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Certiorari Granted, Judgment Vacated by [Couch v. United States](#), U.S.,
June 30, 2022

966 F.3d 1101

United States Court of Appeals, Eleventh Circuit.

UNITED STATES of America, Plaintiff - Appellee,

v.

Xiulu RUAN, John Patrick

Couch, Defendants - Appellants.

No. 17-12653

I

(July 10, 2020)

Synopsis

Background: Defendant medical doctors were convicted in the United States District Court for the Southern District of Alabama, No. 1:15-cr-00088-CG-B-2, [Callie V. S. Granade](#), Senior District Judge, of conspiring to run medical practice constituting racketeering enterprise in violation of Racketeer Influenced and Corrupt Organizations Act (RICO), conspiring to violate Controlled Substances Act by dispensing Schedule II drugs, fentanyl, and Schedule III drugs outside usual course of professional practice and without legitimate medical purpose, conspiracies to commit health care fraud and mail or wire fraud, conspiracies to receive kickbacks in relation to Federal health care program, and substantive drug distribution, and one defendant was convicted of money laundering conspiracy and substantive money laundering. Defendants appealed.

Holdings: The Court of Appeals, [L. Scott Coogler](#), United States District Judge for the Northern District of Alabama, sitting by designation, held that:

[1] jurors could credit testimony of government's expert witness although he may have had mental health issue;

[2] evidence was sufficient to convict defendant of distributing controlled substances outside usual course of professional practice and without legitimate medical purpose;

[3] evidence was sufficient to convict defendant of conspiring to defraud health care benefit program;

[4] evidence was sufficient to prove that defendant medical doctors conspired with each other, sales representative for pharmaceutical company, and other persons to violate Anti-Kickback statute through their participation in company's speaker program;

[5] evidence was sufficient to prove that defendant medical doctors engaged in wire fraud;

[6] evidence was sufficient to prove that defendant engaged in money laundering; and

[7] data about prescriptions written by defendants and co-conspirator nurse practitioner constituted opposing party's statement, and therefore that data was not hearsay.

Affirmed in part, reversed in part, and remanded.

Procedural Posture(s): Appellate Review; Trial or Guilt Phase Motion or Objection; Sentencing or Penalty Phase Motion or Objection.

West Headnotes (129)

[1] **Criminal Law** 🔑 [Review De Novo](#)

Criminal Law 🔑 [Sufficiency of Evidence](#)

The Court of Appeals reviews the sufficiency of the evidence de novo, viewing the evidence and all reasonable inferences and credibility choices in favor of the government and the jury's verdict.

[2] **Criminal Law** 🔑 [Reasonable doubt](#)

A conviction must be affirmed unless there is no reasonable construction of the evidence from which the jury could have found the defendant guilty beyond a reasonable doubt.

[3] **Controlled Substances** 🔑 [Elements in general](#)

Health 🔑 [Pharmaceuticals, drugs, and medical devices](#)

In the medical context, illegal distribution of controlled substances requires proof that either (1) the prescription was not for a legitimate

medical purpose or (2) the prescription was not made in the usual course of professional practice. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841(a)(1).

[4 Cases that cite this headnote](#)

[4] **Controlled Substances** 🔑 Knowledge and intent

The mens rea required for a conviction for illegal distribution of controlled substances is knowledge, not willfulness. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841(a)(1).

[5] **Criminal Law** 🔑 Aiding, abetting, or other participation in offense

To sustain a conviction under an aiding and abetting theory, the prosecution must show that the defendant associated himself with a criminal venture, participated in it as something he wished to bring about, and sought by his actions to make it succeed. 18 U.S.C.A. § 2.

[6] **Criminal Law** 🔑 Opinion evidence

Plain error review applied to defendant medical doctor's argument on appeal that jury should have been made aware that government's expert witness thought he may have mental health issue, in his trial on charges of distributing controlled substances outside usual course of professional practice and without legitimate medical purpose, since defendant never preserved issue. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841(a)(1); Fed. R. Crim. P. 52(b).

[7] **Controlled Substances** 🔑 Sale, distribution, delivery, transfer or trafficking
Criminal Law 🔑 Experts

Jurors could credit testimony of government's expert witness who may have had mental health issue to find defendant medical doctor

guilty under reasonable construction of evidence of distributing controlled substances outside usual course of professional practice and without legitimate medical purpose; although that witness was sole government expert witness relating to substantive drug distribution counts charged against defendant, defense counsel rigorously cross-examined him, during which time, he admitted to several errors and omissions in his testimony and even changed his opinion on several points. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841(a)(1).

[More cases on this issue](#)

[8] **Controlled Substances** 🔑 Sale, distribution, delivery, transfer or trafficking

Criminal Law 🔑 Experts

Evidence was sufficient to convict defendant medical doctor of distributing controlled substances outside usual course of professional practice and without legitimate medical purpose, where expert testified that if patient was able to work it would be only because of amphetamines defendant prescribed her and prescribing those was “simply way below the rational standard of care for dealing with people who are in a near overdose state” and he further explained that subsequent studies had shown that particular controlled substance did not always work as intended when given by family member instead of medical professional and would not help a patient who also was taking other drugs with sedative effects, including benzodiazepines. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841(a)(1).

