and that's okay. Sometimes they come back, and they can see the nurse, or see someone else, and they -- they're checked they get checked. If everything's okay, the doctor says, you know, "Everything's okay, you can give the patient the prescription." That's okay. That's never okay on a first visit. On a first visit, the patient has to see -- it's the doctor who has to decide this drug is okay for this patient.

Q. It is never okay for a medical assistant to lock themselves in a room with a patient, see the patient on their own, and make medical decisions about what that patient's care should be, whether it's in the pain

management field or probably in any other field.

A. Correct. They can't practice medicine. They can't make any decisions. They can really just gather information and do what the doctor has instructed them to do.

Q. So, getting back to the population of patients, patients in pain management practice, for example, will often miss appointments. Is that common?

A. Yes.

Q. And why is that common?

A. Well, I think, you know, all of you have probably been in similar situations things comes up, you miss an appointment, they forget about the appointment, they don't get a ride, they can't drive because of their pain, their ride calls in sick, they get sick, the baby's sick. I mean, you know how that goes. So, patients -- patients miss appointments. It happens.

Q. Is it also because this subset of patients also at times have medical, psychological, financial, social -- I mean all sorts of other issues?

A. All kinds of things can happen. Yeah.

Q. And so, physicians in your practice can treat that sort of one of two ways. And what are those two ways?

A. You continue to prescribe or you don't.

Q. So, you can either fire the patient or keep the patient.

A. Correct. And it's a judgment call on the part of the doctor. I mean I wouldn't -- personally I wouldn't fire a patient because they missed an appointment if they had a reason for missing the appointment.

Q. What about sort of misdocumentation in the patient file? What does that tell you about --

A. Well, you know, I mentioned, you know, in the ivory towers, in the perfect -- best possible practice, we like

to have every bit of information in the chart. But, you know, it happens that it's not always there. Uhm, in terms of old medical records, it's pretty common not to have them. In fact, I rarely ask for old medical records. It's very, very difficult to obtain them. And, you know, as I was trained, and I train our own doctors, if you ask the patient a question, you believe what they tell you. If they said, "I was in a car accident in 1975, and I broke my back," I don't ask for the medical records from 1975 to see if they really broke their back. Or they say, you know, "I have a history of high blood pressure, and I have this, and I have that," I don't say, Ah-ha, I better call for the cardiologist you saw five years ago and who diagnosed that. We believe the patient. You need to have a doctor-patient trust relationship going on. So, if the patient says, uhm, "I'm -- I had an MRI, and here's what it showed, I've been on this medication for so long, my pain is a nine out of ten, I have pain going into my toes," I believe them. I don't say, I need to get information to document that. And then, you know, on the other side of documentation, I don't write down everything the patient tells me. You couldn't possibly do that. When you have a conversation with the patient, we write down what we feel is important. And often some doctors just write down the positive findings. They may not even write down negative findings. So, you document, and in a perfect world, you document everything that happened between you and the patient, and you'd have all those other records. But that doesn't happen.

Q. And so, Dr. Warfield, what is your opinion about whether doctors and the training that they receive, whether in pain management or in other areas, are trained as healers or truth seekers and lie detectors?

A. We're trained to believe the patient and treat the patient. And, you know, I'll go back to the situation where,

you know, you have back pain, you go to your internist, they do an MRI, and it's negative. What do you do in that situation? Do you say, Your MRI's negative, you don't have pain, tough luck? No, that's not what we're trained to do. We say, Your MRI is negative, but, you know, lots of people have severe pain despite the fact that they have a negative MRI. And for lots of people, we never find exactly what causes the pain. But I believe you. I believe you have this severe pain, and here's what we can do to treat the pain. I'm not trained as a detective to try and catch them in a lie or to -- or to find out, as I said, you know, whether they really were you really in a car accident ten years ago? Let me get the police records and see if that really happened. That's not -- it's not what we do. Our job is to do what we can do in good faith to try to help and patient, to treat them.

MR. BEATON: Judge, I know it's five minutes early, but is this is a good time to break in terms of subject matter?

THE COURT: Okay. All right. Members of the jury, we're going to go ahead and recess for lunch. Remember my admonition not to discuss the case or allow it to be discussed in your presence. And I'm gonna ask you to come back at 1:15. So have a nice lunch. We'll see you back at 1:15.

COURTROOM SECURITY OFFICER: All rise.

(The jury exited the courtroom)

THE COURT: Dr. Warfield, during the break in your testimony, you're not allowed to discuss your testimony with anyone. Do you understand?

THE WITNESS: Yes.

THE COURT: And we'll see you back at 1:15.

THE WITNESS: Thank you.

THE COURT: Mr. Beaton, how much longer do you think your direct is going to be?

MR. BEATON: Mr. Gilfarb was just asking me. I expect that it should be maybe another 30 minutes to 40 minutes.

THE COURT: All right. I just want to make sure we get done with Dr. Warfield today.

MR. BEATON: Yeah, we will, for sure. She has to leave today.

THE COURT: That's why I want to make sure we get done

MR. GILFARB: And we're working till five?

THE COURT: Yes.

MR. GILFARB: All right. Then I'm gonna get another witness here, Judge.

THE COURT: Okay. And we'll be in recess until 1:15.

COURTROOM SECURITY OFFICER: All rise.

(The Judge exited the courtroom)

(Luncheon recess taken) 11:56 a.m.).

THE COURT: Please be seated.

All right. We're back on the record.

I guess we're waiting for Dr. Mencia?

MR. BEATON: I think he's using the restroom, yes, So, I told Mr. Gilfarb I think I'm only gonna be like five more minutes. I'm not gonna be that long with her.

THE COURT: Okay.

MR. GILFARB: Our next -- I don't know how long my cross is gonna be, I guess that depends. But our next witness will be here at 2:15.

THE COURT: Okay.

MR. BEATON: But I have made no promises.

(Laughter)

MR. BEATON: My five minutes might be ....

THE COURT: Okay.

(Pause)

THE COURT: All right. We're back on the record. Counsel are present. Dr. Mencia's present. Dr. Warfield, do you understand you're still under

THE WITNESS: Yes, your Honor.

THE COURT: Anything to come before the Court before we bring the jury in?

MR. GILFARB: Not from the government.

MR. BEATON: Not on behalf of the defense, your Honor.

THE COURT: All right. If we have all the jurors, let's bring them in.

COURTROOM SECURITY OFFICER: All rise.

(The jury entered the courtroom)

THE COURT: Counsel concede the presence of the jury and waive its polling?

MR. GILFARB: Yes.

MR. BEATON: Yes, sir.

THE COURT: And did everyone follow my admonition not to discuss the case or allow it to be discussed in your presence?

THE JURORS: Yes, your Honor.

THE COURT: All right, Mr. Beaton, you may continue.

MR. BEATON: Thank you.

DIRECT EXAMINATION (CONTINUED)

BY MR. BEATON:

Q. Good afternoon, Dr. Warfield.

A. Good afternoon.

Q. So, what documents did you review related to this

case on which you based your opinion? Or what records and documents did you review?

A. I reviewed the records of patients Vega, Hernandez, Morales, Erickson, Garcia, Becho, Hewett, and Barfield. And let's see. I also reviewed the medical records of 28 other patients. Was I was given -- I reviewed the CMS – the Medicare records for Dr. Mencia, reviewed the tapes and transcripts of the office visits of Medical Assistant Sampath and Ventura, and the videos of those and the transcripts, and the video of Dr. Mencia seeing patients.

Q. Okay. How many videos with regards to Dr. Mencia did you review?

A. Sorry. Let's see ... the first visit had two tapes. The second visit had two tapes. The third visit had it looks like three tapes. The fourth visit, two; the fifth visit, three; and the sixth visit, three.

Q. And based on your review of these records and these recordings, was it your opinion that Dr. Mencia was acting like a physician for legitimate medical purposes?

A. Yes. I thought he was acting like a physician in the usual course of practice. He wasn't doing things the way I would have necessarily done them, but I think this was a medical practice, and he was acting as a physician within the medical practice.

Q. So, you told us earlier that one of the things that you saw that concerned you was the presigning of prescriptions.

A. Correct.

Q. And we talked a little bit -- a little while ago about civil cases versus criminal cases and medical malpractice versus, for example, criminal liability.

A. Yes.

Q. Do you remember that discussion?

A. Yes.

Q. And am I correct in summarizing your testimony by saying that falling below the standard of care and making mistakes doesn't necessarily rise to the level of criminal conduct in your opinion?

A. Correct. It usually doesn't.

Q. Okay. And I'm gonna show you a statute quickly. And those mistakes that fall below the standard of care and don't rise to the level of criminal conduct are usually handled by disciplinary bodies within the states where physicians are licensed and privileged to practice.

A. Yes. Usually, it's a malpractice case or it's a civil case. If someone's harmed, the doctor gets sued, and the doctor or insurance company has to pay a settlement or a fine or something. Or the Board of Registration -- and/or the Board of Registration in Medicine gets wind of that sort of thing, especially if there are multiple times when the same kind of practice happens, and the Board of Registration reviews that physician's practice. And sometimes they sanction them with probation or with requiring remediation, requiring they go to CME courses, or attend things, or read things, or fines, or, at the worst, they take their license away. So, those are the kinds of things that usually happen to a doctor way before there's consideration that this is something that's criminal and they should go to jail for the rest of their lives.

. BEATON: Fran, can I trouble you? ELMO, please?

THE COURT REPORTER: It is on.

MR. BEATON: I'm sorry, the computer. Wrong thing. It takes a second. Brad, did you highlight those sections?

MR. HORENSTEIN: Yes.

BY MR. BEATON:

Q. So, Dr. Warfield, I am showing you Florida Statute 458.331, and will you agree with me that the title of the statute is "Grounds for Disciplinary Action; Action by the Board and Department"?

A. Correct.

MR. BEATON: And, Christie, can you scroll down, please? Actually, Christie, go back to the top. I want to read the very first line of the statute.

BY MR. BEATON:

Q. So, you see in this next line that's not highlighted, Subparagraph 1, it says: "The following acts constitute grounds for denial of a license or disciplinary action," as specified in another statute.

A. Correct.

Q. And portion?

MR. BEATON: Now can you go down to the highlighted

BY MR. BEATON:

Q. So, you see as one of the things that is subject to disciplinary action and/or board consideration, including, you know, discipline or license revocation, is presigning blank prescription forms.

A. Yeah, I do. I see that now.

Q. And do you understand that to mean that presigning blank prescription forms, although obviously of concern to you and to the Board of Medicine, is the kind of mistake that Florida has disciplinary versus criminal liability for?

A. I do. I see that now.
MR. GILFARB: Objection.
THE COURT: Sustain.

BY MR. BEATON:
Q. Dr. Warfield, was it your opinion when you were hired by the government and is it your opinion today that Dr. Mencia in what you reviewed was acting like a doctor?
MR. GILFARB: Objection. Asked and answered.
THE COURT: I'll allow it one more time.
A. Yes. It's my opinion that he was acting like a doctor.
Q. In the course of usual practice?
A. Yes.
Q. And for legitimate medical purposes.
A. Correct.
MR. BEATON: I have nothing further, your Honor.
THE COURT: Cross-examination.

CROSS-EXAMINATION

BY MR. GILFARB:
Q. Doctor, good afternoon.
A. Good afternoon.
Q. We've spoken on the telephone, but we've never met.
A. Correct.
Q. Certainly without any intended disrespect to the highly
selective process that you have gone through to reach your educational level and teaching level, you would agree that just because you went to or teach at Harvard, that that doesn't make you right on everything.

A. Sure.

Q. All right. That, uhm, people from Harvard make mistakes.

A. Yes, they do.

Q. As a matter of fact, sometimes it's a curse that you're from Harvard, because you hear, You're from Harvard?

A. Everyone can make mistakes.

Q. Right. As a matter of fact, Harvard is not the end-all, be-all on **all** authorities. So, for example, Yale Law School is ranked above Harvard, right?

A. I don't know.

Q. Now, you were asked some questions about whether you wrote the book on pain. I think that was counsel's phrase, that you wrote the book.

A. Yes.

Q. You wrote a book.

A. I wrote one of the very first textbooks on pain.

Q. But it's not -- but -- here's another one, Controlled Substances, Pain Management in Chronic -- you didn't write this one.

A. Never heard of it.

Q. Okay. So, there are other books.

A. Oh, sure.

Q. Oh, okay.

A. There are other books.

Q. So, the book you don't claim that it's the book, do you?

A. I claim that it's one of the most widely used textbooks around the world to teach people about pain.

Q. Well, certainly at Harvard.

A. No, no, around the world. It's been translated into many different languages. And the publisher, McGraw-Hill, has told me just in terms of the numbers --

Q. I'm sorry. Is it used at Harvard, was the question?

A. Oh, yes, it's used at Harvard. Yes.

Q. Where you teach.

A. Yes.

Q. I hated taking classes from teachers who were teaching me who wrote the book.

A. *(Laughter)*

Q. Now, you mentioned earlier that you have not been – strike that. When is the last time you operated a pain management clinic?

A. Operated it or saw patients in it?

Q. No, operated a pain management clinic.

A. Well, I would say between 19 -- let's see ... let me just get my dates correct here -- between 1980 and 2000, I was the director of the Pain Management Center. So, I operated the Pain Management Center. From 2000 until 2007, I was chief of the entire Department of Anesthesia, Critical Care and Pain Medicine at Harvard, at Beth Israel Deaconess, and so I oversaw the management of --

Q. I'm sorry. The question was -- and maybe I wasn't clear -we don't need a recitation of the resume -- when was the last time that you ran --

MR. BEATON: Judge, I'm gonna ask that the witness be allowed to finish her question.

THE COURT: You have to stop your question when I get an objection.

MR. BEATON: I object. I would ask that the witness be allowed --

THE COURT: If you weren't done with your answer, you can finish your answer, Doctor.

A. So, it was until 2007 that I actually oversaw the running of the pain clinic, in addition to the operating

rooms and intensive care units. And then I saw patients -- continued to see patients in the pain clinic, but didn't run the pain clinic per se, until 2013.

Q. So -- I'm sorry -- what is the year that you last ran a pain management clinic?

A. Well, again, I'm not sure what you mean by "run," but I oversaw it until 2007.

Q. Okay. So, you would agree that standards -- well, since 2007, you agree things can change in the field. You keep up to date on changes in the field, do you not?

A. Of course, of course.

Q. As a matter of fact, just recently I believe they added "gaming addiction"

A. Yes, I saw that.

Q. That just happened. That's a new thing that happened.

A. Yes. And I keep up with all those new things, even though I'm not running a pain clinic.

Q. Right. And I guess my point is, is that things changed since you last ran a clinic, correct?

A. Lots of things change, but you don't need to be running a pain --

Q. I'm sorry. My question -- I didn't ask you for the explanation. My question was: Things changed since you last ran a clinic.

MR. BEATON: Judge, I object. I ask that the witness be allowed to finish her answer.

THE COURT: Yes, you can finish your answer. You can answer yes or no, and then you can explain your answer.

THE WITNESS: Thank you, your Honor.

BY MR. GILFARB:

Q. Let me ask it again so that we're clear. Would you agree, yes or no, that things changed since you last ran a pain clinic?

A. Things changed since I last ran a pain clinic, but you don't have to run a pain clinic to know the things that changed.

Q. I didn't ask you that. My question was -- and you'll have all the opportunity you want to explain, if you feel you need to explain -- the answer is yes?

A. Things change, yes.

Q. And you are not licensed to practice medicine in the State of Florida.

A. No, in Massachusetts.

Q. Okay. You are not governed by the statutes that have been gone over here, yes, sir -- yes?

A. I'm not, but I'm familiar with them.

Q. I'm didn't ask you if you were familiar with them. I asked you if you were governed by them.

A. I'm not, but I'm familiar with them.

Q. Okay. And you do not have law enforcement experience.

A. That's correct.

Q. You -- because you were commenting about drug dealing. You have not worked in any capacity with the DEA?

A. I have not.

Q. The FBI?

A. I've worked with the FDA, but not the DEA.

Q. Okay. Well, how about drug dealing investigations with Miami Vice?

A. No, I have not worked with them, just the FDA.

Q. All right. If I understand your testimony, if a patient feels pain, then oxycodone may be appropriate.

A. Oh, I think that's a very much a generality, but if a patient feels pain, any kind of pain treatment might be appropriate.

Q. Oxycodone?

A. Including oxycodone.

Q. Okay. Is it true that if you have a severe diagnosis that is consist I'm sorry -- if you have a diagnosis that is consistent with severe pain, there's a legitimate medical purpose, end of discussion? Would you agree with that?

A. I don't understand what the question is.

Q. Well, do you agree with this statement: That if you have a -- if a person has a diagnosis that is consistent with severe pain, in your mind, there's a legitimate medical purpose in the distribution -- in the prescription of oxycodone.

A. I would say in general, but one has to individualize each
patient. I think in general that probably is true.

Q. Let's put that aside for a moment, because I want to talk to you about something that the defense brought up. We hired you, and we entered into a contract to consult, is that correct?

A. That's correct.

Q. And would you agree that your contract with us was formalized on May 1st, 2018?

A. It sounds about right.

Q. Do you need to review -- refresh your recollection?

A. No, I believe you. It was about

Q. And at that time, you, of course, had no idea that the next day we had formalized a contract with Dr. Silverman, did you?

A. No, I had no idea.

Q. You didn't know that.

A. No.

Q. And you, of course, did not know that whatever we were discussing, I was consulting with Dr. Silverman about.

A. I didn't know anything about that.

Q. Okay. And we were -- all this time we were paying you for your time -- well, when you submitted a bill. Correct?

A. I'm not sure I've been paid yet, but ....

Q. Okay. You intend to get paid?

A. Yes, I intend to get paid.

Q. All right. We're not paying for your testimony today, are we?

A. No. I'm being paid for the time away from my --

Q. All right. And experts deserve to be paid for their time.

A. Sure.

Q. All right. And your testimony on direct examination was that you fully thought that you were gonna come testify for the government until about a week ago when you were advised otherwise.

A. That was that's correct.

Q. And yet you testified on direct examination that your opinion is that Dr. Mencia acted within the scope of his professional responsibilities.

A. That's correct.

Q. And that's the testimony you think the government was gonna call you to give?

A. Well, as I said, when we had -- as you know, we had discussions about this, and I told you that I -- I thought

that his practice was within the usual course of medical practice. And I also told you that I had concerns about the unsigned prescriptions.

Q. And that's really the point I want to get to.

A. Could I finish? And I think I told you that I had concerns about that. Uhm, and, uhm, you never said, Well, you know, based on your opinion, we don't want to have you testify.

Q. Of course not.

A. I thought you wanted to have someone testify about their true opinion, not depending on what my opinion was.

Q. Sure, sure.

A. So, I assumed until last week that you were gonna call me. You never told me you weren't gonna call me. I cleared my schedule

MR. GILFARB: Your Honor, this is a yes or no question.

THE COURT: She's allowed to explain her answer. If you think it's unresponsive, when she's done, you can move to strike.

MR. GILFARB: All right.

BY MR. GILFARB:

Q. Are you done?

A. And with all due respect, I think Dr. Silverman elaborated on many of his questions without objection.

MR. GILFARB: Move to strike everything after "yes."

THE COURT: Denied.

BY MR. GILFARB:

Q. Now -- in fact, it wasn't just that you had some concerns about what the medical assistants -- 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?

A. I believe that --

MR. BEATON: I object, your Honor. Unless Mr. Gilfarb wants to become a witness, I move to strike that.

THE COURT: No, again, 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.

MR. BEATON: Okay.

A. I believe what I said was, I 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. I think -- I think that's pretty much what I said.

Q. Okay. And, uhm, you're -- I don't remember now, it's been a while, whether it was Dr. Silverman or yourself that were asked some questions about whether you're familiar with what a second opinion is?

A. I think that was Dr. Silverman.

Q. Okay. But you're aware of -- you know, patients go get second opinions.

A. Yes, correct.

Q. And then presumably the patient decides, right? The patient isn't forced into one thing or another. The patient gets a second opinion and they decide.

A. That's right.

Q. And the patient decides, presumably, based upon what they see in the doctor, what they know of the doctor, things of that nature, whether they have trust in the doctor?

A. I -- I -- I don't know what the patient uses to decide. But it's up to the patients.

Q. Have you ever been a patient?

A. Yes, I've been a patient. I don't think I've ever had a -got a second opinion personally.

Q. Okay.

A. So, I don't know what the patients are thinking, but second opinions are not uncommon in medicine.

Q. All right. So, would it be fair to say that you have never testified in any court that a doctor acted outside the scope of their professional practice when prescribing oxycodone for a complaint of pain?

A. Not specifically about prescribing oxycodone for a complaint of pain in a court. But I have rendered that opinion, that a doctor was outside the usual course of professional practice when prescribing oxycodone, because there are some doctors who are.

Q. Right. And, in fact, when you've been asked by the defense in those cases what your opinion was, you basically tell them, It's probably best that you don't call me, because this is my opinion.

A. I've never said, It's best that you not call me. I give my opinion. When I'm asked to give my opinion, I get medical records, I review the medical records, and based on those medical records, I will tell the attorney, no matter what side they're on, I think this doctor is practicing outside the usual course of medical practice, or I think this doctor is practicing within, or, you know, these are things he did that I think were within, these are things he did I think were not for a legitimate -- and I give my opinion. I have never said, You shouldn't call me.

Q. All right. We'll return to that in a moment. Would you agree that if someone comes to your office, and they sit

down, and they say, "Give me a prescription for oxycodone or Oxycontin," and then it's just written for them, and you never take a history, you never examine the patient, that that would be outside the course of usual practice?

A. Yes.

Q. That an interaction falls outside the scope of professional practice if a doctor didn't do a history, didn't do an examination, and didn't have a doctor/patient relationship.

A. And we're talking about the first visit here, I assume you're saying. On the first visit, so in other words, the doctor has never taken a history, never met this patient before, never done a physical exam, that would be outside the usual course.

Q. You understand, Doctor, do you not, that -- well, you have testified numerous times in a court of law.

A. Yes.

Q. On these very issues.

A. Yes.

Q. And transcripts are made of those -- of that testimony.

A. Yes.

Q. And you, of course, know that some of these transcripts are publicly available, do you not?

A. Yes.

Q. Of course, every time that you testified, you testified under oath, did you not?

A. Correct.

Q. Swearing to tell the truth and be complete in your answers?

A. Correct.

Q. Do you remember testifying in the matter of United States of America vs. Cadet?

A. Yes.

Q. And isn't it true that on that occasion, you said ....

MR. BEATON: Let me know.

MR. GILFARB: Yeah, I'm looking for the specific one.

(Discussion had off the record between counsel)

BY MR. GILFARB:

Q. Let me ask it a different way. I'm having trouble finding that section. Would you agree that an interaction with a patient is within the usual course of practice when the doctor does an examination, asks you a lot of questions about what's bothering you, and then makes a diagnosis and treats you?

A. On the first visit. On subsequent visits, there's no requirement for that.

Q. And in that case, you indicated that it would be important for a doctor to see the patient, see whether their speech was slurred, to see if their eyes were glassy, if they had track marks, did these examinations on a monthly basis to assure herself -- in that case, Dr. Cadet -- that drugs were appropriate. Do you recall that?

A. I don't recall the specific testimony, but all those things would be appropriate

Q. Okay.

A. -- in that particular case. I mean I don't know which patient you're referring to. It's not a contest --

Q. Well, I'm asking if it is important for a doctor to be present at an examination to check whether a patient's speech is slurred, whether their eyes are glassy, if they had track marks, and did an examination on a monthly basis to assure herself that drugs were appropriate?

A. In that particular case --

MR. BEATON: Your Honor, I object. And excuse me, Dr . Warfield. I object. This is an improper form of impeachment. I don't know what's referring to. I don't know what he's reading from.

THE COURT: He's just asking a question, so overrule.

A. I have no idea what patient we were talking about. In that particular case, we may have been discussing a particular patient in whom it was appropriate to do all those things. I -- it's out of context. And if you tell me the year – I mean it was a long time ago. It was years and years ago. So, I just don't remember.

Q. Well, let me change the question. Isn't it true that a doctor should see a patient to
see if their speech was slurred, if their eyes were glassy, if they had track marks, and do these examinations on a monthly basis to assure themselves that the drugs were appropriate? Do you agree with that statement?

A. Probably for the patient I was talking about, but not for every patient.

Q. So, your testimony is that for the first visit, a doctor should do that, and then after that, the second visit, the doctor does not have to do that.

A. I didn't say that. I said for that particular patient

Q. I'm not asking about that patient. I'm saying

A. Well, you are asking about that patient, because you're reading me a transcript that I was testifying about a particular patient.

Q. I'm not reading -- with all due respect, Doctor, I'm not reading your transcript. Just listen to the question.

Is it your testimony here today that a doctor can -it is within the scope of professional practice for the doctor to see the patient the first time and then not see them the second time that they come in to determine whether they had slurred speech?

A. Absolutely. There's no requirement that the doctor sees the patient on a monthly basis, if that's what you're asking. No requirement whatsoever.

Q. I'm not asking -- okay. I'm not asking whether there's a written rule. I'm asking whether you think it's outside the scope of professional practice to see the patient initially and then not see the patient the second time they come?

A. Of course not. That's not outside the scope. It's done all the time.

Q. Okay. How about the third time the patient comes in?

A. It depends on the patient.

Q. How would you know if you don't see the patient?

A. Because you get feedback.

Q. From who?

A. From your staff, you get feedback from the patient. You know the patient, because you saw them the first time. Or this may be a patient you've been seeing for ten years, and you know you don't have to see them every month, every time they come back. It depends on the patient. There's no requirement. And, in fact, it's not -- it's not there's no necessity that every patient comes back every month. In fact, there are laws that say that you can write prescriptions for three months and never even see the patient or have the patient even come back to the office for the prescriptions, as long as you date them appropriately. So, there's no rule --

MR. GILFARB: Move to strike everything after:

"No, it is not a requirement."

THE COURT: She's allowed to explain her answer. The motion to strike is denied.

BY MR. GILFARB:

Q. Do you agree that in order to be inside the course of practice, you need to see the patient, have a doctor/patient relationship, do a history, a physical exam? If you're not doing that, that's outside the scope of usual practice?

A. On the first visit.

Q. Okay.

A. I think you're reading this out of context, sir.

Q. Well, let's see if it's out of context.

(Discussion had off the record between counsel)

BY MR. GILFARB:

Q. I'm gonna try to pronounce this name. In the United States District Court, Southern District of New York -- this one wasn't so old, 2016 -- Moshe Mirilashvili.

A. Yes, I recall that case.

Q. Okay. And do you recall making the following question and answer? Now, we've been --

"Question: We've been talking a lot about the term the 'usual course of conduct.' In your experience, Doctor, what is outside the course of pain management conduct?

"Answer: Well, as I mentioned earlier, to be inside the course of practice, you need to see the patient, have a doctor-patient relationship, do a history"

A. Yes.

Q. -- "a physical exam. If you're not doing that,

then that's outside the usual course." Do you remember that question and answer?

A. If you don't ever do that with a patient, and you prescribe drugs, it's outside the course, yes.

Q. I'm sorry. In this document, you don't limit it the way you just limited it now, is that correct?

A. Well, you're reading it out of context. I may have limited it three pages before that, sir. I'm telling you what I said and what I meant. There is a requirement that a physical exam and history be done the first time you see the patient.

Q. If you're giving --

A. After that, there is no requirement -- none of those guidelines that you've quoted or that you heard about this week say that you have to see the patient a month --

Q. I'm not asking about guidelines --

THE COURT REPORTER: Excuse me.

MR. GILFARB: I'm sorry.

A. And do a physical examination or do a history. Nothing requires that. And, in fact, the law permits a doctor to write prescriptions for these drugs for three months.

MR. GILFARB: I object to her interpretation of the law.

THE COURT: Okay. You can't just interrupt her talking, because Fran can only take one person talking at a time. So, you have to wait until she's finished with her answer, then you can make your objection or your motion to strike. So, if you weren't done with your answer, you can continue, Doctor.

THE WITNESS: Thank you, your Honor.

A. The law permits doctors to write prescriptions for patients for three months at a time, as long as you date for

example, if the patient sees you on January 1st, you can write a prescription January 1st for the oxycodone. Then you can write a prescription dated January 1st that says: "Do not fill until February 1st." And you can write another prescription dated January 1st that says: "Do not fill until March 1st." And never see that patient for those three months. So -- and that, in fact, shows that there's absolutely
no requirement that a patient has to come back. And even after that, the patient can call in, tell -- tell the office, tell people what's going on, and they can get a prescription issued. There is no requirement whatsoever for that. Many doctors see these patients on a monthly basis, but it's certainly not criminal not to.

MR. GILFARB: Your Honor, I move to strike any mention of her interpretation of the law, any of her interpretation about what's criminal and not, and any interpretation about what does and doesn't violate a guideline.

THE COURT: All right. I'll tell the jury what the law is, and I allow wide latitude during an expert's testimony. You may continue.

BY MR. GILFARB:

Q. If a doctor prescribes -- sees the patient, prescribes oxycodone, can he go six months without seeing the patient?

A. It depends on the patient. Yes. I mean, as far as the guidelines are concerned and such, and as far as any of these things are concerned, yes. And is it done? Yes.

Q. He or she is relying on the information provided by their medical staff.

A. It could be the patient calls in. It could be they've been seeing this patient for a long time, so they understand what the patient needs. There are many, many different

reasons. But as I said, there are no requirements that a patient come back every month.

Q. Could he go eight months?

A. I believe the guideline -- the word the guidelines use is "periodic." And they purposely leave out the number of months. Is it eight months, is it nine months, is it a year? They purposely leave out and say periodically the patient should come back to see the doctor. And they say that because there are situations where a year might be appropriate. There are situations where a week might be appropriate in a particular patient, or two weeks, and others maybe a month. There's no cut and fast -- hard and fast rule.

Q. Okay. And the doctor, of course, in making the decision what is periodic, relies on the information that he or she is given.

A. By whom?

Q. By whomever you said is appropriate. They're relying on that in deciding what is an appropriate period of time.

A. Well, they rely on that or their own experience with the patient. There are many, many reasons why --

Q. So, after one experience with a patient -- I'll move on. I think the jury gets the point. Do you agree that patients who are prescribed these Schedule IIs or oxycodone, that within the first six weeks, that about 95 percent of the patients their lower back pains or their symptoms resolve without taking the drugs again after that?

A. That's acute pain, sir, not a chronic pain. I think you're confused.

Q. Okay. That's

A. For acute low back pain, most people -- 95 percent

of people get better within six weeks -- or six months, I should say, with low back pain if you do nothing. But this is chronic pain we're talking about here, not acute pain.

Q. Do you agree it's not okay to prescribe chronic opioid therapy carte blanche, just leave it up to the medical assistants to decide?

A. I would say that was incorrect. The medical assistants should never be making those kinds of judgments. That's up to the doctor. That being said, a doctor can say, you know, this patient's gonna get prescriptions for the next three months and provide them assistant. the doctor provides them, though, not the

Q. Right. Not turning over signed prescription pads and say, For the next three months when this doctor -- when this patient comes in, just write them for oxycodone.

A. I agree that that's not appropriate.

Q. Okay. All right. Would you agree that a patient who is prescribed oxycodone and shows up negative for oxycodone in their urine, that that could indicate that the patient was selling the drug and not taking the drug?

A. It could indicate a number of things, including –

Q. I'm asking if it could

A. It could indicate

Q. You know, Doctor, I'm sorry. I'm sorry. It is two o'clock, and we're trying to

MR. BEATON: I object. I object. I object.

THE COURT: Sustain. If you can answer yes or no, then you can explain your answer.

BY MR. GILFARB:

Q. Doctor, let me ask the question so we can follow that formula. Do you agree with the following statement: A patient who is prescribed oxycodone, yes or no, that shows

up negative for oxycodone in their urine could indicate that the patient was selling the drug and not taking the drug? Could that be one of the possibilities?

A. Yes, that could be one of many, many possibilities in that case. Probably the most common possibility in that situation is that the urine drug screen that was given did not detect oxycodone. That's a common misconception that even doctors don't know about. So, for example, if you show up in an emergency room today, and you look unconscious, and they order a urine drug screen for opiates, it usually doesn't test for oxycodone. So, your urine drug screen would be negative. And there have been lawsuits about this, actually, about patients coming up negative for oxycodone when they were supposed to be taking oxycodone, and the physician dismissing them because of that, not knowing that a urine drug test for opiates often does not come up positive for oxycodone. Another reason might be the patient hasn't taken the oxycodone for a little -- they ran out of the oxycodone. They haven't taken it for a while. The patient drank a lot of water. I mean there are many, many reasons. And one of them -- you're correct, one of them could be they're not taking the drug and they're just selling it. There are lots of reasons.

Q. So, that's a yes.

A. Yes, there are lots of reasons, and that's one of them.

Q. So, that's a yes.

A. Yes.

Q. That wasn't so hard. Would you agree that in a physician-owned clinic, physicians may be more aware of how patients are paying?

A. I guess --

Q. Do you agree with that statement?

A. I guess I don't know the answer to that. I mean

I'm not aware in our clinic how patients are paying. I can't really speak for physician-owned clinics. I guess the answer is I don't know.

Q. Do you remember giving testimony in the United States District Court for the Northern District of Texas, in United States vs. -- that's another hard one Okechuku?

A. I don't remember. But, you know, it's possible. I suppose if someone owned a clinic, they might know more about the billing or something.

Q. I'm sorry.

A. But I guess I just –

Q. I'm sorry. I'm sorry. The question was: Do you remember testifying in that

A. Yes, I remember testifying in the case, but not about this particular

Q. Well, let's not get ahead of ourselves. Let's take it step by step. Do you remember the following question and answer: "In a physician-owned clinic, do you think physicians are more aware of how patients are paying? "Answer: They may be."

A. Yeah, I would agree with that. They may be.

Q. Okay. Are you aware that -- well, let me ask you -- well, let me phrase it in a hypothetical. Would you agree that patients who come to a pain clinic who pay in cash, and then are separated into patients that pay for cash with copays and things like that, versus patients that pay for cash who the office and the doctor know are there for controlled substances, and then that money is taken home and hidden from the business, that would be an indication that the doctor knows that he shouldn't be giving those people prescription medications?

A. I'm confused. Can we do it one by one?

Q. No.

A. Say it again.

Q. I can't break that down again. We're gonna move forward.

A. I guess --

Q. Do you agree that if you are buying a prescription, that would not be for a legitimate medical purpose?

A. If you say, "Here, I'll give you a thousand dollars if you give me a prescription"?

Q. Yes.

A. That's not a legitimate medical purpose.

Q. All right. Perfect. That was an easy one. I'm showing you Government's Exhibit 38A. I want you to assume the following when you're looking at these text messages: That a medical assistant says, "Doctor, here one Code-G, but have seven days early. It's Skippy Thompson."