[9] **Controlled Substances** 🔑 Sale, distribution, delivery, transfer or trafficking

Reasonable jury convicting defendant medical doctor of distributing controlled substances outside usual course of professional practice and without legitimate medical purpose could conclude that manner in which defendant medical doctor prescribed controlled

substances was outside usual course of professional practice by crediting government's expert witness over patient even if patient felt that she benefited from medications defendant prescribed. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841(a)(1).

3 Cases that cite this headnote
More cases on this issue

[10] **Controlled Substances** 🔑 Sale, distribution, delivery, transfer or trafficking

Totality of evidence was sufficient for jury to determine that defendant medical doctor dispensed controlled substances to patient outside usual course of professional practice, where patient sought pain medication shortly after completing 19-month prison sentence, defendant did not refer patient to psychiatrist when it was noted in her file that she had bipolar disorder with schizophrenic features, urine test performed during visit did not detect drugs that defendant recently had prescribed to patient, she later tested positive for several drugs, including hydromorphone, that defendant had not prescribed, and defendant rapidly increased patient's opioid dosages beyond minimum necessary for pain control. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841(a)(1).

[11] **Controlled Substances** 🔑 Sale, distribution, delivery, transfer or trafficking

Criminal Law 🔑 Experts

Evidence was sufficient to convict defendant of distributing controlled substances outside usual course of professional practice and without legitimate medical purpose, where expert testified that opioid-dependent 50-year-old patient was high-risk, defendant did not prescribe absolute minimum dose of opioids that would have helped his pain yet addressed his opioid dependence, he combined opioid prescriptions with prescriptions for sedative-hypnotic drug, which created risk of accidental respiratory arrest, and agonist-antagonist drug

that could cause patient to go into painful withdrawal if patient was not detoxed from opioids first. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841(a)(1).

[12] **Controlled Substances** 🔑 Elements in general

In order to secure a conviction for unlawful controlled substances dispensation, the government must prove that the defendant dispensed controlled substances for other than legitimate medical purposes in the usual course of professional practice, and that he did so knowingly and intentionally. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841(a)(1).

1 Case that cites this headnote

[13] **Conspiracy** 🔑 Agreement; buyer-seller rule

To establish a drug conspiracy, the government must prove that: (1) there was an agreement between two or more people to commit a drug crime; (2) the defendant knew about the agreement; and (3) the defendant voluntarily joined the agreement. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 406, 21 U.S.C.A. § 846.

2 Cases that cite this headnote

[14] **Conspiracy** 🔑 Knowledge, intent, and participation

A drug conspiracy conviction will be upheld if the circumstances surrounding a person's presence at the scene of conspiratorial activity are so obvious that knowledge of its character can fairly be attributed to him. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 406, 21 U.S.C.A. § 846.

[15] **Conspiracy** 🔑 Controlled Substances
Criminal Law 🔑 Experts

Evidence was sufficient to convict medical doctor defendants of conspiracy to distribute controlled substances outside usual course of professional practice and without legitimate medical purpose, where defendants altered their prescribing habits where they had financial interest, nurse practitioner was forging prescriptions with defendant's signature and he did this for his patients and for those of other nurses in clinic, defendant was aware of and acquiesced to that practice, defendants would leave blank prescription pads, which sometimes only had doctors' signatures on them, for use by nurses when doctors were out of the office, and patient files suggested to government experts that there were serious gaps in patients' quality of care. Comprehensive Drug Abuse Prevention and Control Act of 1970 §§ 401, 406, 21 U.S.C.A. §§ 841(a)(1), 846.

[16] Criminal Law 🔑 Sentencing and Punishment

Any error was harmless in jury finding that defendant medical doctors prescribed over 40 grams of fentanyl in manner outside usual course of professional practice and without any legitimate medical purpose, as required to trigger five-year mandatory minimum sentence, since five-year mandatory minimum sentence was well below sentences defendants received. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841(b)(1)(B)(vi).

[17] Conspiracy 🔑 Health care and medical benefits fraud

A health care fraud conspiracy exists when defendants agree to submit false claims to health care benefit programs. 18 U.S.C.A. § 1347(a).

2 Cases that cite this headnote

[18] Conspiracy 🔑 Knowledge, intent, and participation

The defendants must have known that the claims submitted to a health care benefit program were

actually false to convict them of health care fraud conspiracy. 18 U.S.C.A. § 1347(a).

[19] Conspiracy 🔑 Health care and medical benefits fraud

A person makes a false claim, as required to convict a defendant of health care fraud conspiracy, if the treatments billed were not medically necessary or were not delivered to the patients. 18 U.S.C.A. § 1347(a).

1 Case that cites this headnote

[20] Conspiracy 🔑 Health care and medical benefits fraud

To sustain a health care fraud conspiracy conviction, the government has to establish beyond a reasonable doubt that: (1) a conspiracy existed to commit health care fraud; (2) the defendants knew of the conspiracy; and (3) the defendants knowingly and voluntarily joined it. 18 U.S.C.A. § 1347(a).

2 Cases that cite this headnote

[21] Conspiracy 🔑 Health care and medical benefits fraud

Evidence was sufficient to convict defendant medical doctors of conspiring to defraud health care benefits program, where defendants falsely certified to insurers that some patients had cancer so that insurers would pay for their transmucosal immediate-release fentanyl (TIRF) prescriptions. 18 U.S.C.A. § 1347(a).

More cases on this issue

[22] Conspiracy 🔑 Health care and medical benefits fraud

Evidence was sufficient to convict defendant medical doctor of conspiring to defraud health care benefit program, where defendant routinely billed for office visits conducted entirely by nurse practitioners under defendant's identification number and program did not allow that "incident to billing" practice of allowing submission of bills under doctor's provider

number if doctor was involved in treatment through participation or oversight. 18 U.S.C.A. § 1347(a).

[More cases on this issue](#)

[23] Conspiracy 🔑 [Health care and medical benefits fraud](#)

Evidence was sufficient to convict defendant medical doctor of conspiring to defraud health care benefit program; although defendant personally saw all of his patients, he acquiesced in practice of doctor in clinic of permitting nurse practitioner and others to see patients independently, other defendant routinely billed for office visits conducted entirely by nurse practitioners under defendant's identification number, and program did not allow that "incident to billing" practice of allowing submission of bills under a doctor's provider number if the doctor was involved in the treatment, through participation or oversight. 18 U.S.C.A. § 1347(a).

[More cases on this issue](#)

[24] Conspiracy 🔑 [Health care and medical benefits fraud](#)

Evidence was sufficient to convict defendant medical doctors of conspiring to defraud health care benefits program by billing for expensive off-site urine screen tests that were medically unnecessary; one defendant ordered them for every patient because they generated more revenue than in-house tests, and defendants rarely discussed inconsistent test results with patients, whether to counsel them into compliance or terminate them as patients. 18 U.S.C.A. § 1347(a).

[2 Cases that cite this headnote](#)

[More cases on this issue](#)

[25] Conspiracy 🔑 [Health care and medical benefits fraud](#)

Defendant medical doctors could be convicted of health care fraud conspiracy on basis that they illegally prescribed drugs outside course

of professional practice and they billed insurers for clinic office visits at which patients were prescribed those drugs that their pharmacy then dispensed. 18 U.S.C.A. § 1347(a).

[More cases on this issue](#)

[26] Conspiracy 🔑 [Health care and medical benefits fraud](#)

Health 🔑 [Medicare fraud](#)

On charges of conspiracy to receive kickbacks, exhibits showing that U.S. Department of Labor paid for physician services, but not prescriptions, was not sufficient to establish beyond reasonable doubt that federal longshoreman insurance program administrator that was not named in statute listing Federal health care funding programs, like Medicare and Medicaid, paid for prescriptions with federal funds or that federal monies otherwise passed through workers' compensation dispensary of pharmacy of defendant medical doctors. 18 U.S.C.A. § 371; Social Security Act § 1128B, 42 U.S.C.A. §§ 1320a-7b(b)(1), 1320a-7b(f), 14402(d).

[1 Case that cites this headnote](#)

[More cases on this issue](#)

[27] Criminal Law 🔑 [Jurisdiction of Offense](#)

In determining whether federal jurisdiction exists for a particular charge against a defendant, the court examines the sufficiency of the evidence offered by the government, and all evidence and inferences therefrom are viewed in the light most favorable to the verdict.

[2 Cases that cite this headnote](#)

[28] Criminal Law 🔑 [Jurisdiction of Offense](#)

The relevant inquiry in making the determination of whether federal jurisdiction exists for a particular charge against a defendant is whether a reasonable jury could have found the jurisdictional element to have been satisfied beyond a reasonable doubt.

[2 Cases that cite this headnote](#)

[29] **Conspiracy** 🔑 [Health care and medical benefits fraud](#)

Evidence was sufficient to prove that defendant medical doctors conspired with each other, sales representative for pharmaceutical company, and other persons to violate Anti-Kickback statute through their participation in company's speaker program, where evidence showed that company was using its program as cover to funnel money to defendants. 18 U.S.C.A. § 371.

[1 Case that cites this headnote](#)
[More cases on this issue](#)

[30] **Conspiracy** 🔑 [Mail and wire fraud](#)

Evidence was sufficient to prove that defendant medical doctors engaged in wire fraud conspiracy, where defendants routinely billed health care benefit program for more expensive doctor visits when only nurse practitioner saw patient, program did not allow that “incident to billing” practice of allowing submission of bills under doctor's provider number if doctor was involved in treatment through participation or oversight, and clinic submitted those bills electronically. 18 U.S.C.A. § 1349.

[More cases on this issue](#)

[31] **Conspiracy** 🔑 [Mail and wire fraud](#)

To prove a wire fraud conspiracy, the government need not demonstrate an agreement specifically to use the interstate wires to further the scheme to defraud; instead, it is enough to prove that the defendant knowingly and voluntarily agreed to participate in a scheme to defraud and that the use of the interstate wires in furtherance of the scheme was reasonably foreseeable. 18 U.S.C.A. § 1349.

[32] **Conspiracy** 🔑 [Mail and wire fraud](#)

A scheme to defraud through the mail or wires, as element of conspiracy to commit mail or wire fraud, requires proof of material misrepresentations, or the omission or

concealment of material facts. 18 U.S.C.A. § 1349.

[33] **Conspiracy** 🔑 [Mail and wire fraud](#)

Evidence was sufficient to prove that defendant medical doctors engaged in wire fraud conspiracy, where defendants falsely certified to insurers that some patients had cancer so that insurers would pay for their transmucosal immediate-release fentanyl (TIRF) prescriptions and defendant's clinic and insurers sent forms and letters related to coverage via fax and mail. 18 U.S.C.A. § 1349.