A. Yes. Do you see that there at the bottom?

Q. I want you to assume that Skippy Thompson is someone that he and the office recognize as somebody that's at the office purely to get controlled substances. And then the answer is from the medical assistant: And the doctor says: "Yes. "Can I give to him?" "It's okay. He buy it cash? "Then it's okay *(sic)."* That would not be appropriate -- that would not be for a legitimate medical purpose.

A. Well, it depends why he's asking that question. I mean, for example, if you want to give a prescription seven days early, and you have insurance, the insurance company probably wouldn't pay for a refill seven days early, because they have their protocols. It depends on why he asks the question.

Q. If the testimony is -- strike that. I want you to assume for purposes of this hypothetical that this person doesn't have insurance. This person is a person who comes in and pays $300 in exchange for a prescription for oxycodone, and the doctor then says: it cash? "Yes. "It's okay

then." Is that

A. Well, I need to "He buy

Q. Doctor, I just want to know -- I haven't asked the question yet. Is that within or outside the scope of professional practice?

A. I have to answer that question with a question, which is,
what do you mean he gives $300 to buy the drugs? You're saying this is not a medical patient who has a doctor-patient relationship, and the patient's just coming in saying, "I'm gonna give you 300 bucks, give me some drugs"?

Q. Well, would you agree

A. That's different.

Q. Would you agree that in order to have a doctor-patient relationship, the doctor has to see the patient at some point?

A. Right. And the patient typically pays the doctor for the office visit. So because there's cash exchanged doesn't necessarily mean the patient is buying the drugs or giving them money for the drugs. So, I guess I need more information. And I guess the point I was making there was that sometimes the question about is this a cash patient or an insurance patient has to do with will the insurance cover this or will they not.

Q. There's no insurance. No insurance.

A. Then you can give a patient something earlier, and there would be no insurance problem.

Q. So, "he buy it cash," he's saying he's buying the prescription. You do not find that to be outside categorically outside the scope of professional practice.

A. I don't personally find that statement -- what I'm saying, it's possible, but is he buying the drugs at the drugstore in cash, is that what the question is? I guess I

need to have more information.

Q. He's buying the prescription.

A. Well, is that what he's asking? Is he buying the prescription or is he buying the drugs at the drugstore?

Q. The prescription.

MR. BEATON: Objection.

A. Well, how do you know that? I didn't see that there.

MR. BEATON: Objection to facts not in evidence.

THE COURT: Sustain.

MR. GILFARB: I'm posing a hypothetical, your Honor, based upon the evidence that's been presented.

THE COURT: Okay. Let's move on.

BY MR. GILFARB:

Q. Do you agree, based upon what -- the answer you just gave, that when a patient runs out of medication early or specifically names a medication, that that could be a sign of pill-seeking behavior?

A. It could be, but more likely pseudoaddiction.

Q. But you have to take that into account.

A. Yes. You take a lot of things into account, yes.

Q. Including that.

A. Yes.

Q. I mean let's not bury the answer.

A. No, no, you take that into account, of course.

Q. Okay. Would you agree that if medications -- that – what you should see in a legitimate medical practice is a fluctuation in the kinds of medications or dosages. That would be one sign that this is not a pill **mill** or that this is not a drug transaction.

A. I wouldn't agree with that. I think that there are some doctors who have particular drugs they are very familiar with, and that they use all the time, and they use

particular doses all the time. You know, if you go to a cardiologist, who treats blood pressure all day long, they probably have one or maybe two blood pressure medicines that they use for everybody. And they start them all at the same dose or they use similar doses. I don't find that indicative of being outside the usual course because a doctor prefers oxycodone or prefers morphine or prefers a particular drug and feels that this is the dose that typically works for my patient.

Q. I did not ask about outside the scope. Let me be more specific with you. If medications are adjusted within a patient's file, within a patient's history --

A. Yes.

Q. -- you would expect to see adjustments downward as an indication that this isn't just somebody -- a doctor who is just selling drugs. Would you agree with that?

A. I don't think the fact that the doses are just increased upwards means the doctor is selling drugs, by any means.

Q. I'm sorry, I didn't ask that. I didn't ask about upwards.

A. Well, you said if they weren't prescribing down, if they weren't titrating downwards, did that mean they were outside of the course. And absolutely not. It has nothing to do with it.

Q. Do you remember testifying in District of Massachusetts, U.S. vs. Zolot?

A. Yes.

Q. That's your home turf out there, right?

A. Yes.

Q. Do you remember making the following statements: "The medications were adjusted, and many times they were adjusted down. Again, I think if somebody

was selling drugs, they wouldn't be doing that." Do you remember making that statement?

A. I think that's a true statement. But that does the corollary of that doesn't mean that if someone doesn't adjust down, that they must be selling drugs.

Q. I didn't ask that.

A. Well, you asked it before. That was your question before.

Q. No, my asking *(sic)* is: Do you agree that medications that are adjusted, and many times they were adjusted down, or if they're adjusted down -- those are your words -- would you like to see them?

A. No, but what I'm saying is if you would just

Q. I'm sorry, the question was: Would you like to see the words?

A. No, thank you. I understand.

Q. Hold on. Let me finish the question. Let me finish the question.

THE COURT: Well, you interrupted the question with another question.

THE WITNESS: Yes, you did.

MR. GILFARB: I'm trying to get some answers here,

A. I'm trying to answer.

Q. Dr. Warfield, how many times have you testified in federal court?

A. Oh, 12, maybe, close to 15.

Q. Okay. So, you know that Mr. Beaton is gonna get up after I'm done and ask you whatever questions he feels are necessary, right?

A. I understand that.

Q. Okay. I just want to make sure that you know that you'll have a chance to expound on your answers.

A. I understand that.

Q. All right. Are these your words: "The medications were adjusted, and many times they were adjusted down. And, again, I think if somebody was selling drugs, they wouldn't be doing that"? Do you agree with that statement?

A. I agree with that statement. If I were selling drugs, I would just continue to increase the drugs upwards. That doesn't mean, though, by any means, that if a doctor is not adjusting the drugs down, that they're selling them. I mean if that were the case, half the doctors in the country would be in jail.

Q. Right.

A. It's not selling drugs just because they don't go down. In fact, it's much more common to titrate the dose upwards. You start with a certain dose, and they say, "My pain is not relieved, I'm not having any side effects," and you gradually go up until you hit the right dose. Sometimes the side effects are so bad that you have to titrate back down. But if that doesn't happen in the handful of patients that you're seeing here, that doesn't mean you're selling drugs, by any means.

Q. You have to look at the totality of the circumstance.

A. I think that never means you're selling drugs. The fact that a doctor doesn't titrate downward, I would say doesn't ever mean that they're selling drugs.

Q. I'm not I didn't ask that.

A. I think you did.

Q. I said you have to look at the totality of the circumstances. Do you agree with that?

A. Yes.

Q. Okay for All right. You mentioned earlier about the need or the lack of need for it, depending on the patient for the doctor to actually see and examine the patient -- I want to ask you a question about that -- in subsequent

follow-up visits.

A. In subsequent visits, okay, yes.

Q. I'm sorry. The typical would you agree with this statement: The typical interaction that a doctor would have with a patient in the usual course of its medical practice is seeing the patient monthly or so for follow-up if the patient is on pain medication? Do you agree with that statement?

A. In whatever case that was, it probably was typical for that group of patients.

Q. But in this case, it's not?

A. It depends very much on the patient, on the circumstances, on the practice. And I would say that -- that a lot of doctors see these patients monthly. I'm not denying that a lot of doctors don't see these patients monthly; they do. But there's no requirement for it. And there are other doctors who don't see them monthly, and that is not illegal or criminal. It's a way of practicing.

MR. GILFARB: Move to strike anything about "legal" or "criminal."

THE COURT: Denied.

BY MR. GILFARB:

Q. Doctor, you don't have a law degree, right?

A. Correct.

Q. Okay. Just checking. You've never worked in a prosecutor's office?

A. No, I haven't.

Q. Defense lawyer's office?

A. No.

Q. You indicated that you reviewed files in this case.

A. Yes.

Q. Do you have an opinion about whether those files you reviewed required a monthly follow-up by the doctor?

A. No -- yes, my opinion is that they didn't require a

monthly follow-up of the doctor. If the doctor wanted to see them monthly, I wouldn't have objections to that, but there was no requirement that he do so.

Q. Have you met any of these patients?

A. No.

Q. And yet you're able to determine that without seeing them.

A. By reviewing the medical records, yes.

Q. So, you don't even need to see them to know that.

A. Correct.

Q. Oh, okay. Do you think that the best way to determine what's going on with a patient is to sit there with the patient, talk to the patient, and make an individualized determination about that patient?

A. Probably, yes.

Q. Can you commit a little bit more on that?

A. I think the best way to see what's going on with the patient is to ask the patient. It's not the only way, but it's probably the best way.

Q. And that, in fact, the best way to be vigilant about what's going on with the patient is to be sitting there in the room, looking at them, talking to them, and knowing the patient. Do you agree with that?

A. I agree that that's probably the best way, but not a required way, and not the way everybody does it.

Q. Do you agree with this statement: If a doctor isn't acting as a doctor but as a drug dealer, so, for example, the doctor doesn't ever do an examination on the patient or take a medical history or anything like that, that would be outside the scope of professional practice?

A. Doesn't ever do a physical exam, so even on the first visit, I agree. That would be outside of the usual course if a doctor doesn't ever do a physical exam or history.

Q. And you would agree that, in fact, there's no substitute for a doctor sitting with a patient and being vigilant about what's happening with that patient's care when they're getting Schedule II substances. Would you agree with that?

A. Again, I think it's the best practice, but there's no requirement that everybody practices the best practice. And that's not what we're talking about here. We're talking about whether it's outside the usual course. We're not talking about whether Dr. Mencia practiced the best possible practice.

Q. Well, I understand that you are equating the fact that there are no written rules about it to there being no violation. I'm not asking that. You keep saying there are no written requirements. I'm not asking that. My question was: Do you agree that there's no substitute for the vigilance that a doctor can give when prescribing Schedule II substances than to be there with the patient?

A. That's probably the best possible practice, but not what is done in practice, and there's no rule against it.

Q. And you indicated that you relied on the medical records in this case in forming these opinions?

A. Yes .

Q. And you would agree, obviously, that if the records were cut and pasted and had a bunch of false and made-up information, then the records would not be reliable.

A. Well, I think if there were made-up things in the records, then, you know, they -- that's not reliable. I think cut and pasting is done pretty commonly in medical records. I don't have a problem with that.

Q. From another patient's file?

A. No, no. But from the same patient's file.

Q. How about making up MRI results?

A. No, I think if something is made up, obviously that's not appropriate.

Q. Okay. And you obviously -- you're a scientist, and you've heard the expression "garbage in, garbage out," right? You use bad data to draw a conclusion, then you have a bad conclusion.

A. Right. And I've had patients bring me fake MRIs and such. I mean there are --

Q. Okay. But you --

A. -- these patients get really, really good at faking their symptoms. And I've had people cut and paste somebody else's MRI and bring it in and say, you know, "Here's my MRI," and I haven't caught it.

Q. I'm not talking about a cut and paste by the patient. I'm talking about a cut and paste and falsification of records by the doctor and the doctor's staff pursuant to his instructions .

A. If the -- if the doctor puts false information in the medical record, it's not appropriate.

Q. So, the conclusions that you reached about the appropriateness of care for the patients that you reviewed are only as good as the information in the record. Would you agree with that?

A. Well, again, I reviewed the videos, and so my –

Q. I'm not asking about the videos.

A. Well, you asked me what I based my conclusions on.

Q. No, I did not.

A. I didn' t --

Q. I asked you about the patient records, the files.

MR. BEATON: Judge, I object.

A. I based my --

THE WITNESS: Oh, I'm sorry.

THE COURT: You can't talk at the same time. You've got to talk one at a time. You keep talking over each other.

BY MR. GILFARB:

Q. All right. Doctor, let me -- let's try again. You would agree that based upon your patient review of the files, that if the files are made up, your conclusion that it was within the scope of practice would not have as much weight.

A. It's possible, but I saw videos, also, not just files.

Q. I'm not -- you saw videos for all those patients?

A. No, not for all those patients.

Q. Okay.

A. But a video of several patients usually gives me a good idea of how a particular doctor treats his patients, whether they do exams, the questions they ask. It usually gives me a pretty good handle of how the practice is done. As I said, doctors don't write down everything they do with the patient, but a video gives you a nice idea of what typically happens.

Q. I think I heard this right. So, let me ask you if I did. On direct examination, I think I heard you say that if the doctor exercises any measure of medical expertise, then it may be bad doctoring, but it's still doctoring. Would you

A. I don't recall saying that specifically.

Q. Did I say it better?

A. What's the question? No, I don't think I said that, but what's the question?

Q. My question is: Do you agree with that -- well, let me ask a different -- let me change the question so that we can all understand what the question is. Do you agree that

if a doctor is exercising some measure of medical judgment, then that person is acting like a doctor and not outside the scope of professional practice?

A. I mean, it's kind of a confusing question. I could probably come up with a scenario where the doctor wasn't practicing within the usual course, but they were -- they had some judgment. I mean, I think it's --

Q. Okay. Well, I mean the jury will rely upon their recollections, but I think during direct examination, that's what you said, that if the doctor is using some measure of doctorship in analyzing the situation, then he's acting within the scope of --

A. I think what I probably said is if the doctor is prescribing these drugs in good faith in trying -- and was talking about specifically prescribing these drugs -- if the doctor is prescribing these drugs to treat the patient's pain in good faith, not to get these patients high or not to collect a thousand dollars from them for the prescription, that that's practicing within the usual course of medical practice where concerns writing a prescription for opiates. I might have said that.

Q. And my question is: You said that -- I believe you said this -- that practicing medicine is part art and part science.

A. Correct.

Q. So, you want to leave, and you think it's appropriate to leave, that art and science to the judgment of the doctor. The doctor is there and has the expertise. Do you agree with that?

A. Yes.

Q. And, therefore, the doctor is making a judgment. My question to you is: If the doctor exercises any measure of expertise in making that judgment, you believe that's within the scope of professional practice.

A. Not necessarily.

Q. Can you think of an example which it is not?

A. Again, the doctor could make the judgment that the patient needs -- you know, needs opiates, but, uhm, you know, also gives them some other drug, does something else, gives them some other drug that isn't indicated or that there isn't a legitimate purpose for.

Q. Like Xanax?

A. Not -- any drug, any schedule drug.

Q. Including Xanax.

A. It could be. I mean, you know, it's kind of a difficult question to ask. But the doctor --

Q. Well, I'm not gonna ask you easy questions.

A. True, true.

Q. Okay.

A. If the doctor is doing this in good faith, I'm trying to help this patient by prescribing these drugs, I'm not selling these drugs, I'm not giving the drugs to make the patient high, uhm, then -- then that's -- in that specific range, that's practicing during the usual course. He could be doing something else that's outside of the usual course, I suppose. It's a matter of intent.

Q. Okay. In the times that you've been called to testify, would it be fair -- on whether a doctor is acting within or outside the scope of professional practice, would you agree it's been for the defense?

A. I've testified for the government before.

Q. Well, I believe you told me about that one time -

A. Yes.

Q. -- where I think there was trading sex for it.

A. There was that. I testified for a -- for a Medicare fraud case.

Q. I'm not asking --

A. I think that was for the government.

Q. I'm asking with regards to -- and maybe I should have been more specific -- dispensing oxycodone and Schedule II substances outside the course of professional conduct.

A. I think for that particular one, except for the one thing you mentioned, I think it's been -- it's been the defense that has called me, yes.

Q. Okay.

A. But I've been asked many times to review cases for the government, as you had asked.

Q. Just like I did.

A. Yes.

Q. Doctor, have you lectured or -- let me change the question. You've lectured at the International Conference on Opioids in the past?

A. Yes, I have. I've run the meeting, actually.

Q. All right. And on at least some occasions, you presented legal issues from a physician's viewpoint.

A. Correct.

Q. You're not a lawyer.

A. Correct. I've had a lawyer as a co-presenter.

Q. Okay. But you're not a lawyer.

A. No.

Q. And at the -- who attends these conferences?

A. Doctors, nurses, some other -- actually, we've had some DEA agents and lawyers and people involved in this. You know, anyone who has an interest in this area. It's all about what's current in opioids.

Q. And in 2015, and before, you had a slide presentation.

A. Yes.

Q. Is that right?

A. Yes.

Q. Okay. Do you -- may I show --

MR. GILFARB: May I approach the witness, your Honor?

THE COURT: Okay.

BY MR. GILFARB:

Q. Do you recognize this as your presentation?

A. Yes.

Q. All right. Now, you indicated earlier that this is a conference to, given mostly doctors. Would you agree with that, as you just said?

A. Medical professionals of different sorts. But DEA agents, we've had -- we had, actually, the undersecretary for the U.S. Department of Health Substance Abuse and Mental Health there this time. And we had the governor of Massachusetts there. I mean lots of different concerns about the opioid crisis. different people who have

Q. And there's a slide that's entitled "Anatomy of a Criminal Case."

A. Yes.

Q. And this is a slide in your presentation that basically sets out the steps that in your experience has led to doctors getting criminally charged.

A. Yes. That's my experience with a number of cases, this is what happens.

Q. Okay.

MR. GILFARB: One moment, your Honor.