[More cases on this issue](#)

[34] **Conspiracy** 🔑 [Mail and wire fraud](#)

Evidence was sufficient to prove that defendant medical doctors engaged in wire fraud conspiracy, where person with workers' compensation dispensary associated with defendant's clinic frequently discussed profit margin of various drugs for formulary, those discussions occurred over e-mail between defendant in Alabama and that person in Maryland, defendant never talked with that person about drugs' clinical aspects, defendant selected most lucrative controlled substances to stock at his clinic's dispensary, and he and other medical doctor prescribed those drugs, making their medical decisions based on profit, not needs of patients. 18 U.S.C.A. § 1349.

[1 Case that cites this headnote](#)
[More cases on this issue](#)

[35] **Conspiracy** 🔑 [Other particular substances](#)
Conspiracy 🔑 [Mail and wire fraud](#)

Evidence was sufficient for jury to conclude that defendant medical doctors were members of Racketeer Influenced and Corrupt Organizations (RICO) Act “enterprise,” and therefore they could be convicted of conspiring to violate RICO based on predicate acts of drug distribution and mail or wire fraud, on basis that they jointly owned clinic and pharmacy and that they were associated in fact; although defendants operated

clinic as separate medical practices at two different locations, clinic and pharmacy were legal entities jointly owned by defendants, they made financial and business decisions together, they discussed practice-management issues via email, shared in profits of pharmacy, and they worked at each other's primary location once per week. 18 U.S.C.A. §§ 1349, 1961(4), 1962(d).

[More cases on this issue](#)

[36] Conspiracy 🔑 **Racketeering conspiracies in general**

To establish a conspiracy to violate Racketeer Influenced and Corrupt Organizations Act, the government must prove that the defendants objectively manifested, through words or actions, an agreement to participate in the conduct of the affairs of the enterprise through the commission of two or more predicate crimes. 18 U.S.C.A. § 1962(d).

[37] Conspiracy 🔑 **Racketeering conspiracies in general**

A Racketeer Influenced and Corrupt Organizations Act conspiracy differs from an ordinary conspiracy in two respects: it need not embrace an overt act, and it is broader and may encompass a great variety of conduct. 18 U.S.C.A. § 1962(d).

[38] Racketeer Influenced and Corrupt Organizations 🔑 **Mail and wire fraud**
Racketeer Influenced and Corrupt Organizations 🔑 **Drug related activity**

Predicate acts requirement under Racketeer Influenced and Corrupt Organizations Act was satisfied through defendant medical doctors' illegal drug distribution and wire fraud. 18 U.S.C.A. §§ 1349, 1962(d); Comprehensive Drug Abuse Prevention and Control Act of 1970 §§ 401, 406, 21 U.S.C.A. §§ 841(a)(1), 846.

[More cases on this issue](#)

[39] Currency Regulation 🔑 **Monetary transactions in unlawfully derived property**

Evidence was sufficient to prove that defendant engaged in money laundering, where government provided evidence that defendant medical doctor made millions from health care fraud and distribution of controlled substances and government traced those proceeds to bank account used to purchase cars for hundreds of thousands of dollars. 18 U.S.C.A. § 1957(a).

[1 Case that cites this headnote](#)

[More cases on this issue](#)

[40] Conspiracy 🔑 **Money laundering**

A money laundering conspiracy requires proof of (1) an agreement between two or more persons to commit a money-laundering offense, and (2) knowing and voluntary participation in that agreement by the defendant. 18 U.S.C.A. § 1956(h).

[2 Cases that cite this headnote](#)

[41] Currency Regulation 🔑 **Monetary transactions in unlawfully derived property**

A defendant can be convicted of money laundering if the government proves: (1) the defendant knowingly engaged in a financial transaction greater than \$10,000 and (2) at least \$10,000 of that money came from a "specified unlawful activity." 18 U.S.C.A. § 1957(a).

[42] Criminal Law 🔑 **Admissions by party opponent**

Did prescription data from state monitoring program constitute opposing party's statement and thus not hearsay? **Yes**

Data about prescriptions written by defendant medical doctors and co-conspirator nurse practitioner that had been pulled from Alabama's Prescription Database Monitoring Program, which was database of all controlled substance prescriptions dispensed, constituted opposing party's statement, and therefore that data was not hearsay in defendants' trial on charges of

conspiring to violate Controlled Substances Act. Comprehensive Drug Abuse Prevention and Control Act of 1970 §§ 308, 401, 406, 21 U.S.C.A. §§ 828, 841(a)(1), 846; 21 C.F.R. § 1304.04(a) 1304.04(h)(2), 1304.04(h)(4); Ala. Code §§ 20-2-210, 20-2-213(d), 20-2-214; Fed. R. Evid. 801(d)(2)(D) & (E).

[1 Case that cites this headnote](#)

[More cases on this issue](#)

[43] Criminal Law 🔑 Reception and Admissibility of Evidence

Evidentiary rulings are reviewed for abuse of discretion.

[44] Criminal Law 🔑 Computer records; printouts

Reports regarding prescriptions written by defendant medical doctors and co-conspirator nurse practitioner that had been generated from Alabama's Prescription Database Monitoring Program, which was database of all controlled substance prescriptions dispensed, were “data compilation,” and therefore were not hearsay in trial on charges of conspiring to violate Controlled Substances Act. Comprehensive Drug Abuse Prevention and Control Act of 1970 §§ 401, 406, 21 U.S.C.A. §§ 841(a)(1), 846; Fed. R. Evid. 803(6).

[1 Case that cites this headnote](#)

[More cases on this issue](#)

[45] Criminal Law 🔑 Medical and hospital records

Pharmacists’ statements that they filled prescriptions written by doctors, which had been pulled from Alabama's Prescription Database Monitoring Program, as database of all controlled substance prescriptions dispensed, were business records of reporting pharmacies, and therefore they were admissible under business records exception to hearsay rule in defendants' trial on charges of conspiring to violate Controlled Substances Act. Comprehensive Drug Abuse Prevention and

Control Act of 1970 §§ 401, 406, 21 U.S.C.A. §§ 841(a)(1), 846; Fed. R. Evid. 803(6).

[More cases on this issue](#)

[46] Criminal Law 🔑 Computer records; printouts

Custodian established that records were made at or near time by, or from information transmitted by, someone with knowledge, as required in defendants' trial on charges of conspiring to violate Controlled Substances Act for business records exception to apply to records generated from Alabama's Prescription Database Monitoring Program (PDMP), which was database of all controlled substance prescriptions dispensed, where custodian testified that pharmacists, who had knowledge of prescriptions, entered data in database at same time they dispensed controlled substances. Comprehensive Drug Abuse Prevention and Control Act of 1970 §§ 401, 406, 21 U.S.C.A. §§ 841(a)(1), 846; Ala. Code § 20-2-214.

[More cases on this issue](#)

[47] Criminal Law 🔑 Medical and hospital records

Custodian established that keeping records was part of pharmacies’ “regularly conducted activity” as well as “regular practice” of their business, as required in defendants' trial on charges of conspiring to violate Controlled Substances Act for business records exception to apply to records generated from Alabama's Prescription Database Monitoring Program (PDMP), which was database of all controlled substance prescriptions dispensed, where custodian testified that federal law and regulations required keeping prescription records and state law required submitting data to PDMP. Comprehensive Drug Abuse Prevention and Control Act of 1970 §§ 401, 406, 21 U.S.C.A. §§ 841(a)(1), 846; Ala. Code § 20-2-214; Fed. R. Evid. 803(6).

[More cases on this issue](#)

[48] **Criminal Law** 🔑 Medical and hospital records

Custodian established that it was “business practice” of Alabama Department of Public Health (ADPH) to obtain and maintain records in Prescription Database Monitoring Program (PDMP), which was database of all controlled substance prescriptions dispensed, as required for business records exception to apply in defendants’ trial on charges of conspiring to violate Controlled Substances Act, where custodian testified that ADPH considered PDMP reports its business records and relied on records through its daily assistance to doctors and pharmacists in accessing database as tool for prescribers and dispensers to make best clinical decision for their patient. Comprehensive Drug Abuse Prevention and Control Act of 1970 §§ 401, 406, 21 U.S.C.A. §§ 841(a)(1), 846; Fed. R. Evid. 803(6).

[More cases on this issue](#)

[49] **Criminal Law** 🔑 Medical and hospital records

Records in Prescription Database Monitoring Program (PDMP), which was database of all controlled substance prescriptions dispensed, were trustworthy, as required for PDMP data to be admitted under business records exception to hearsay rule in defendants’ trial on charges of conspiring to violate Controlled Substances Act; although disclaimer on each page of report stated that Alabama Department of Public Health (ADPH) “does not warrant the above information to be accurate or complete” because report was “based on the search criteria and the data provided by the dispensing entities,” pharmacists had every incentive to ensure that data they entered was accurate. Comprehensive Drug Abuse Prevention and Control Act of 1970 §§ 401, 406, 21 U.S.C.A. §§ 841(a)(1), 846; Fed. R. Evid. 803(6).

¹ Case that cites this headnote

[More cases on this issue](#)

[50] **Criminal Law** 🔑 Use of documentary evidence

Admission of reports from Alabama’s Prescription Database Monitoring Program (PDMP), which was database of all controlled substance prescriptions dispensed, as business records in defendants’ trial on charges of conspiring to violate Controlled Substances Act did not violate Confrontation Clause; even if PDMP assisted law enforcement in prosecuting violators of controlled substance laws, reports were not testimonial. U.S. Const. Amend. 6; Comprehensive Drug Abuse Prevention and Control Act of 1970 §§ 401, 406, 21 U.S.C.A. §§ 841(a)(1), 846; Fed. R. Evid. 803(6).

[More cases on this issue](#)

[51] **Criminal Law** 🔑 Review De Novo

A defendant’s claim that an evidentiary ruling deprived him of a constitutional right is reviewed de novo.

[52] **Criminal Law** 🔑 Out-of-court statements and hearsay in general

Under the Confrontation Clause, testimonial statements are ones that declarants would reasonably expect to be used prosecutorially. U.S. Const. Amend. 6.

[53] **Criminal Law** 🔑 Out-of-court statements and hearsay in general

A statement is testimonial under the Confrontation Clause when its primary purpose is to establish or prove past events potentially relevant to later criminal prosecution, and when the statement is “formal,” akin to affidavits, depositions, prior testimony, or confessions. U.S. Const. Amend. 6.