BY MR. GILFARB:

Q. Do you agree that when it comes to Schedule II substances, that there is a heightened responsibility by the doctor with regards to the appropriateness of prescribing that medication as opposed to lesser schedule substances?

A. There's a heightened responsibility, the more -- the more dangerous or the more issues there are with drugs, yes.

Q. Okay.

MR. GILFARB: One moment, your Honor.

BY MR. GILFARB:

Q. You indicated before that you are licensed to practice medicine in Boston -- in Massachusetts?

A. Correct.

Q. And Massachusetts, like most states, have various regulations with regards to the practice of medicine, obviously?

A. Yes.

Q. And some of those deal with Schedule II substances and –

A. Yes.

Q. Is that correct?

A. Yes.

Q. And, in fact, like many states, Boston, and Massachusetts in general, is dealing with its opioid crisis.

A. Well, everybody's concerned about it, yes. It's a problem, a big problem.

Q. All right. And in order to help combat these -- the opioid crisis as those in power see it, laws are constantly being updated and renovated --

A. Yes.

Q. -- to kind of meet the times. Would you agree with that?

A. Yes, yes.

Q. And the standard of what is and what is not within the scope of professional practice may change depending upon what we start to learn through our investigation of why there's an opioid crisis, how to deal with addicts, and things of that nature.

A. It's possible.

Q. And there are medical societies, just like here, they exist in Massachusetts, and Boston in particular.

A. Yes.

Q. And they also promulgate or put out into the media for doctors and others to see what they believe guidelines should be. Do you agree with that?

A. Yeah, as I said before, there's -- there's no consensus. There are lots of different opinions out there about how – how this should be done and how the guidelines should be done, but, unfortunately, there's no great consensus. But I'm sure some medical societies and individual doctors have published what they think -- what they think the answer is.

Q. Okay. .

MR. GILFARB: No further questions at this time, your Honor.

THE COURT: Redirect?

MR. BEATON: Thank you.

REDIRECT EXAMINATION

BY MR. BEATON:

Q. Dr. Warfield, have you ever experienced a dynamic like this in your entire career?

MR. GILFARB: Objection. Relevance.

A. You mean

THE COURT: You have to wait for my ruling. Overrule.

A. You mean where I'm hired by the government, and they decide -- they are gonna put me on the stand, and then they don't put me on the stand, I come on for the defense? No, this has never happened to me, in my experience.

Q. You heard Mr. Gilfarb ask you if you testified mostly for the defense. You heard that question?

A. Yes.

Q. Did the defense hire you in this case?

A. No.

Q. You were asked that question, in fact, by the person who hired you.

A. Correct.

Q. And when you agreed to review the files and records that the government sent you, did Mr. Gilfarb tell you that they were falsified and that you shouldn't rely on them?

A. No.

Q. Did he ever suggest to you that you would be relying on bad information?

A. No, he never suggested that.

Q. And when you agreed to review the case for the government, did -- the government, I presume, didn't tell you what opinion to render. They wanted your honest opinion.

A. Yes.

MR. GILFARB: Objection. That would call for speculation into the mind of the person she's speaking with.

THE COURT: Sustain.

MR. BEATON: Maybe the government is willing to stipulate that they were asking for an honest opinion?

MR. GILFARB: No, I'm just tired of her –

THE COURT: Ask another question.

BY MR. BEATON:

Q. Did you believe that you were being hired to render an honest opinion?

A. Yes.

Q. To say what you believed.

A. Correct.

Q. Were you told that you had to come to an opinion that the doctor was acting outside the scope of practice for the government to use you?

A. No. I was asked to review the medical records and to give my opinion based on what I saw in those medical records and the videos.

Q. Okay. And Mr. Gilfarb asked you questions about whether Harvard is the be-all and end-all. When Mr. Gilfarb emailed anything to you, at what -- what email address was it to?

A. Uhm, I have a Harvard email address, and I have a Yahoo email address. It might have been the -- I guess -- I think sometimes it was one, and sometimes it was the other.

Q. And did you --

A. It might have been the Yahoo one.

Q. Did you provide the prosecutor with your curriculum vitae?

A. I probably did, yes. I don't remember specifically, but that's the usual course of ....

Q. Okay. And he hired you.

A. Yes. He said he had heard about me and respected me and would I review these records for him.

Q. And eventually you gave Mr. Gilfarb your honest, good faith, learned opinion.

A. Correct.

Q. Prior to rendering that opinion, did the conversations with Mr. Gilfarb resemble the tone and manner that they did today?

A. No.

Q. Were you asked about other cases that you had testified and statements that you had made?

A. No.

Q. Were you cross-examined on your slide sheet?

A. No.

Q. Prior to giving an opinion that the government didn't like, were the questions, to use Mr. Gilfarb's words, a little bit easier than the ones today in terms of the tone, manner, and delivery?

MR. GILFARB: Objection to what the prosecution liked or didn't like, your Honor.

THE COURT: Overrule.

A. The tone was very different.

Q. And you were asked about all of these statements in a vacuum -- do you agree with this statement, do you agree with that statement, do you agree with this statement. Were you asked any of those questions by Mr. Gilfarb prior to giving the opinion that you gave to him?

A. No.

Q. And what is your understanding about whether this jury would have ever heard from you if I hadn't called you as a

MR. GILFARB: Objection.

THE COURT: Sustain.

BY MR. BEATON:

Q. Was it your understanding that the government would be calling you as a witness?

MR. GILFARB: Objection. That's pure speculation, your Honor.

THE COURT: Sustain.

BY MR. BEATON:

Q. Were you told that you would not be called as a witness?

MR. GILFARB: Objection. Hearsay and speculation.

THE COURT: No, I'll allow that.

A. I was not told until after you contacted me, and I sense when you contacted me, you emailed me and said, Can we talk? And I emailed you back and said, you know,

I'm a witness for the government. I'm not sure I should be talking to you. And I immediately emailed Mr. Gilfarb to tell him that you had tried to contact me, and I said, you know, What's going on? And Mr. Gilfarb called me immediately on the telephone and said that he had -- he had been required to send you some information about my opinion. And that he had sent that to you, and that I could speak to you or not speak to you, depending on my own personal feelings, that it was okay. And I asked him, Are you going to -- am I testifying for you? What's going on? And at first, he said, Well, we're not sure, it's unlikely. And then I said, Well, are you or aren't you? Because I thought I was coming -- I had cleared my schedule. I thought I was coming down to testify. That was my understanding, that I was coming to testify for the government. And I said, Am I testifying for you or not, because I feel very uncomfortable talking to the defense attorney if I'm testifying for you. And he essentially said, No, we're not gonna call you. And that was the first I knew that I wasn't gonna be called. And he said, It's up to you. Do you want to talk to Mr. Beaton? And I said, If that's the case, I'm happy to talk with him. And he said, you know, It might be that I have to be on the line when you talk to him. And I said, Well, you know, I'm not the lawyer. If that's the case, then fine, you can be on the line. You know, if that's required, that's fine. And then he got back to me and said, you know, Let me think about this, get back to me. And he said, No, there's not -- apparently, there's not a requirement that I be on the line when you talk to him. So, it's okay for you to go ahead and talk to him. So, I emailed you, and I said, Okay, I can talk to you. And you asked me what my opinion was. And I told you what I had you asked me what I reviewed and what my opinion was, and I told you. And -- and you said, you

know, would I could I come down and testify. And that's kind of where we are.

Q. Would I be correct in saying that you are neither a witness for the government or for the defense, but, instead, just a witness telling the truth as you see it?

A. You know, that's -- that's how I look at it. As I said, I feel -- and I do this for every case. I feel like I was asked to look at these records, and I gave my opinion. And when I spoke to Mr. Gilfarb on the phone, he said, you know, Are you gonna talk to the defense? And I said, you know, If I talk to the defense, it's
not gonna change my opinion. My opinion is my opinion, and it's the same opinion I gave you that I'm going to give the defense, and, you know, it's not gonna change. It's my opinion. That's it. And it is. So, my opinion is my opinion. It has nothing to do with whether I'm testifying for the defense or for the government. It's my opinion based on what I saw in the records and my years and years of experience looking at -- knowing pain practices, knowing pain management, and knowing rules and the
guidelines and such.

Q. And your opinion, whether it's been for -- whether it's been submitted to the government or whether it's been submitted to the defense, has been that Dr. Mencia, based on your review of the records and the videos, was acting as a medical doctor.

A. That's correct.

Q. In the usual course of practice, correct?

A. Yes.

Q. For legitimate medical purposes.

A. Correct.

Q. Dr. Warfield, thank you for coming down.

MR. BEATON: Judge, thank you for the indulgence

of calling her out of turn.

Thank you, Doctor. You're excused.

(Witness excused)

THE COURT: All right, members of the jury, we're going to take a 15-minute recess. Remember my admonition not to discuss the case or allow it to be discussed in your presence. And we'll see you back in the jury room in about 15 minutes.

COURTROOM SECURITY OFFICER: All rise.

(The jury exited the courtroom)

THE COURT: And if there's nothing else to come before the Court, we'll be in recess for 15 minutes.

MR. BEATON: Thank you, Judge.

APPENDIX C

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
FORT LAUDERDALE DIVISION
CASE NO. 17-60301-CR-WPD

UNITED STATES OF AMERICA,

Plaintiff,
v.

ANDRES MENCIA,

Defendant.

Fort Lauderdale, Florida
June 19, 2018
10:15 a.m.

Transcript of Trial Proceedings had
before the Honorable William P. Dimitrouleas,
United States District Judge, and a Jury.

VOLUME 2

APPEARANCES:

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Court Reporter:	Francine C. Salopek, RMR, CRR Official Court Reporter United States District Court 299 E. Broward Blvd., Room 207B Fort Lauderdale, Florida 33301 (954)769-5686

DIRECT EXAMINATION

BY MR. GILFARB::

Q. Is your full name Oscar Ventura-Rodriguez?

A. Yes.

Q. So, I know that you speak English, but you have asked for the services of the Spanish interpreter to assist you in expressing yourself more clearly.

A. Yes

.

Q. While you were working there, did you ever hear the term "gypsy patient" or "gypsy "?

A. Yes.

Q. Do you recall how long you were working there before you first heard that term?

A. Around almost a year.

Q. Did you ever have a discussion with Dr. Mencia about what is a gypsy patient?

A. Yes.

Q. And what did he say?

A. That these were people with different accents when they spoke, and that they lived from one state to another.

Q. Did he ever talk to you about -- strike that. Did you ever notice yourself that some of these gypsy patients were coming from as far as Sarasota?

A. Yes.

Q. When the gypsy patients would come to the office, who was first seeing those kind of patients in the beginning?

A. Juan Calle.

Q. When Juan Calle was seeing them, was -- to the best of your ability to observe, was Dr. Mencia also seeing them?

A. No.

Q. Did you ever speak with Juan Calle about these patients?

A. No.

Q. I want to draw your attention to 2014 and whether there was a meeting between you and Dr. Mencia. Do you recall such a meeting?

A. Yes.

Q. Can you please tell us who was at this meeting? This is 2014.

A. Juan Calle, Homer, myself, and Dr. Mencia.

Q. Can you please tell the members of the jury to the best of your recollection what it is that Dr. Mencia said at this meeting?

A. We were talking about the process in the clinic, and that -- about the fact that we were already -- ready to see gypsy patients.

Q. At that time, did Dr. Mencia explain how these gypsy patients were going to pay for their consultation?

A. Yes.

Q. What did he say?

A. That they would be paying cash.

Q. And what, if anything, did he say they would get in exchange for cash?

A. A prescription, medical prescription.

Q. At that time, was there any explanation about what kind of prescription specifically?

A. No.

Q. And after that then, did you start seeing gypsy patients

APPENDIX D

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
CASE NO. 17-60301-CR-WPD

UNITED STATES OF AMERICA
Plaintiff,

vs.
ANDRES :MENCIA
Defendant.

COURT'S INSTRUCTIONS TO THE JURY

Members of the Jury:
It's my duty to instruct you on the rules of law that you must use in deciding this case. After I've completed these instructions, you will go to the jury room and begin your discussions - what we call your deliberations. You must decide whether the Government has proved the specific facts necessary to find the Defendant guilty beyond a reasonable doubt. Your decision must be based only on the evidence presented during the trial. You must not be influenced in any way by either sympathy for or prejudice against the Defendant or the Government. You must follow the law as I explain it - even if you do not agree with the law - and you must follow all of my instructions as a whole.

You must not single out or disregard any of the Court's instructions on the law.

The indictment or formal charge against a Defendant isn't evidence of guilt. The law presumes every Defendant is innocent. The Defendant does not have to prove [his] [her] innocence or produce any evidence at all. A Defendant does not have to testify, and if the Defendant chose not to testify, you cannot consider that in any way while making your decision. The Government must prove guilt beyond a reasonable doubt. If it fails to do so, you must find the Defendant not guilty.

The Government's burden of proof is heavy, but it doesn't have to prove a Defendant's guilt beyond all possible doubt. The Government's proof only has to exclude any "reasonable doubt" concerning the Defendant's guilt. A "reasonable doubt" is a real doubt, based on your reason and common sense after you've carefully and impartially considered all the evidence in the case. "Proof beyond a reasonable doubt" is proof so convincing that you would be willing to rely and act on it without hesitation in the most important of your own affairs. If you are convinced that the Defendant has been proved guilty beyond a reasonable doubt, say so. If you are not convinced, say so. As I said before, you must consider only the evidence that I have admitted in the case. Evidence includes the testimony of witnesses and the exhibits admitted. But, anything the lawyers say is not evidence and isn't binding on you. You shouldn't assume from anything I've said that I have any opinion about any factual issue in this case. Except for my instructions to you on the law, you should disregard anything I may have said during the trial in arriving at your own decision about the facts. Your own recollection and interpretation of the evidence is what matters. In considering the evidence you may use reasoning and common sense to make deductions and reach conclusions. You shouldn't be concerned about whether the evidence is direct or circumstantial.

"Direct evidence" is the testimony of a person who asserts that he or she has actual knowledge of a fact, such as an eyewitness.

"Circumstantial evidence" is proof of a chain of facts and circumstances that tend to prove or disprove a fact. There's no legal difference in the weight you may give to either direct or circumstantial evidence.

When I say you must consider all the evidence, I don't mean that you must accept all the evidence as true or accurate. You should decide whether you believe what each witness had to say, and how important that testimony was. In making that decision you may believe or disbelieve any witness, in whole or in part. The number of witnesses testifying concerning a particular point doesn't necessarily matter.

To decide whether you believe any witness I suggest that you ask yourself a few questions:

- Did the witness impress you as one who was telling the truth?
- Did the witness. have any particular reason not to tell the truth?
- Did the witness have a personal interest in the outcome of the case?
- Did the witness seem to have a good memory?
- Did the witness have the opportunity and ability to accurately observe the things he or she testified about?
- Did the witness appear to understand the questions clearly and answer them directly?

• Did the witness's testimony differ from other testimony or other
evidence?

You should also ask yourself whether there was evidence that a witness testified falsely about an important fact. And ask whether there was evidence that at some other time a witness said or did something, or didn't say or do something, that was different from the testimony the witness gave during this trial.
To decide whether you believe a witness, you may consider the fact that the witness has been convicted of a felony or a crime involving dishonesty or a false statement.
But keep in mind that a simple mistake doesn't mean a witness wasn't
telling the truth as he or she remembers it. People naturally tend to forget some things or remember them inaccurately. So, if a witness misstated something, you must . decide whether it was because of an innocent lapse in memory or an intentional deception. The significance of your decision may depend on whether the misstatement is about an important fact or about an unimportant detail.

You must consider some witnesses' testimony with more caution than others. In this case, the Government has made a plea agreement with a Codefendant m exchange for [his] [her] testimony. Such "plea bargaining," as it's called, provides for the possibility of a lesser sentence than the Codefendant would normally face. Plea bargaining is lawful and proper, and the rules of this court expressly provide for it. But a witness who hopes to gain more

favorable treatment may have a reason to make a false statement in order to strike a good bargain with the Government.

So while a witness of that kind may be entirely truthful when testifying, you should consider that testimony with more caution than the testimony of other witnesses. And the fact that a witness has pleaded guilty to an offense isn't evidence of the guilt of any other person.

You must consider some witnesses' testimony with more caution than others. For example, a witness may testify about events that occurred during a time when the witness was using addictive drugs, and so the witness may have an impaired memory of those events. And a witness who has been promised immunity from prosecution or witnesses who hope to gain more favorable treatment in [his] [or] [her] own case may have a reason to make a false statement in order to strike a good bargain with the Government. So while a witness of that kind may be entirely truthful when testifying, you should consider that testimony with more caution than the testimony of other
witnesses When scientific, technical or other specialized knowledge might be helpful, a person who has special training or experience in that field is allowed to state an opinion about the matter. But that doesn't mean you must accept the witness's opinion. As with any other witness's testimony, you must decide for yourself whether to rely upon the opinion.

You've been permitted to take notes during the trial. Most of you – perhaps all of you-have taken advantage of that opportunity. You must use your notes only as a memory aid during deliberations. You must not give your notes

priority over your independent recollection of the evidence. And you must not allow yourself to be unduly influenced by the notes of other jurors.

I emphasize that notes are not entitled to any greater weight than your memories or impressions about the testimony.

Stipulation

The evidence in this case includes facts to which the lawyers have agreed or stipulated. A stipulation means simply that the Government and the Defendant accept the truth of a particular proposition or fact. Since there is no disagreement, there is no need for evidence apart from the stipulation. You must accept the stipulation as fact to be given whatever weight you choose.

The indictment charges the Defendant with 11 separate crimes, called "counts." Each count has a number and refers to a criminal charge against the Defendant in this case. You will be given a copy of the indictment to refer to during your deliberations.

Count 1 charges that the Defendant knowingly and willfully conspired to commit wire fraud and health care fraud.

Count 2 charges that the Defendant knowingly and willfully conspired to distribute and dispense a controlled substance, outside the scope of professional practice and not for a legitimate medical purpose, namely a mixture and substance containing a detectable amount of Oxycodone.

Count 3 charges that the Defendant knowingly and intentionally distributed and dispensed
a controlle4 substance, outside the scope of professional practice and not for a legitimate medical purpose, namely a mixture and substance containing a detectable amount of Oxycodone, and that the Oxycodone resulted in the death of the user, J.H.; that is, that the Oxycodone was a but-for cause of the death of J.H.

Counts 4 through 10 charge that the Defendant knowingly committed money laundering.

Count 11 charges that the Defendant knowingly evaded a currency-transaction reporting requirement.

I will explain the law governing conspiracy and the law governing the substantive offenses in a moment.
But, first note that the Defendant is not charged in

Counts 1 and 2 with committing a
substantive offense - the Defendant is charged with *conspiring* to commit those offenses.

Conspiracy to Commit Health Care Fraud and wire Fraud

Count 1 charges that the Defendant with conspiracy to commit wire fraud and health care fraud.
It's a Federal crime to knowingly and willfully conspire or agree with someone to do something that, if actually carried out, would result in the crime of wire fraud or health care fraud. A "conspiracy" is an agreement by two or more persons to commit an unlawful act. In other_ words, it is a kind of partnership for criminal purposes. Every member of the conspiracy becomes the agent or partner of every

other member.

The government does not have to prove that all the people named in the indictment were members of the plan, or that those who were members made any kind of formal agreement. The heart of a conspiracy is the making of the unlawful plan itself, so the Government does not have to prove that the conspirators succeeded in carrying out the plan. In addition, some of the people who may have been involved in these events are not on trial. This does not matter. There is no requirement that all members of a conspiracy be charged and prosecuted, or that they all be tried together in one proceeding.

A Defendant can be found guilty of this conspiracy offense only if all the following facts are proved beyond a reasonable doubt:

(1) two or more persons, in some way or manner, agreed to try to accomplish a common and unlawful plan, that is a plan to commit wire fraud or health care fraud, as charged in the indictment; and
(2) defendant knew the unlawful purpose of the plan and willfully joined in it.

A person may be a conspirator even without knowing all the details of the unlawful plan or the names and identities of all the other alleged conspirators.
If a Defendant played only a minor part in the plan but had a general understanding of the unlawful purpose of the plan- and willfully joined in the plan on at least one occasion- that's sufficient for you to find a Defendant guilty. But simply being present at the scene of an event or merely associating with certain people and discussing

common goals and interests doesn't establish pro9f of a conspiracy. Also, a person who doesn't know about a conspiracy but happens to act in a way that advances some purpose of one doesn't automatically become a conspirator.

Health Care Fraud 18 U.S.C. § 1347

It's a Federal crime to knowingly and willfully execute, or attempt to execute, a scheme or artifice to defraud a health-care benefit program,' or to get any of the money or property owned by, or under the custody or control of, a healthcare benefit program by means of false or fraudulent pretenses, representations, or pretenses.
The Defendant can be found guilty of this offense only if all the following facts are proved beyond a reasonable doubt:
(l)the Defendant knowingly executed, or attempted to execute, a scheme or artifice to defraud a health-care benefit program, or to obtain money or property owned by, or under the custody or control of, a health-care benefit pr:0gram] by means of false or fraudulent pretenses, representations, or promises;
2) the health care benefit program affected interstate commerce;
(3)the false or fraudulent pretenses, representations, or promises
related to a material fact;
(4)the Defendant acted willfully and intended to defraud; and
(5) the Defendant did so in connection with the delivery of or payment for health-care benefits, items, or services.
"Health-care benefit program" means any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided

to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract.

A health care program affects interstate commerce if the health care program had any impact on the movement of any money, goods, services, or persons from one state to another or between another country and the United States. The Government need only prove that the health care program itself either engaged in interstate commerce or that its activity affected interstate commerce to any degree. The Government need not prove that [the] [a] Defendant engaged in interstate commerce or that the acts of [the] [a] Defendant affected interstate commerce.

A "scheme to defraud" includes any plan or course of action intended to deceive or cheat someone out of money or property by using false or fraudulent pretenses, representations, or promises relating to a material fact.

A statement or representation is "false" or "fraudulent" if it is about a material fact that the speaker knows is untrue or makes with reckless indifference as to the truth and makes with intent to defraud. A statement or representation may be "false" or "fraudulent" when it's a half truth or effectively conceals a material fact and is made with the intent to defraud.

A "material fact" is an important fact that a reasonable person would use to
decide whether to do or not do something. A fact is

"material" if it has the capacity or natural tendency to influence a person's decision. It doesn't matter whether the decision-maker actually relied on the statement or knew or should have known that the statement was false.

To act with "intent to defraud" means to do something with the specific intent to deceive or cheat someone, usually for personal financial gain or to cause financial loss to someone else. The Government doesn't have to prove all the details alleged in the indictment about the precise nature and purpose of the scheme. The Government also doesn't have to prove that the alleged scheme actually succeeded in defrauding anyone. What must be proved beyond a reasonable doubt is that the Defendant knowingly attempted or carried out a scheme substantially similar to the one alleged in the indictment.
It's a Federal crime to use interstate wire, radio, or television communications to carry out a scheme to defraud someone else.

The Defendant can be found guilty of this crime only if all the following facts are proved beyond a reasonable doubt:
(1) the Defendant knowingly devised or participated in a scheme to defraud, or to obtain money or property by using false pretenses, representations, or promises;
(2) the false pretenses, representations, or promises were about a material fact;
(3) the Defendant acted with the intent to defraud; and
(4) the Defendant transmitted or caused to be transmitted by [wire] [radio] [television] some communication in interstate commerce to help carry out the scheme to defraud.
The term "scheme to defraud" includes any plan or course of action intended to deceive or cheat someone out of money or property by using false or fraudulent pretenses,

representations, or promises.

A statement or representation is "false" or "fraudulent" if it is about a material fact that the speaker knows is untrue or makes with reckless indifference to the truth, and makes with the intent to defraud. A statement or representation may be "false" or "fraudulent" when it is a half truth, or effectively conceals a material fact, and is made with the intent to defraud.

A "material fact" is an important fact that a reasonable person would use to decide whether to do or not do something. A fact is "material" if it has the capacity or natural tendency to influence a person's decision. It doesn't matter whether the decision-maker actually relied on the statement or knew or should have known that the statement was false.

The "intent to defraud" is the specific intent to deceive or cheat someone, usually for personal financial gain or to cause financial loss to someone else.
The Government does not have to prove all the details alleged in the indictment about the precise nature and purpose of the scheme. It also doesn't have to prove that the material transmitted by interstate [wire] [radio] [television] was itself false or fraudulent; or that using the [wire] [radio] [television] was intended as the specific or exclusive means of carrying out the alleged fraud; or that the Defendant personally made the transmission over the [wire] [radio] [television]. And it doesn't have to prove that the alleged scheme actually succeeded in defrauding anyone. To ':use" interstate [wire] [radio] [television] communications is to act so that something would normally be sent through wire, radio, or television

communications in the normal course of business.
Each separate use of the interstate [wire] [radio] [television] communications as part of the scheme to defraud is a separate crime.

Controlled Substances: Conspiracy

Title 21, United States Code, Section 846 makes it a separate Federal crime for anyone to conspire or agree with someone else to do something which, if actually carried out, would be a violation of Title 21 United States Code Section 84l(a)(l). Section 841(a)(l) makes it a crime
for anyone to knowingly distribute or dispense Oxycodone.
A "conspiracy" is an agreement by two or more persons to commit an unlawful act. In other words, it is a kind of partnership for criminal purposes. Every member of the conspiracy becomes the agent or partner of every other member.

The Government does not have to prove that all the people named in the indictment were Members of. the plan, or that those who were members made any kind of formal agreement.

The heart of a conspiracy is the making of the unlawful plan itself, so the Government does not have to prove that the conspirators succeeded in carrying out the plan.
In addition, some of the people who may have been involved in these events are not on trial. This does not matter. There is no requirement that all members of a- conspiracy be charged and prosecuted, or that they all be tried together in one proceeding.

The Defendant can be found guilty only if all of the following facts are proved beyond a reasonable doubt:

(1) two or more people in some way agreed to try to accomplish a shared and unlawful plan to distribute or dispense a controlled substance, outside the scope of professional practice and not for a legitimate medical purpose;

(2) the Defendant, knew the unlawful purpose of the plan and willfully joined in it; and

(3) the object of the unlawful plan was to distribute or dispense a controlled substance, outside the scope of professional practice and not for a legitimate medical purpose.

I will explain the law governing outside the scope of professional practice and not for a legitimate medical purpose in a moment.

But first, a person may be a conspirator even without knowing all the details of the unlawful plan or the names and identities of all the other alleged conspirators.

If the Defendant played only a minor part in the plan but had a general understanding of the unlawful purpose of the plan - and willfully joined in the plan on at least one occasion - that's sufficient for you to find the Defendant guilty.

But simply being present at the scene of an event or merely associating with certain people and discussing common goals and interests doesn't establish proof of a conspiracy.

Also a person who doesn't know about a conspiracy but happens to act in a way that advances some purpose of one doesn't automatically become a conspirator.

Controlled Substances:
Distributing and Dispensing a Controlled Substance Resulting in Death

As it concerns Count 3 and the crime underlying the conspiracy charged in Count 2, Title 21, United States Code, Section 841(a)(l), which is the Controlled Substances Act, makes it a federal crime or offense for anyone to unlawfully distribute or dispense, or possess with intent to distribute or dispense, a "controlled substance." Oxycodone is a controlled substance within the meaning of the law. The Defendant is charged with distributing or dispensing, outside the scope of professional practice and not for a legitimate medical purpose, a mixture and substance containing a detectable amount of Oxycodone which resulted in the death of J.H.

- .

The.Defendant can be found guilty of this crime only if the following facts are proved beyond a reasonable doubt:

(1) That-the Defendant dispensed or.distri6uted a controlled substance

2) That the Defendant acted knowingly and intentionally ; and

(3) That the Defendant's actions were not for legitimate medical purposes in the usual course of his professional medical practice or were beyond the bounds of medical practice. that the death of J.H. resulted from-the defendant distributing or dispensing. ..

To "distribute" means to deliver a controlled substance to another person, with, without any financial interest in the transaction.

To "dispense" means to deliver a controlled substance to an-ultimate user

Pursuant to. a lawful order of; a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for delivery. The term "dispenser" means a practitioner who delivers a controlled substance to an ultimate user or research subject.

The term "practitioner" means a physician, pharmacist or other person licensed registered, or otherwise permitted by the United States or the jurisdiction in which he or she practices to distribute or dispense, or cause to be distributed or dispensed, controlled substances in the course of professional practice or research.

The law provides that persons registered by the Attorney General under Title 21 to manufacture, distribute, or dispense controlled substances are authorized to possess, manufacture, distribute or dispense such substances to the extent authorized by their registration. A medical doctor or physician is exempted from the prohibitions of Section 841 when he issues a prescription for a legitimate medical purpose within the usual course of professional practice. A controlled substance is prescribed by a physician in the usual course of professional practice_ and, therefore, lawfully if the substance is prescribed by him as part of his medical treatment for the patient in accordance with the standards of medical practice generally recognized and accepted in the --------
Thus, a medical doctor has violated the Controlled Substances Act when the government has proved, beyond a reasonable doubt, that the doctor's actions were not for legitimate medical purposes or were beyond the bounds of

professional medical practice.

The Defendant is not on trial for medical malpractice and is not charged with acting negligently with respect to the care of his patients. Again, he is charged with knowingly and willfully prescribing controlled substances to his patients outside the usual course of professional medical practice in violation of the Controlled Substances Act.

To find the Defendant guilty of distributing a controlled substance or dispensing, outside the course of professional practice and without a legitimate medical purpose, resulting in death you must find that the controlled substance was a but-for cause of J.H. 's death.

There is no requirement that the Government prove that the Defendant knew that he was distributing or dispensing out the course of professional practice and without legitimate medical purpose a particular kind of controlled substance. Rather, the Government must only prove that the Defendant knew he was distributing or dispensing, outside the course of professional practice and without a legitimate medical purpose, a controlled substance.

Money Laundering

It's a Federal crime for anyone to engage in certain kinds of financial transactions commonly known as money laundering. The Defendant is charged with this crime in Counts 4 through 10.

A Defendant can be found guilty of this offense only if all the following are proved beyond a reasonable doubt;

(1) the Defendant knowingly engaged or attempted to engage in a monetary transaction;

(2) the Defendant knew the transaction involved

property or funds that were the proceeds of some criminal activity; the property had a value of more than $10,000;

(4) the property was, in fact, proceeds of a conspiracy to commit health care fraud and wire fraud or a conspiracy to distribute or dispense a controlled substance; and

(5) the transaction took place in the United States.

The term "monetary transaction" means that deposit, withdrawal, transfer or exchange of funds or a monetary instrument by, through, or to a. financial institution in a way that affects interstate commerce.

A "financial institution" means an insured bank.

The term "proceeds" means any property derived from or obtained or retained, directly or indirectly, through some form of unlawful activity, including the gross receipts of the activity.

In this case, the form unlawful activity from which the property was derived is alleged to be: conspiracy to commit health care fraud and wire fraud and conspiracy to dispense a controlled substance. It doesn't matter whether the Defendant knew the precise nature of' the
crime or that the property was obtained or derived from the crime. But the Government must prove that the Defendant knew that the property involved in the monetary transaction was obtained or derived from committing some crime. Also it doesn't matter whether all the property involved was derived from a crime. The
Government only has to prove that $10,000 worth of the property was obtained or derived from committing a crime.

Evading a Currency-Transaction Reporting Requirement

It's a Federal crime under certain circumstances for anyone to knowingly evade a currency-transaction reporting requirement. Domestic financial institutions and banks (with specific exceptions) must file currency... transaction reports (Form 4789) with the Government. They must list all deposits, withdrawals, transfers, or payments involving more than $10,000 in cash or currency.

The Defendant can be found guilty of this crime only if all the following facts are proved beyond a reasonable doubt:

1) the Defendant knowingly structured or helped to structure a currency transaction;

(2) the purpose of the structured transaction was to evade the transaction-reporting requirements;

(3). the structured transaction involved one or more domestic financial institutions and

(4) the currency transaction with the domestic financial institutions furthered another Federal crime as part of a pattern of illegal activity involving more than $100,000 in a 12-rnonth period. __ ...

To "structure" a transaction means to *deposit,* withdraw, or otherwise participate in transferring a total of more than $10,000 in cash or currency using a financial institution or bank by intentionally setting up or arranging a series of separate transactions, each one involving less than $10,000, in order to evade the currency-reporting requirement that would have applied if fewer transactions had been made.

It's possible to prove the Defendant guilty of a crime even without evidence that the Defendant personally performed every act charged. Ordinarily, any act a person can do may be done by directing another person, or "agent." Or it may be done by acting with or under the direction of others.

A Defendant "aids and abets" a person if the Defendant intentionally joins with the person to commit a crime.

A Defendant is criminally responsible for the acts of another person if the Defendant aids and abets the other person. A Defendant is also responsible if the
Defendant willfully directs or authorizes the acts of an agent, employee, or other associate.
But finding that a Defendant is criminally responsible for the acts of another person requires proof that the Defendant intentionally associated with or participated in the crime - not just proof that the Defendant was simply present at the scene of a crime or knew about it.
In other words, you must find beyond a reasonable doubt that the Defendant was a willful participant and not merely a knowing spectator.

Civil/Regulatory Violations Not a Crime

During this trial you have heard testimony regarding Medicare's civil rules and regulations.

I caution you that a violation of these civil statutes, rules, and regulations is not a crime. This is not a civil case. The Defendant is not on trial for civil violations. Even if you find the claims to Medicare were not allowable under the applicable statutes, rules, and regulations, a Defendant

cannot be convicted of a crime merely for breaching civil statutes, rules, and regulations, applicable to his conduct. However, Medicare's rules and regulations may be relevant in determining whether a Defendant acted with criminal intent; that is, knowingly, willfully, and with the intent to defraud Medicare. That is how you may consider this evidence.

1. Good Faith Defense

The Defendant asserts that he acted in good faith in attempting to treat his patients and prescribe controlled substances. A doctor's good faith is relevant to a determination of whether the doctor acted outside the bounds of medical practice or, instead, with a legitimate medical purpose when prescribing controlled substances. Because of the fluidity (flexibility) of the boundaries of acceptable medical practice and the applicable standard of care, some latitude must be given to a doctor trying to determine the current boundaries of acceptable medical practice .

Thus, even if a doctor's treatment and prescription practice fall below what you determine to be
the applicable standard of care, the doctor should not be held criminally liable if the doctor acted with a .reasonable good faith belief that his treatment prescription of controlled substances ....
complied with the applicable standard of care. Accordingly, even if you find that the Defendant acted below what you determine to be the applicable standard of care in treating his patients and prescribing them controlled substances, you must find him not guilty of unlawful dispensation or distribution of controlled

substances unless you find that the government proved beyond a reasonable doubt that the doctor'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.