[54] **Criminal Law** 🔑 Coconspirators’ statements
Criminal Law 🔑 Use of documentary evidence

Business records or statements in furtherance of a conspiracy are not testimonial under the Confrontation Clause by their nature. [U.S. Const. Amend. 6](#).

rules do not abridge an accused's right to present a defense so long as they are not arbitrary or disproportionate to the purposes they are designed to serve. [U.S. Const. Amend. 6](#).

[55] Criminal Law 🔑 Use of documentary evidence

Pharmacists' awareness when they input data into Alabama's Prescription Database Monitoring Program (PDMP), which was database of all controlled substance prescriptions dispensed, that law enforcement also had access to database if needed during investigation did not transform that data entry into type of formal statement required under Confrontation Clause for testimonial evidence, in defendants' trial on charges of conspiring to violate Controlled Substances Act; even if reports were not business records, pharmacists were required by law to enter PDMP data for primary purpose of aiding physicians in treating patients, such as combating addiction. [U.S. Const. Amend. 6](#); Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, [21 U.S.C.A. § 841\(a\)\(1\)](#); [Fed. R. Evid. 803\(6\)](#).

[More cases on this issue](#)

[56] Criminal Law 🔑 Review De Novo

Whether the exclusion of evidence violated a constitutional guarantee is a legal question reviewed de novo. [U.S. Const. Amend. 6](#).

[1 Case that cites this headnote](#)

[57] Criminal Law 🔑 Necessity and scope of proof

The Constitution guarantees criminal defendants a meaningful opportunity to present a complete defense. [U.S. Const. Amend. 6](#).

[58] Criminal Law 🔑 Necessity and scope of proof

State and federal rulemakers have broad latitude under the Constitution to establish rules excluding evidence from criminal trials; such

[59] Criminal Law 🔑 Necessity and scope of proof

A trial judge has the role as gatekeeper to ensure that the factfinder bases its decision only on relevant and reliable information; while a criminal defendant must be given every meaningful opportunity to present a complete defense, in doing so he must comply with the procedural and evidentiary rules designed to facilitate a search for the truth. [U.S. Const. Amend. 6](#).

[60] Controlled Substances 🔑 Admissibility of evidence

Whether one patient approved of his treatment by defendant medical doctor did not directly pertain to whether defendant's treatment of many other patients identified by government was outside course of professional practice, and therefore preclusion of that patient's testimony did not violate defendant's right to present complete defense in his trial on charges of violating Controlled Substances Act by knowingly or intentionally prescribing controlled substances outside usual course of professional practice or without legitimate medical purpose, since defendant was not charged with illegally prescribing medicine to all his patients, and jury was aware that he had thousands of patients to whom he may have provided legitimate care. [U.S. Const. Amends. 5, 6](#); Comprehensive Drug Abuse Prevention and Control Act of 1970 §§ 401, 406, [21 U.S.C.A. §§ 841\(a\)\(1\), 846](#).

[More cases on this issue](#)

[61] Controlled Substances 🔑 Admissibility of evidence

Patient's testimony that he approved of his treatment by defendant medical doctor did not tend to negate mens rea element of Controlled

Substances Act offenses of knowingly or intentionally prescribing controlled substances outside usual course of professional practice or without legitimate medical purpose, and therefore preclusion of that patient's testimony did not violate defendant's right to present complete defense, since government did not allege defendant's treatment of that patient was outside usual course of professional practice, and nothing about that patient's testimony would have been probative of defendant medical doctor's actions towards other patients that government asserted were provided with illegal prescriptions. [U.S. Const. Amends. 5, 6](#); Comprehensive Drug Abuse Prevention and Control Act of 1970 § 406, [21 U.S.C.A. § 846](#).

[1 Case that cites this headnote](#)

[More cases on this issue](#)

[62] Controlled Substances 🔑 [Admissibility of evidence](#)

Defendant medical doctors had not been tainted with perception that their clinic was a sham, and therefore “good patient” evidence was not necessary for defendants to present complete defense in their trial on charges of violating Controlled Substances Act by knowingly or intentionally prescribing controlled substances outside usual course of professional practice or without legitimate medical purpose, since government admitted that majority of patients that went to defendants' clinic had legitimate pain needs and were in need of legitimate pain treatment and clinic's former manager and government witness described clinic as one of the best, well-rounded pain centers in that area. [U.S. Const. Amends. 5, 6](#); Comprehensive Drug Abuse Prevention and Control Act of 1970 § 406, [21 U.S.C.A. § 846](#).

[More cases on this issue](#)

[63] Criminal Law 🔑 [Necessity and scope of proof](#)

Defendants have a right in presenting a complete defense to combat the government's selective presentation of entirely truthful evidence that

casts a defendant in an inaccurate, unfavorable light or that makes entirely legitimate, normal, or accepted acts appear unusual or suspicious. [U.S. Const. Amends. 5, 6](#).

[1 Case that cites this headnote](#)

[64] Criminal Law 🔑 [Special types of photographs; enlargements, motion and sound pictures, X-rays](#)

Defendant was not prejudiced in his trial on charges of violating Controlled Substances Act by knowingly or intentionally prescribing controlled substances outside usual course of professional practice or without legitimate medical purpose by exclusion of undercover videos of Drug Enforcement Agency (DEA) agents acting as “patients” seeking opioids from him but being denied, since those videos did not refute inculpatory evidence against defendant demonstrating that he did prescribe opioids at other times to other patients outside usual course of professional practice or without legitimate medical purpose. [U.S. Const. Amends. 5, 6](#); Comprehensive Drug Abuse Prevention and Control Act of 1970 § 406, [21 U.S.C.A. § 846](#).

[6 Cases that cite this headnote](#)

[More cases on this issue](#)

[65] Criminal Law 🔑 [Comments by prosecution on failure of accused to present evidence](#)

Defendant medical doctors' right to present complete defense in their trial on charges of violating Controlled Substances Act by knowingly or intentionally prescribing controlled substances outside usual course of professional practice or without legitimate medical purpose was not violated by government's closing arguments addressing ability of defendant medical doctors to call statisticians or other experts to critique its charts. [U.S. Const. Amends. 5, 6](#); Comprehensive Drug Abuse Prevention and Control Act of 1970 § 406, [21 U.S.C.A. § 846](#).

[1 Case that cites this headnote](#)

[66] **Criminal Law** 🔑 Matters not sustained by evidence

Right of defendant medical doctors to present complete defense was not prejudiced by prosecutor's improper closing remarks which implicated "good patient" evidence that defendants were not allowed to present in their trial on charges of violating Controlled Substances Act by knowingly or intentionally prescribing controlled substances outside usual course of professional practice or without legitimate medical purpose, since jury knew that defendants had treated thousands of patients and were not alleged to have mistreated them all, remarks were minor portion of lengthy closing arguments in lengthy trial, district court repeatedly instructed the jury that the attorneys' arguments were not evidence, and evidence of defendants' guilt was substantial. [U.S. Const. Amends. 5, 6](#); Comprehensive Drug Abuse Prevention and Control Act of 1970 § 406, [21 U.S.C.A. § 846](#).

[67] **Criminal Law** 🔑 Duty to allow fair trial in general

A prosecutor must refrain from improper methods calculated to produce a wrongful conviction.

[68] **Criminal Law** 🔑 Statements as to Facts and Arguments

A prosecutor may not make improper suggestions, insinuations and assertions calculated to mislead the jury.

[69] **Criminal Law** 🔑 Statements as to Facts and Arguments

To establish prosecutorial misconduct, a defendant must establish that the remarks were improper and that they prejudicially affected his substantial rights.

[70] **Criminal Law** 🔑 Statements as to Facts and Arguments

A defendant's substantial rights are prejudicially affected when a reasonable probability arises that, but for prosecutor's improper remarks, the outcome of the trial would have been different.

[1 Case that cites this headnote](#)

[71] **Criminal Law** 🔑 Statements as to Facts and Arguments

In determining whether a prosecutor's remarks had a reasonable probability of changing the trial's outcome, a court may look to: (1) the degree to which the challenged remarks have a tendency to mislead the jury and to prejudice the accused; (2) whether they are isolated or extensive; (3) whether they were deliberately or accidentally placed before the jury; and (4) the strength of the competent proof to establish the guilt of the accused.

[72] **Criminal Law** 🔑 Cumulative evidence in general

Right of defendant medical doctors to present complete defense in their trial on charges of wire and health care fraud was not violated by not allowing witness to explain that pre-populated fields in computer program were not used to select billing level that clinic submitted to insurers, since government successfully proved health care and wire fraud through other illegal acts unrelated to witness testimony about billing codes, such as that clinic falsely certified to insurers that some patients had cancer so that insurers would pay for their transmucosal immediate-release fentanyl (TIRF) prescriptions, and that clinic improperly billed insurer for office visits conducted by nurse practitioners using defendant's physician identification number. [U.S. Const. Amends. 5, 6](#); [18 U.S.C.A. §§ 371, 1349](#).

[More cases on this issue](#)

[73] **Conspiracy** 🔑 Fraud and false pretenses

Health 🔑 **Evidence**

Right of defendant medical doctors to present complete defense in their trial on charges of wire and health care fraud conspiracy was not violated by not allowing evidence on Alabama Board of Medical Examiners' guidance on collaborative practice or that other insurers may not have had policy that required doctors to actually see patients before using higher billing number, since that evidence was not relevant to charge that defendants violated policy specific to other insurer. [U.S. Const. Amends. 5, 6](#); [18 U.S.C.A. §§ 371, 1349](#).

[More cases on this issue](#)

[74] Controlled Substances 🔑 **Admissibility of evidence**

Right of defendant medical doctors to present complete defense in their trial on charges of violating Controlled Substances Act by knowingly or intentionally prescribing controlled substances outside usual course of professional practice or without legitimate medical purpose was not violated by not allowing evidence that undercover medical doctor threatened employee of defendant medical doctors to allow undercover "patient" to have appointment in violation of clinic rules, since that evidence did not affect defendants' decisions to prescribe drugs that undercover patient did not need. [U.S. Const. Amends. 5, 6](#); Comprehensive Drug Abuse Prevention and Control Act of 1970 § 406, [21 U.S.C.A. § 846](#).

[More cases on this issue](#)

[75] Criminal Law 🔑 **Admissibility**

A district court's decisions regarding the admissibility of expert testimony will not be set aside unless the Court of Appeals determines that the court abused its discretion.

[76] Criminal Law 🔑 **Discretion of Lower Court**

The abuse of discretion standard of review allows the Court of Appeals to affirm the district court even if it would have gone the other way

had it been its call; in order to reverse, the Court of Appeals must find that the district court made a clear error of judgment or has applied the wrong legal standard.