Legitimate Medical Purpose and Usual Course of Medical Practice:· Standard of Care

To convict the Defendant of unlawfully dispensing or distributing controlled substances, the Government must prove beyond a reasonable doubt that the Defendant was not acting "for legitimate medical purposes in the usual course of his professional medical purpose" or "beyond the bounds of medical purpose." This requires you to measure the Defendant's conduct against the prevailing standard of care or practice within the Defendant's professional community. Such a standard of care is determined from the laws, rules, and guidelines which govern the Defendant's medical practice where he works. There is no uniform national standard. Accordingly, you should look to the laws, rules, and guidelines that exist in Florida where the Defendant was licensed to, and did, practice medicine.

· Standard of care: Physician or Drug Pusher

In determining whether the Government has proven beyond a reasonable doubt that the Defendant dispensed or distributed controlled substances "outside the usual course of professional medical practice and without a

legitimate medical purpose," you should consider whether, by failing to abide by the applicable standard of care, he left the role of medical doctor and became a drug "pusher." If you find beyond a reasonable doubt that the Defendant failed to abide by the applicable standard of care and, in effect, became a drug "pusher," you should find him guilty of unlawfully dispensing or distributing controlled substances as charged in Count 3.

Standard of Care: Applicable Florida Statutes, Rules, Guidelines

The Defendant was a medical physician licensed and practicing in the State of Florida.

Accordingly, Florida statutes, rules, and guidelines establish the standard of care at, or above, which the Defendant must practice medicine. As you recall, you may only find the Defendant guilty of unlawfully dispensing or distributing controlled substances if the Government proves beyond a reasonable doubt that he acted below the applicable standard of care. The following are some of the important laws, rules, and guidelines that applied to the Defendant as a Florida physician and established the applicable standard of care:

Civil Rights, Health Care Advance Directives, Pain Management and Palliative Care.

In Florida, every competent adult has a fundamental right to self-determination regarding decisions pertaining to his or her own health, including the right to choose or refuse medical treatment. This right is subject to certain interests of society, such as the protection of human life and the preservation of ethical standards in

medical profession. Palliative care is the comprehensive management of the physical, psychological, social, spiritual, and existential needs of patients. It includes an assurance that physical and mental suffering will be carefully attended to by licensed health care providers and practitioners must comply with a request for pain management or palliative care from a patient under their care. A health care provider is not subject
to criminal law, prosecution or civil liability, and will not be deemed to have engaged in unprofessional conduct, as $1 result of carrying out a health care decision made in accordance with these provisions. Sections 765.102(1), 765.109(1), 765.1103(2), Florida Statutes.

Florida residents enjoy the certain rights to health care to promote the interests and wellbeing of the patients of health care providers and health care facilities. This includes the right to access any mode of treatment that is, in his or her own judgment and the judgment of his or her health care practitioner, in the best interests of the patient.

Medical Practice, Intractable pain; authorized treatment

Intractable pain means pain means pain for which, in the generally accepted course of medical practice, the cause cannot be removed or otherwise treated. Notwithstanding any other provision of law, a physician may prescribe or administer any controlled substance under
Schedules II-V to a person for the treatment of intractable pain, provided the physician does so in accordance with that level of care, skill, and treatment recognized by a reasonably prudent physician under similar conditions and circumstances.

Workers' Compensation, Medical services

Whenever a Florida physician provides care in the context of Workers' Compensation, he shall provide such care on the premise that returning to work is an integral part of the treatment plan. He shall provide any and all such medically necessary service or treatment that is appropriate to the patient's diagnosis and status of recovery, and is consistent with the location of service, the
level of care provided, and applicable practice parameters. The service must be widely accepted among practicing health care providers, based on scientific criteria, and determined to be reasonably safe. The care shall_ utilize a high intensity, short duration treatment approach that
focuses on early activation and restoration of function whenever possible .

Board of Medicine Standards for Use of Controlled Substances for Pain Treatment

The Board of Medicine recognizes that principles of quality medical practice dictate that the people of the State of Florida have access to appropriate and effective pain relief. The Board encourages physicians to view effective pain management as a part of quality
medical practice for all patients with pain, acute or chronic. Fears of investigation or sanction by
federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agencies for prescribing or dispensing, or administering controlled substances including opioid analgesics, for a legitimate medical purpose and that is

supported by appropriate documentation establishing a valid medical need and treatment plan. The Board will consider prescribing, ordering, administering, or dispensing controlled substances _ for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. Each case of prescribing
for pain will be evaluated on an individual basis. The Board will not take disciplinary action
against a physician for failing to adhere strictly to the provisions of these standards, if good cause is shown for such deviation.

Entrapment

"Entrapment" occurs when law-enforcement officers or others under their direction persuade a defendant to commit a crime that the defendant had no previous intent to commit. The Defendant has claimed to be a victim of entrapment regarding the charged offenses. The law
forbids convicting an entrapped defendant. But there is no entrapment when a defendant is willing to break the law and the Government merely provides what appears to be a favorable opportunity for the defendant to commit a crime. For example, it's not entrapment for a Government agent to pretend to be someone else -and offer - directly or through another person - to engage in an unlawful transaction. So a defendant isn't a victim of entrapment if you find beyond a reasonable doubt tp.at the government only offered the defendant an opportunity to commit a crime the defendant was already willing to commit. But if there is a reasonable doubt about whether the
Defendant :was willing to commit the crime without the persuasion of a Government officer or a

person under the Government's direction, then you must find the Defendant not guilty.

You'll see that the indictment charges that a crime was committed "on or about" a certain date. The Government doesn't have to prove that the crime occurred on an exact date. The Government only has to prove beyond a reasonable doubt that the crime was committed on a date reasonably close to the date alleged.

The word "knowingly" means that an act was done voluntarily and intentionally and not because of a mistake or by accident.

[The word "willfully" means that the act was committed voluntarily and purposely, with the intent to do something the law forbids; that is, with the bad purpose to disobey or disregard the law. While a person must have acted with the intent to do something the law forbids before you can find that the person acted "willfully," the person need not be aware of the specific law or rule that [his] [her] conduct may be violating.]

Each count of the indictment charges a separate crime. You must consider each crime and the evidence relating to it separately. If you find the Defendant guilty or not guilty of one crime, that must not affect your verdict for any other crime

I caution you that the Defendant is on trial only for the specific crimes charged in the indictment. You're here to determine from the evidence in this case whether the Defendant is guilty or not guilty of those specific crimes.

You must never consider punishment in any way to decide

whether the Defendant is guilty. If you find the Defendant guilty, the punishment is for the Judge alone to decide later.

Your verdict, whether guilty or not guilty, must be unanimous - in other words, you must all agree. Your deliberations are secret, and you will never have to explain your verdict to anyone. Each of you must decide the case for yourself, but only after fully considering the evidence with the other jurors. So you must discuss the case with one another and try to reach an agreement. While you're discussing the case, don't hesitate to reexamine your own opinion and change your mind if you become convinced that you were wrong. But don't give up your honest beliefs just because others think differently or because you simply want to get the case over with. Remember that, in a very real way, you're judges - judges of the facts. Your only interest is to seek the truth from the evidence in the case.

When you get to the jury room, choose one of your members to act as foreperson. The foreperson will direct your deliberations and will speak for you in court.

A verdict form has been prepared for your convenience.

[Explain verdict]

Take the verdict form with you to the jury room. When you've all agreed on the verdict, your foreperson must fill in the form, sign it, date it, and carry it. Then you'll return it to the courtroom. If you wish to communicate with me at any time, please write down your message or question and give it to the marshal. The marshal will bring it to me and I'll respond as promptly as possible - either in writing or by talking to you in the courtroom. But I caution you not to tell me how many jurors have voted one way or the other at that time.

APPENDIX E

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
CASE NO. 17-60301-CR-WPD

UNITED STATES OF AMERICA,

Plaintiff,
V.

ANDRES MENCIA, MD

Defendant.

DEFENDANT ANDRES MENCIA'S MOTION TO DISMISS OR IN THE ALTERNATIVE FOR A NEW TRIAL

The Defendant, Dr. Andres Mencia moves this Honorable Court to enter an order vacating the conviction as to Count Two of the Indictment and dismissing that count because the statute under which Dr. Mencia was convicted is unconstitutionally vague, creates an impermissible uncertainty in the law and/or seeks to impose criminal liability based on alleged violations of administrative regulations. In the alternative, and pursuant to Rule 33 of the Federal Rules of Criminal Procedure, Dr. Mencia moves for a new trial on procedural, evidentiary and substantive grounds as detailed below.

VAGUENESS AND UNCERTAINTY IN THE LAW

Vagueness

Section 841 of Title 21 of the United States Code (the underlying statute of which Dr. Mencia was convicted of conspiring to violate) is unconstitutionally vague, particularly as it is applied to the practice of medicine. While this case, like many overprescribing cases, was about the "standard of care," the statute does not mention, much less define, that phrase. Indeed, the phrase the meaning of which everyone was chasing in the courtroom was "legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," a phrase that also does not appear in the statute and is not defined (even in the regulations from which it is taken). Dr. Mencia was convicted of one count of conspiring to depart so drastically from the "standard of care" for the treatment of chronic pain with controlled substances that he should be treated as a "drug pusher," *Moore v. United States,* 423 U.S. 122, 124 (1975), rather than as a physician. To comply with the notice requirements of the Fifth and Sixth Amendments, the unstated premise for such a charge is that Congress (or a federal agency with the properly delegated authority) has identified and published a "standard of care" against which the Court, and more importantly the jury, could have measured Dr. Mencia's conduct. As demonstrated below, no federal statute or administrative regulation even attempts to define that baseline standard.

In 1970, Congress enacted the Controlled Substance Act ("CSA") as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (1970) (codified at 21 U.S.C. §§ 801-904). Under 2 l U.S.C. §841 (a)(l), "it shall be unlawful
for any person to knowingly or intentionally distribute ... or possess with intent to ... distribute, a controlled substance." However, in findings accompanying the CSA, 21 U.S.C. §801(1), Congress specifically recognized that "[m]any of the drugs included within this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." Therefore, Congress created several exceptions to the ban on distribution. The relevant one here is 21 U.S.C. §822(6), which empowers the Attorney General to implement a registration process to authorize medical professionals, referred to as "registrants," to dispense controlled substances. Section 829 permits "a practitioner" to dispense controlled substances by prescription. A physician is a "practitioner" under 2 l U.S.C. §802(21) and is therefore authorized to dispense controlled substances by being registered with the Attorney General under the provisions of 21 U.S.C. §822(a)(2). Section 844 makes it "unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, *while acting in the course of his professional practice* .... " (Emphasis added.)

In 1971, pursuant to his alleged authority to issue rules regulating controlled substances under the CSA, *see* 21 U.S.C. § 871 (b), then-Attorney General John Mitchell

promulgated the following regulation:

> A prescription for a controlled substance to be effective must be issued for *a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice* . ... An order purporting to be a prescription issued not in the usual course of professional treatment ... is not a prescription within the meaning and intent of ... the Act and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04 (originally designated as 21 C.F.R. § 306.04).

Three years later, the Supreme Court in *Moore v. United States,* 423 U.S. 122, 124 (1975), upheld the government's right to prosecute physicians for illegally distributing controlled substances, holding that registered physicians "can be prosecuted under §841 when their activities fall outside the usual course of a professional practice." In so ruling, however, the Supreme Court recognized that the CSA's legislative history indicated that Congress did not mean to prevent physicians from treating drug "addicts" and that "[t]he practicing physician has ... been *confused* as to when he may prescribe narcotic drugs to an addict." *Moore,* 423 U.S. at 143-44 (emphasis added). The Supreme Court then found that Congress's "solution to this problem" was to place the duty in the hands of the Secretary of Health, Education and Welfare [now the Secretary of the

HHS] "'to determine the appropriate methods of professional practice in medical treatment of ... narcotic addiction." *Id.* at 144, citing H.R. Rep. No. 91-1444, accompanying the enactment of 42 U.S.C. §257a (now §290bb-2a). Placing this function under the authority of the HHS, rather than the Department of Justice, was intentional, the Supreme Court found, because Congress was aware that "'criminal prosecutions' in the past had turned on the opinions of federal prosecutors." *Id.* It was Congress's intent"' *to clarify* for the medical profession ... the extent to which they may safely go in treating narcotic addicts as patients"' so that "'[t]hose physicians who comply with the recommendations made by the **[HHS]** will no longer jeopardize their professional careers." *Id.* (emphasis added). Although the Supreme Court in *Moore* affirmed the conviction of a doctor, it did so without describing the "standard of care" from any source. Nor was it required to do so, since, as the Supreme Court noted, "Respondent *concedes in his brief that he did not observe generally accepted medical practices." Id.* at 126 (emphasis added). The only guidance provided by the Supreme Court in *Moore* was that a physician had to prescribe controlled substances "as a physician" rather than "as a large-scale pusher." *Id.* at 143. The scope of the DOJ's authority to define the practice of medicine remained unsettled until 2006. In *Gonzalez v. Oregon,* 546 U.S. 243 (2006), the Supreme Court conclusively established that, absent Congressional action, the Attorney General has no properly-delegated authority to define the contours of the practice of medicine, including what constitutes a "legitimate medical purpose" for the prescribing of controlled substances and when prescribing practices are within a physician's "professional practice." At issue in

Gonzalez was whether 21 C.F.R. § 1306.04 gave the Attorney General authority to outlaw the medical conduct considered legitimate under Oregon law - in particular, an Oregon statute authorizing physicians in the State of Oregon to prescribe a lethal dose of drugs to an Oregon resident with a terminal illness. The Attorney General declared that the prescription practice protected by Oregon law, a lethal dose of drugs to a terminally ill patient, violated§ 1306.04 (and hence §841(a)) because such prescriptions would not be "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." The case, therefore, called upon the Supreme Court to address squarely the question of "[w]ho decides whether a particular activity is in 'the course of professional practice' or done for a 'legitimate medical purpose.'" *Gonzalez,* 546 U.S. at 257. Before answering this question, the Supreme Court recognized the inherent ambiguity in these terms: "All would agree, we should think, that the statutory phrase 'legitimate medical purpose' *is a generality, susceptible to more precise definition* and *open to varying constructions, and thus ambiguous* in the relevant sense." *Id.* at 258 (emphasis added). After analyzing the CSA as a whole, the Supreme court held that Congress had given the Attorney General the power to "promulgate rules relating *only* to 'registration' and 'control,' and 'for the efficient execution of his functions'" and had *not* delegated to the Attorney General the power to "define standards of medical practice." *Id.* at 769 (citations omitted).

The Supreme Court went on to explain that *post-Moore* amendments to the CSA did not alter this conclusion. In 1984, Congress amended the CSA

to authorize the Attorney General to revoke a physician's prescription privileges upon his determination that the physician has "committed such acts as would render his registration .. . inconsistent with the public interest(.]" 21 U.S.C. § 824(a)(4). When determining what acts are inconsistent with the public interest, the Attorney General must consider the following factors:

(l) The recommendation of the appropriate State licensing board or professional
disciplinary authority;

(2) The applicant's expertise in dispensing .. . controlled substances;

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances;

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances;

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823(f).

The Supreme Court, however, held that the enactment of§ 824(a)(4) did not give the Attorney General the power to define the scope of a physician's authority to prescribe drugs. *Id.* at 262. The Supreme Court then reiterated what it noted in *Moore* - that in enacting the CSA, "Congress sought to change the fact 'that criminal prosecutions in the past had turned on the opinions of federal prosecutors.'" *Id.* at 226, quoting *Moore,* 423 U.S. at 144. Therefore, the CSA "allocates decision-making powers among statutory actors so that medical judgments, if they are to be decided at the federal level and for limited objects of the statute, are placed in the hands of
the [HHS]." *Id.* at 265. *See also id* at 250 (recognizing that

"on scientific and medical matters [the Attorney General] is required to accept the findings of the [HHS]"). In the absence of any rules promulgated by the HHS to define appropriate medical practice, the Supreme Court held that the Attorney General "is not authorized to make a rule declaring illegitimate a medical standard for care and treatment of patients *that is specifically authorized by state law." Id.* at 258 (emphasis added). After examining the entire structure of the CSA and related enactments, the Supreme Court concluded that "[t]he structure of the CSA ... [c]onveys unwillingness to cede medical judgments to an Executive official who lacks medical expertise." *Id.* at 266. To be sure, the Supreme Court left open whether the Attorney General would have authority under the CSA to promulgate regulations or interpretive statements "concerning matters closer to his role under the CSA, namely preventing doctors from engaging in illicit drug trafficking." *Id.* at 268.

The Court also stated in dicta that "there is no question that the Federal Government can set uniform national standards in these areas." *Id.* at 271.4 However, the Court recognized that to date Congress had done so in "only one area," the treatment of narcotic addicts. *Id.* at 272, citing 42 U.S.C. §290bb-2a. Regarding the prescription of controlled substances for other reasons, such as pain relief, the Supreme Court recognized that Congress had so far only intended to bar "doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking *as conventionally understood.* Beyond this, however, the (CSA] manifests no intent to regulate the practice of medicine generally." *Id.* at 270 (emphasis added).

Indeed, the Court found that Congress clearly intended to limit federal authority to define the practice of medicine

through the statute's non-preemption clause, 21 U.S.C. § 903, which provides that the CSA shall not be construed to preempt state law unless there is a "positive conflict" between the text of the statute and state law. *Id.* at 270-71. Despite the fact that the language of§ 290bb-2a is mandatory in nature, the HHS has never promulgated regulations defining "the appropriate methods of professional practice in the medical treatment" of patients who suffer from intractable or chronic pain and become physically dependent or "addicted" to the medication used to treat the pain. Congress has, however, enacted a statute that *prohibits restrictions* on federal funding of health care programs where the service was furnished to the patient "for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as such item, good, benefit, or service is not also furnished for the purpose of causing, or the purpose of assisting in causing, death, for any reason." 42 U.S.C. 4. It is unclear what the Supreme Court meant by this dicta, since the Supreme Court has consistently held that the practice of medicine is governed by the states. *See Linder v. United States,* 268 U.S. 5, 18 (1925) ("[o]bviously, direct control of medical practice in the States is beyond the power of the federal government"). *See also Barsky v. Board of Regents,* 347 U.S. 442, 449 (1954).§ 14402.

In conclusion, the lessons to be learned from this review of federal law are: (l) no federal statute or regulation exists which establishes a "standard of care" for the use of controlled substances to treat chronic pain; (2) the DOJ has no authority to do so and the agency that might have that authority, the HHS, has failed to act; (3) in the absence of binding federal authority, state law governs the practice of medicine; (4) the statutory phrase

"legitimate medical purpose" is "a generality, susceptible to more precise definition and open to varying constructions, and thus [is] ambiguous .... " *Gonzalez,* 546 U.S. at 257; and (5) Congress did not intend "criminal prosecutions" in this area to "turn[] on the opinions of federal prosecutors.'" *Id.* at 226, quoting *Moore,* 423 U.S.
at 144.

Further complicating the analysis, and a subject of much debate at trial, is Florida's statutes and regulations regarding the practice of medicine, prescription of controlled substances and the treatment of pain. Indeed, and to begin with, Florida law, like Federal law, exempts physicians from being charged with drug trafficking when they write prescriptions for controlled substances, so long as the physician is "acting in the course of his or her professional practice." Fla. Stat.§ 893.13(6)(a). Subsection 895. l 3(8)(b) further provides that if a doctor writes one or more controlled substance prescriptions for a patient or "other person" for which there was "no medical necessity or which was in excess of what was medically necessary" to treat the person, *"that fact does not give rise to any presumption that the prescribing practitioner violated subparagraph (a)l.,* but may be considered with other competent evidence" in determining whether the physician committed a crime. Section 893.13(6)(a) was based on, and is nearly identical to, a parallel *civil* statute, Fla. Stat. §458.333(1), which sets forth a list of disciplinary infractions punishable by the Board of Medicine ("BOM").1 Subsection 458.331 (l)(q) prohibits physicians from prescribing drugs "other than in the course of a physician's professional practice"and establishes that prescribing legend drugs "inappropriately or in excessive quantities" is presumed to not be in the course of professional practice. However, neither the Florida Legislature nor the Board of

Medicine have defined when - under what circumstances, for what illnesses and conditions, and in what quantities and doses - physicians in Florida may prescribe opioid medications "inside" the course of their medical practices. Yet, Florida law requires - even to impose civil sanctions under§ 458.33l (l)(q) – the establishment of a "standard of care" and that this "standard" be established by reference to *published* guidelines and not just the *ad hoc* opinions of paid experts. *See AFCA v. Hoover,* Case No. 94-46 28 (Sept. 25, 1995), *1995 Fla. Div. Adm. Hear. LEXIS 4834,* at *22 (the BOM's "failure to offer any standard against which Respondent's conduct can be measured" *standing alone* "prevents [the BOM] from meeting its burden of proof') (emphasis added), *aff'd, Hoover v. Agency for Health Care Administration,* 6 76 So.2d 13 80, 1381, 13 84 (Fla. 3d DCA 1996); *Purvis v. Dept. of Prof Reg., Brd. of Vet. Med.,* 46 1 So. 2 d 134 (Fla. 1st DCA 1984) ("An essential element of proof of a deviation from acceptable standards of care, skill and treatment is proof of what constitutes acceptable standards"). *Cf Hill v. Med/antic Health Care Group,* 933 A.2d 314 , 319, 325 (D.C. App. 2 007) (affirming summary judgment in favor of physician in malpractice action, holding that the opinion of Hill's expert was insufficient because there was no "independent basis for his knowledge of the applicable national standard of care and for his opinion regarding The BOM is a Division of the Department of Health. *See* Fla. Stat.§§ 20.43 and 458.307. Through§ 458.225, the Florida Legislature authorized the BOM to investigate complaints against physicians and initiate proceedings against them governed by Florida's Administrative Procedure Act. The actions of the Board are then reviewable in the District Courts of Appeal.

compliance with or breach of such standard"). *See also In the Matter of Lucas Anthony Dileo, MD.,* 661 So.2d 162,

165-67 (La. App. 1995), *rev. den.*, 666 So.2d 1085 (La. 1996) (reversing the discipline of a physician for allegedly overly prescribing opioids where the Medical Board's case was based only upon "the subjective interpretation" of an expert who "failed to cite to any regulation or statute that had been violated" and where there were "no written standards published governing how long pain medicine is to be prescribed," holding that "the Board must prove by competent evidence the appropriate standard of care and how it has been violated in this particular incident"); *Williams v. Tenn. Board of Medical Examiners,* No. 0 l -A-01-9402-CH-00060 (Tenn.App. Aug. 12, 1994), *1994 Tenn. App. LEXIS 443,* at **16-22 (reversing discipline against a physician for overtreating 4 patients with pain medication where the expert never interviewed the patients, no physicians who treated the patients testified and where "the record failed to articulate a standard of care from which the petitioner allegedly deviated"); *In re Williams,* 60 Ohio St. 3d 85, 573 N.E.2d 638, 638-39 (Ohio 1991) (reversing doctor's suspension for insufficient evidence, noting the medical experts were divided and "there is no statute or rule governing the situation"). If the establishment of a "standard of care" is a necessary predicate for mere civil disciplinary actions, it must certainly be necessary in criminal cases. Moreover, although the standards for committing a criminal violation of§ 893.13(6)(a) and a civil violation under Fla. Stat. §458.333(l)(q) appear to be identical, in fact they are not. Although no Florida court has articulated a clear means of distinguishing between civil and criminal violations, the United States Supreme Court requires proof that the physician so exceed the standard of care that "he acted as a large-scale 'pusher' - not as a physician." *United States v.*

Moore, 423 U.S. 122, 143 (1975). *Cf Dept. of Health, Brd. of Med. v. Waters,* Case Nos. 04- 0400PL, *2005 Fla. Div. Adm. Hear. LEXIS 1257* (August 30, 2005), at *_ ("The wrongdoing that

Section 458.331 (l)(q) seeks to prevent, it bears repeating, is 'prescribing ... a legend drug ... other than in the course of the physician's professional practice .... .' To establish guilt, the Department must prove that the accused doctor was not practicing medicine when he prescribed the drugs in question but instead was engaged in an illicit (and probably oftentimes criminal) activity, e.g. selling narcotics to a 'patient' who was not really sick but wanted the drugs for recreational purposes"), *aff'd, Waters v. Dept. of Health,* 962 So.2d 1011 (3d DCA 2007). Accordingly, the line between a civil violation for acting "other than in the course of a physician's professional practice" and a criminal violation for what sounds like the same thing is really a matter of degree. "[I]t is *the extent and severity of departures* from the professional norms that underpin a jury's finding of criminal violations." *United States v. McIver,* 470 F.3d 550, 559-62 (4th Cir. 2006). Malpractice and even gross malpractice are not enough. "It is immaterial whether the physician is correct in his diagnosis, improvident in his administration of controlled substance[s] or varies from the practice of other physicians, *unless he varies so much* as to be unreasonable in quantity or length of time" that criminal sanctions are appropriate. *People v. Schade,* 30 Cal. App. 4th 1515, 1546, 32 Cal. Rptr. 2d 59, 79 (1994), *review dismissed,* 895 P.2d 55, 41 Cal. Rptr. 2d 219 (1995). *See also United States v. Feingold,* 454 F .3d 1001, 1007 (9th Cir. 2006) (the "essential issue for a jury to determine" is "whether a practitioner has acted not as a doctor, or even as a *bad* doctor, but as a 'pusher' whose conduct is without a legitimate justification" and that "[a]

practitioner becomes a criminal not when he is a *bad* or *negligent* physician, but when he ceases to be a physician *at all")* (emphasis in original). In order to determine any degree of variance from the standard of care obviously first requires there to *be* an ascertainable baseline standard of care. "[O]nly after assessing the standards to which medical professions generally hold themselves is it possible to evaluate whether a practitioner's conduct has deviated so far from the 'usual course of professional practice' that his actions become criminal." *Feingold,* 454 F.3d at 1007. Since "direct control of medical practice
in the States is beyond the power of the federal government," *Linder v. United States,* 268 U.S. 5,
18 (1925), the applicable standard of medical care for the use of opioids is governed by Florida law. With no *specific* statutes or rules dictating when and how physicians may prescribe opioids, Dr. Mencia necessarily had to rely on a hodgepodge of statutes scattered in disparate parts of the code. We summarize these provisions, some of which were discussed at trial on the government's instigation below.

Florida's Statewide Standards

In Florida, those standards meant to apply to all practitioners in the State are determined, at least in part, by the Florida Legislature and the BOM through its rule-making authority. These standards, in turn, may be further defined in the published disciplinary opinions of the BOM and ultimately the opinions of Florida courts if the BOM rulings are appealed. The Florida Legislature
has enacted a smorgasbord of statutes that permit, and frequently require, physicians licensed to practice medicine in Florida to provide certain types of treatment, or treatment for specific purposes, to patients that may require the use of controlled substances. For example,

Florida law authorizes physicians to prescribe or administer controlled substances to treat "intractable" pain -defined broadly as pain for which "the cause cannot be removed and otherwise treated" and that this power trumps every other Florida law or regulation. *See* Fla. Stat. § 458.326(3) *("Notwithstanding any other provision of law,* a physician may prescribe or administer any controlled substance under Schedules II-V .... to a person for the treatment of intractable pain ... ").

l. Chapter 765

Physicians in Florida must also comply with the provisions of Chapter 765, part of Title 44 governing civil rights in general. While Chapter 765 is entitled "Health Care Advance Directives," its provisions are broadly worded to apply beyond situations involving the terminally ill. Several provisions are unique to Florida.

First, Fla. Stat. 765 .102(1) gives *patients* "fundamental rights" over their own treatment options: "The Legislature finds that every competent adult has *the fundamental right of self-determination regarding decisions* to his or her own health, *including the right to choose* or refuse *medical treatment."* (Emphasis added.) Subsection (I) only subjugates with fundamental right to "certain interest of society, such as the protection of human life and the preservation of ethical standards in the medical profession." In the Patient Bill of Rights and Responsibilities, Fla. Stat.§ 381.026, the Florida Legislature reiterated that the patient's decisions about treatment have at least equal weight as the doctor's. Thus, subsection 38 I .026(4)(d)(3) *provides that "[a} patient has the right to access any mode of treatment that is,* in his or her own judgment and the judgment of his or her health care practitioner, in the best interests of the patient...." (Emphasis added.)

Second, Fla. Stat. § 765.1103(1), governing "Pain management and palliative care," states, as a threshold matter, that a patient "shall be given information concerning pain management and palliative care" when they are treated by a physician. Subsection (2) then sets forth a mandatory obligation on all Florida doctors: "Health care providers and practitioners regulated under chapter 458, chapter 459, or chapter 464 *must,* as appropriate, comply with *a request for pain management or palliative care from a patient under their care* .... " The term "palliative care" is then specifically defined in Fla. Stat. § 765.102(5)(a) as "the comprehensive management of the physical, psychological, social, spiritual, and existential needs of patients."

Subsection (5)(b) then provides a list of what palliative care "must include." Among other things, palliative care must include "[a]ssurance that physical and mental suffering will be carefully attended to."

Third, Fla. Stat. 765.109(1) protects physicians who follow the dictates of Chapter 765 by making them immune from both censure by the BOM, civil liability *and* criminal prosecution:

"A health care ... provider ... is not subject to criminal prosecution or civil liability, and will not be deemed to have engaged in unprofessional conduct, as a result of carrying out a health care decision made in accordance with the provisions of this chapter." Subsection (2) provides that this immunity applies "unless it is shown by a preponderance of the evidence that the person authorizing or effectuating a health care decision did not, in good faith, comply with the provisions of this chapter."

2. Chapter 440 (Workers' Compensation

The Florida Legislature has also defined medical standards in Chapter 440, which contains

Florida's Workers' Compensation provisions, which although the government attempted to intimate only applied to those patients who are privileged enough to work for an employer that carries this type of insurance, can fairly be read to inform the standard of care due to those who want- and often need -- to return to work, but cannot because of some medical condition, including

chronic or acute pain. Under Fla. Stat. § 440.13(2), employers are required to pay for "medically necessary

remedial treatment, care, and attendance for such period as the nature of the injury or the process of recovery may require, which is in accordance with established practice parameters and protocols of treatment as provided for in this chapter, including medicines .... " The term "medically necessary" is defined in Fla. Stat. § 440.13(1)(I) and

"Medical necessity" thus includes "any medical service ... which is used to identify or treat an illness or injury, is appropriate to the patient's diagnosis and status of recovery, and is consistent with the location of service, the level of care provided, and applicable practice parameters." To guide a physician in determining the appropriate treatment of an ailing worker, the Florida Legislature has dictated specific "Standards of Care" in Fla. Stat.§ 440.13(16). Subsection (16)(6) sets forth a *mandatory* rule that physicians are "[a]t all times" *required* to use, in choosing treatment options, the treatment that will allow the patient to return to work in the shortest period of time: *"At all times during* evaluation and treatment, the provider *shall* act on the premise that

returning to work is an integral part of the treatment plan. The goal of removing all restrictions and limitations *as early as appropriate* ***shall*** be part of the treatment plan on a continuous basis." (Emphasis added.) Subsection (16)(c)(l) goes even further and defines the "reasonable necessary medical care" that physicians must provide to be *"a high intensity, short duration treatment approach* that focuses on *early activation and restoration of function* whenever possible." (Emphasis added.) Dr. Silverman, the government's expert on "standard of care," agreed that the prescription of opioid analgesics squarely fit within the definition of "a high intensity, short duration treatment approach that focuses on early activation and restoration of function." In order to fulfill the mandatory obligation to use a "high intensity, short duration treatment approach" in order to allow the patient to "return[] to work" as "early" as possible, the Florida Legislature has encouraged doctors to use pain medication. This is not surprising, as leaving long term pain undertreated has cost the economy billions of dollars annually in lost productivity and health care utilization.2 In Fla. Stat. § 440.13(2), the Florida Legislature therefore defines "remedial treatment" as including "pain management programs credited by the Commission on Accreditation of Rehabilitation Facilities or Joint Commission on the Accreditation of Health Organizations or pain-management programs affiliated with medical schools .... " The use of pain medication is also encouraged by the fact that the statute specifically covers "palliative care," which is defined (consistent with the definition used in Chapter 765) as "noncurative medical services that mitigate the conditions, effects, or pain of an injury." *See* Fla. Stat.§ 440.13(n). *See,*
e.g., Baron Transport v. Riley, 491 So.2d 1220, 1220 (Fla.

151 DCA 1986). *Accord Clements v. Morrow's Nut House,* 598 So.2d 279 (Fla. 1st DCA 1992); *Professional Administrators v. Nationwide Ins. Co.,* 448 So.2d 1159, 1160 (Fla. 151 DCA 1984) (back pain) (citations omitted); *Thomas v. U Haul of West Coast,* 467 So.2d 719 (Fla. 1st DCA 1985) (back pain).

3. The Patient Bill of Rights and Responsibilities

At the same time that the Florida Legislature has told physicians, through Fla. Stat. §§765.1103(1) and Fla. Stat.§ 381.026(4)(d)(3), that they are required to comply with a patient's "request for pain management or palliative care from a patient under their care" and that patients have "the right to access any mode of treatment that is, in his or her own judgment ... in the best 2 *See* Amy J. Dilcher, *Damned ff They Do, Damned ff They Don't: the Need/or a Comprehensive Public Policy to Address the Inadequate Management of Pain,* 13 Ann. Health 81,136 (Winter 2004) (estimating "a cost of$ I 00 billion dollars to society in lost productivity and increased health care costs") (citations omitted). *Accord* Leeyn, 27 T. Jefferson L. Rev. at 134; Rima J. Oken, *Note: Curing Healthcare Providers' Failure to Administer Opioid in the Treatment of Severe Pain,* 23 Cardozo L. Rev. 1917, 1921 (May 2002); Beth Packman Weinman, *Freedom From Pain: Establishing a Constitutional Right to Pain Relief,* J. Legal Med. 24, at nn. 65-68 (December 2003). *See also* National Institutes of Health, *The Management of Chronic Pain, Program Announcement* PA NUMBER: PA-01-115 (July 2, 200 I), available on line at ww.ninds.nih.gov/funding/nindsnotes/102001 /nindsnotes_ I 0-01.htm?css=print;

American Pain Foundation, *Facts About Pain,* available online at www.painfoundation.org; National Institutes of Health, National Institute of Neurological Disorders and Stroke, *Chronic Pain: Hope Through Research* (1997).
3 A Florida statute dealing with nursing homes contains a similar definition. *See* Fla. Stat. 400.60 I (7) (defining "palliative care" as "services or interventions which are not curative but are proved for the reduction or abatement of pain and human suffering"). interests of the patient," Florida's Patient Bill of Rights and Responsibilities places the onus on *patients* to provide "accurate and complete information about present complaints, past illnesses, hospitalizations, medications, and other matters relating to his or her health" to their doctors. *See* Fla. Stat. § 381.026(6). And the patient, not the doctor, "is responsible for his or her actions if he or she refuses treatment or does not follow the health care provider's instructions." *Id.*

4. The Ban on "Unnecessary" Tests

In determining whether to order diagnostic tests, Florida doctors are encouraged to err on the side of *not* testing. Under Fla. Stat. § 766.111, physicians in Florida are subject to disciplinary actions if they order or provide "unnecessary diagnostic tests." Moreover, Florida's medical malpractice statute protects physicians from patient complaints that they should have conducted more tests. Thus, Fla. Stat. § 766.102(4) provides that the failure to provide or perform "supplemental diagnostic tests shall not be actionable if the health care provider acted in good faith and with due regard for the prevailing professional standard of care."

5. Fla. Admin. Code Rule 64B8-9.013i

At trial, the government introduced, and relied heavily on, Section 64B of Florida's Administrative code. As discussed above, the Florida Legislature has given Florida residents: (1) the "fundamental right of self-determination" to "choose" their own "medical treatment (Fla. Stat. 765.102(1)), (2) the "right to access any mode of treatment that is, in his or her own judgment ...in the bests interest of the patient" (Fla. Stat.§ 381.026(4)(d)(3)), and (3) the right to both "pain management [and] palliative care" (Fla. Stat. § 765.1103(1)), including "the comprehensive management of the physical, psychological, social, spiritual, and existential needs of patients" (Fla.Stat. § 765.102(5)(a)) and treatment that would "otherwise make the injured worker feel better." *Schaerffer, 2005 Fla. Wrk. Comp. LEXIS 1098,* at *9; *Lupinsky, 2005 Fla. Wrk. Comp. LEXIS J 09 J,* at *7. The Florida Legislature has also promised physicians immunity from "criminal prosecution" it they comply with these provisions (Fla. Stat. 765.109(1)). Through its rule-making authority, the BOM has similarly urged Florida physicians not to "fear" sanctions "from the Board or other state regulatory or enforcement agencies for prescribing, dispensing, or administering controlled substances *including opioid analgesics,* for a legitimate medical purpose and that is supported by appropriate documentation establishing a valid medical need and treatment plan." Fla. Admin. Code. § 64B8-9.013(l)(b). According to the BOM, prescribing controlled substances will be considered "for a legitimate medical purpose" if based "on sound clinical grounds." Fla. Admin. Code. § 64B8-9.013(l)(e). The BOM has further assured physicians that it "will not take disciplinary action against

a physician for failing to adhere strictly to the provisions of these standards, if good cause is shown for such deviation." Fla. Adm in. Code. § 64B8-9.013(l)(f). And, consistent with the Workers' Compensation statute's emphasis on treatment to restore functioning, the BOM has promised that "[t]he physician's conduct will be
evaluated to a great extent *by the treatment outcome,* taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs *including any improvement in functioning,* and recognizing that some types of pain cannot be completely relieved." *Id.* (Emphasis added.) Substance "abuse" is defined as using controlled substances for "non-therapeutic purposes." Fla. Admin. Code. § 64B8-9.013(2)(h). Finally, the BOM has defined "pain" broadly as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage." Fla. Admin. Code. § 64B8-9.013(2)(e). Subsection 64B8-9.013(3) of the Rule sets forth what the BOM calls "standards for the use of controlled substances for pain control." However, these standards are not *medical* ones - *i.e.,* they do not inform the physician about what types of conditions for which it is medically proper to prescribe controlled substances. The medical standards are the ones previously described herein. Rather, the standards in subsection (3) are really *procedural* requirements, or the steps physicians are supposed to take in order to document that the drug treatment fits a medically appropriate need.

Uncertainty in the Law

The fact that prosecutions of physicians which include a determination of whether a physician acted for "legitimate medical purpose by an individual practitioner acting in

the usual course of his professional practice," and exposes the physician to criminal liability based on, for example, Florida's morass of rules and regulations, leads to the similar, but distinct, issue of leaving a prospective defendant to deal with an "uncertainty in the law."
When criminal charges are predicated upon allegations that the defendant has breached some legal duty, the charges are subject to dismissal when the application of the law is uncertain.

Thus, "' [i]t is settled that when the law is vague or highly debatable, a defendant - actually or imputedly- lacks the requisite intent to violate it."' *United States v. Heller,* 830 F .2d l 50, 154 (11th Cir. 1987), quoting *United States v. Critzer,* 498 F.2d 1160, 1162 (4th Cir. 1974). *Accord James v. United States,* 366 U.S. 213 (1961); *United States v. Garber,* 607 F.2d 92 (5th Cir. 1979) (en banc) (citing *Critzer* with approval); *United States v. McClain,* 593 F.2d 658 (5th Cir. 1979). Whether a law or its interpretation is sufficiently certain to permit criminal sanctions is a matter of law for the Court to determine in the first instance. *See James v. United States,* 366 U.S.213 (1961) (uncertainty in the tax law created by conflicting or ambiguous Supreme Court precedents bars prosecution as a matter of law); *Critzer,* 498 F.2d at 1162 (taxability of income uncertain as a matter of law due to disagreement between the Bureau of Indian Affairs and the IRS). Indeed, if the law is uncertain, "the defendant's actual intent is irrelevant." Critzer, 498 F.2d at 1162 (emphasis added). See also *McClain,* 593 F.2d at 670. The "uncertainty of the law" doctrine differs from traditional void-for-vagueness challenges to criminal statutes in that it focuses on the interpretation or application of a law rather than the statutory language itself. For example, in *Heller,* an attorney was convicted of

tax evasion.
The Eleventh Circuit reversed, not because the tax statute was itself vague, but because the legality of the attorney's tax reporting system - a "closed-case method of reporting advance payments to an attorney of costs and fees" - was uncertain due to the existence of a twenty-year old decision of the Tax Court which had approved the reporting system. *Heller,* 830 F.2d at 155. Although the
Eleventh Circuit recognized that the reporting method had since been discredited and was "inconsistent with established general principles," the existence of the decision still made "it inappropriate to impose criminal liability" for using it. Id. at 155, n. 7 (emphasis by the Eleventh Circuit).

Similarly, the former Fifth Circuit, sitting en banc in *Garber,* emphasized that a law's interpretation or extension to a set of facts can be legally "uncertain" so as to preclude prosecution even without the benefit of conflicting court decisions. In *Garber,* the court held that the proper tax treatment accorded to rare blood donations was too uncertain to permit prosecution even though the tax treatment was an "uncharted area in tax law." Garber, 607 F.2d at 99. Indeed, a criminal law's application to a particular set of facts can be legally "uncertain"
due to problems in foreign law. Thus, in *United States v. McClain,* 593 F.2d 658 (5th Cir. 1979), the defendant was charged with receiving stolen property and with engaging in a conspiracy to do so under 18 U.S.C. §§ 371 and 2314. The property at issue was pre-Colombian art, which allegedly belonged to the government of Mexico. However, the determination of whether the artifacts were "owned" by Mexico depended upon testimony by historians,

professors and others concerning the Mexican Constitution and statutes which had changed over time. After hearing all the experts, the jury was given the task of deciding whether and when Mexico actually declared national ownership of the artifacts and then determining the defendant's guilt on that basis. Despite the "near overwhelming" evidence of the defendant's guilt and intent to violate the law, the Fifth Circuit reversed the convictions finding that Mexican law, before 1972, was not set forth "with sufficient clarity to survive translation into terms understandable by and binding upon American citizens." Id. at 670.

Finally, the statutory framework under which Dr. Mencia was convicted, and particularly its reliance on both state and federal regulatory provisions also creates an impermissible basis on which Dr. Mencia can be convicted - essentially allowing a jury to convict a defendant criminally for violating was what is otherwise a regulatory provision. *See United States v. Izurieta,* 710 F.3d 1176 (11th Cir. 2013). In *Jzurieta,* the Eleventh Circuit analyzed a provision that imposed criminal liability on a person that imports goods in the United States "contrary to law." The government claimed that contrary to law included a violation of any statute or regulation that governed importing goods and was a sufficient basis for criminal liability. The Court rejected this reasoning, insisting that there must be a showing that Congress intended that a violation of the particular regulation would support a criminal prosecution. Very much like the registration requirement under the CSA, where a regulation was designed only to establish civil obligations and penalties (presumably like the revocation of a registrants controlled substance prescription privileges under the CSA), it may not be used to support a criminal prosecution.

Accordingly, the Court should vacate the guilty verdict on Count 2 of the indictment and subsequently dismiss it.

NEW TRIAL

In the alternative, Dr. Mencia moves for a new trial. Rule 33 permits a trial judge to "vacate any judgment and grant a new trial if the interest of justice so requires." Fed.R.Crim.P.33. The interest of justice standard is broad, and there are many reasons why a court can order a new trial.

The decision of a district court to grant a new trial is reviewed under the clear abuse of discretion standard. *United States v. Cox,* 995 F.2d 1041 (11th Cir. 1993). When the review is being done after the grant of a new trial under a traditional post-trial "manifest weight of the evidence" analysis. That is, the trial judge considered the evidence and found the manifest weight of the evidence to preponderate against the verdict. Under this standard, although the evidentiary concerns may not legally rise to a level to justify a Rule 29 acquittal, they can still justify a new trial. The Rule 29 and Rule 33 standards are not identical. In a proper case - a case in which the evidence of guilt although legally sufficient is thin and marked by uncertainties and discrepancies, - there is room between the two standards for a district court to reweigh the evidence and reevaluate the credibility of witnesses." *Butcher v. United States,* 368 F.3d 1290, 1297, n.4 (11th Cir. 2004).

Dr. Mencia is entitled to a new trial on any or all of the following grounds. First, the untimely disclosure of the government's experts, the disarray in the government's discovery production, and the failure to conduct *Daubert*

hearings deprived Dr. Mencia of a fair trial. Second, admitting and permitting expert witnesses like Dr. Silverman, Dr. Sullivan and Dr. Goldstein to testify as experts without first inquiring into each witnesses methodology and support for their relative opinions deprived Dr. Mencia of a fair trial and the ability to effectively confront the admissibility, much less the substance, of their testimony. Finally, and related to both the vagueness and uncertainty in the law argument in our motion to dismiss, Dr. Mencia was deprived a fair trial when the government's experts were permitted to testify as to legal conclusions, including that signing blank prescription pads was a violation of the law and that Florida Statutes prohibit medical assistants from filling out prescriptions - neither is true. This prejudice was compounded when the government was permitted to argue in closing that the pre-signing of prescription pads imposed a kind of strict liability culpability on Dr. Mencia by telling the jury that the pre-signing of prescriptions meant "game over." The prejudice was further compounded when the defense was not permitted to demonstrate through Dr. Warfield that the pre-signing of prescription pads - although a bad practice - was a disciplinary matter governed by a specific Florida Regulation.

Untimely Disclosure of Experts

Just 13 days before trial, the government disclosed seven experts, six of which it ended up calling at trial. The defense filed a motion attempting to exclude their testimony and for a *Daubert* hearing [see DE_] and renewed this motion prior to the testimony of each expert. There are a combination of issues at play with regard to the government's experts. First, and notwithstanding any of the other issues, the fact that the government disclosed seven experts (six of which it called) less than two calendar weeks before trial, left Dr.

Mencia insufficient time to prepare to test the experts methodology, attempt to obtain experts of his own, and prepare to confront the government's experts on the substance of their proffered testimony. Rule 16(a)(l)(G) "is intended to minimize surprise that often results from unexpected expert testimony, [to] reduce the need for continuances, and to provide the opponent with a fair opportunity to test the merit of the expert's testimony through focused cross-examination." Fed.R.Crim.P. 16 advisory committee's note (1993 Amendment). It is irrelevant that the defense could anticipate some of the issues about which the experts testified as issues that might come up at trial.

Indeed, such anticipation "does not excuse the government of its duty under Rule 16(a)(l)(G) to give timely notice of its intent to call an expert who would marshal evidence on that issue in service of the government's case. It is one thing to be prepared to argue about a fact at trial, but quite another to prepare to rebut an expert who can testify about implications of that fact in a way different from a lay witness." *United States v. Bresil,* 767 F.3d 124, 127-28 (1st Cir. 2014) (holding that government's disclosure of expert five days before trial violated Rule 16 but
defendant failed to demonstrate prejudice). As with most Rule 16 violations, there must be a demonstration of substantial prejudice to the defendant for the Court to grant relief or for there to be reversible error. *See United States v. Chastain,* 198 F.3d 1338 (11th Cir. 1999). Such prejudice requires a demonstration the defendant
was unduly surprised and lacked an adequate opportunity to prepare a defense, or if the mistake substantially influenced the jury. *United States v. Camargo-Vergara,* 57 F.3d 993 (I 1th Cir. 1995). However, inadvertence is a not a factor in determining whether substantial prejudice

existed and whether the defendant is entitled to relief or reversal because Rule 16 violations are designed as a mechanism by which to protect a defendant's right to a fair trial, not as a mechanism by which to punish the government. See *United States v. Noe,* 821 F .2d 604 (11th Cir. 1987).

In Dr. Mencia's case, experts were permitted to testify on a variety of subjects without having first been subjected to any of the rigors required by *Daubert v. Merrell Dow Pharms.,* 509 U.S. 579 (1993) and its progeny. It is axiomatic that the *Daubert* rule applies to ALL expert testimony. *Kumho Tire Co.,Ltd. v. Carmichael,* 526 U.S. 137 (1999); *United States v. Frazier,* 387 F.3d 1244 (11th Cir. 2004 (en banc). Indeed, a *Daubert* hearing should be conducted when, as in Dr. Mencia's case, conflicting medical literature and expert testimony exists. *United States v. Hansen,* 262 F .3d 1217, 1234 (I Ph Cir. 2001). As the Court will recall, the testimony of Dr. Silverman and Dr. Warfield were diametrically opposed. The Florida statutory and regulatory scheme was a morass of often inconsistent, and even more often conflicting, rules and laws. Dr. Goldstein, was permitted to testify that she rejected nearly 80% of Dr. Mencia's controlled substance prescriptions while only rejecting about five percent of prescriptions in general. She gave no testable methodology as to how she came to this opinion. It was just the opinion of one pharmacist in one pharmacy in Broward. There was insufficient time and indeed insufficient information on which to test whether Dr. Goldstein's passed the rigors required under *Daubert.* The same can be said of Dr. Sullivan, another pharmacist, who based on the apparent review of prescription database information, which included the trial presentation of only one patient, formed the basis of her opinion that Dr. Mencia fell below the

"standard of care," whatever that phrase and its iterations means. Similarly, there was insufficient time and information to test this opinion and its basis under *Daubert.* The government also called Dr. Marrero, who was admitted as an expert to testify that he treated one of Dr. Mencia's patients (Ronald Erickson) differently, and ultimately dismissed the patient for testing positive for marijuana. Dr. Marrero's opinion differed not only from Dr. Mencia's opinion but from that of Carol Warfield, the head of Harvard Medical School's pain management center.

Thus, the proof at trial was that numerous experts had opinions that fell into different areas of the morass of rules, regulations, practices and statutes that governed Dr. Mencia's practice of medicine (and every other Florida physician's practice of medicine). Again, where there are conflicting opinions and literatures, not to mention conflicting regulations and statutes, the trial court should conduct a *Daubert* hearing. *See United States v. Hansen,* 262 F.3d 1217 (11th Cir 200 I). The most prejudicial testimony came from Dr. Silverman and was instigated by the government's questioning and introduction of exhibits regarding Florida rules and regulations. Dr. Silverman and delved into the morass of Florida statutes and regulations, often exaggerating or misstating the meaning and significance of these provisions. Dr. Silverman opined that Dr. Mencia had violated Florida Statutes, repeatedly insisting that statutes ***"must"*** be followed. The statutes to which he referred were not criminal statutes, but instead statutes codifying Florida Board of Medicine guidelines. For example, he relied on the Florida Statute regarding Medical assistants (Fla. Stat. §458.3485) to state that medical assistants are prohibited from filling out prescriptions, when the statute says no such thing. As another example, Dr. Silverman stated that presigning

blank prescription forms violated the law, a position that the government adopted in closing, saying that if prescription forms were presigned it was "game over" - i.e., Dr. Mencia was guilty. The defense was then prohibited from questioning Dr. Warfield and developing for the jury that Dr. Silverman and the government were wrong. This presentation would have informed the jury that the presigning of prescription forms is government by Florida Statute § 458.331, which is titled: ***Grounds for disciplinary action; action by the board and department,*** and which provides in subsection I (a)(a) that the presigning of blank prescription forms is one of the acts that could constitute grounds for denial of a license or disciplinary action, as specified in section 456.072(2) (Florida's Healthcare Occupation Grounds for discipline; penalties; enforcement). Ultimately the jury was exposed to the very morass that makes pinning the correct standard of criminal liability by which Dr. Mencia should have been judged even more uncertain.

Accordingly, for the reasons stated above Dr. Mencia moves this Court to vacate his conviction as to Count Two and dismiss that charge, or in the alternative for a new trial.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I **HEREBY CERTIFY** that on July 20, 2018, the foregoing document was electronically filed with the Clerk of Court using CM/ECF.

By: *Isl Marcos Beaton*
MARCOS BEA TON, ESQ.