[77] Criminal Law 🔑 **Knowledge, Experience, and Skill**

District court did not abuse its discretion allowing hospitalist to testify as expert in defendants' trial on charges of violating Controlled Substances Act by knowingly or intentionally prescribing controlled substances outside usual course of professional practice or without legitimate medical purpose as to whether defendants' treatment of some patients was outside usual course of professional pain management practice; although hospitalist was not board-certified pain management physician, did not have her own specialty clinic, and referred patients with significant amount of pain to someone else, she was familiar with prescribing opioids and treating chronic pain, defendants questioned her on cross-examination about her experience treating pain, and weight of her testimony was for jury to evaluate. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 406, [21 U.S.C.A. § 846](#); [Fed. R. Evid. 702](#).

[More cases on this issue](#)

[78] Criminal Law 🔑 **Subjects of Expert Testimony****Criminal Law** 🔑 **Basis of Opinion**

A district court's gatekeeper role for admissibility of expert testimony is not intended to supplant the adversary system or the role of the jury; vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking debatable but admissible evidence. [Fed. R. Evid. 702](#).

[79] Witnesses 🔑 **Particular matters in general**

District court did not abuse its discretion in sustaining government's relevance objection

to questioning hospitalist as to whether she could practice pain management in Mississippi, in defendant medical doctors' trial on charges of violating Controlled Substances Act by knowingly or intentionally prescribing controlled substances outside usual course of professional practice or without legitimate medical purpose; hospitalist's lack of license in Mississippi as pain management specialist would have been repetitive and would have risked confusing the jury because expert's cross-examination already had established that she had never been board certified in pain management, she never had residency or fellowship in pain management, she had not been peer reviewed in pain management journal, and Mississippi's standards did not govern defendants' Alabama practice and did not go into effect until after indictment period. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 406, 21 U.S.C.A. § 846; Fed. R. Evid. 702.

[More cases on this issue](#)

[80] Witnesses 🔑 Grounds for limiting cross-examination

A district court enjoys wide latitude to impose reasonable limits on cross-examination based on, among other things, confusion of the issues and interrogation that is repetitive or only marginally relevant.

[More cases on this issue](#)

[81] Witnesses 🔑 Contractual relationship in general

District court abused its discretion in defendant medical doctors' trial on charges of violating Controlled Substances Act by knowingly or intentionally prescribing controlled substances outside usual course of professional practice or without legitimate medical purpose by limiting scope of cross-examination of hospitalist regarding her previous work for government; all jury knew was that hospitalist had been paid roughly \$7,600 in expert fees for current case, but defendants sought to show that she had signed contracts over 40 times that much from

government over the years, that evidence was not cumulative, and it would have been probative of hospitalist's credibility in light of her extensive relationship with government. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 406, 21 U.S.C.A. § 846; Fed. R. Evid. 702.

[More cases on this issue](#)

[82] Criminal Law 🔑 Necessity and scope of proof

Criminal Law 🔑 Cross-examination and impeachment

While the district court has discretionary authority to rule on the admissibility of evidence, including the power to limit cross-examination, this discretion is limited by the guarantee of the Sixth Amendment's Confrontation Clause that a criminal defendant has the right to cross-examine prosecutorial witnesses; in particular, a presumption favors free cross-examination on possible bias, motive, ability to perceive and remember, and general character for truthfulness. U.S. Const. Amend. 6.

[83] Criminal Law 🔑 Cross-examination and impeachment

The test for the Confrontation Clause as to bias, motive, ability to perceive and remember, and general character for truthfulness is whether a reasonable jury would have received a significantly different impression of the witness' credibility had counsel pursued the proposed line of cross-examination. U.S. Const. Amend. 6.

[84] Witnesses 🔑 Extrinsic evidence in general

Proof of bias or motive to lie is almost always relevant, as a successful showing of bias on the part of a witness would have a tendency to make the facts to which he testified less probable in the eyes of the jury than it would be without such testimony. Fed. R. Evid. 402.

[2 Cases that cite this headnote](#)

[85] Criminal Law 🔑 [Opinion evidence](#)

District court's abuse of its discretion by limiting scope of cross-examination of hospitalist regarding her previous work for government was harmless, when testifying whether defendant medical doctors distributed controlled substances outside usual course of professional practice and without legitimate medical purpose, since expert testimony was not required, evidence suggested that defendant prescribed controlled substances to undercover "patient" only after cursory visit with him and without showing of medical need, and there was ample other evidence aside from hospitalist's testimony to convict defendants of other charges, including Racketeer Influenced and Corrupt Organizations Act conspiracy, drug distribution conspiracies, and health care fraud conspiracy. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 406, [21 U.S.C.A. § 846](#); [Fed. R. Evid. 702](#).

[1 Case that cites this headnote](#)

[More cases on this issue](#)

[86] Criminal Law 🔑 [Prejudice to Defendant in General](#)**Criminal Law** 🔑 [Rulings as to Evidence in General](#)

Evidentiary and other nonconstitutional errors do not constitute grounds for reversal unless there is a reasonable likelihood that they affected the defendant's substantial rights; where an error had no substantial influence on the outcome, and sufficient evidence uninfected by error supports the verdict, reversal is not warranted.

[1 Case that cites this headnote](#)

[87] Controlled Substances 🔑 [Sale, Distribution, Delivery, Transfer or Trafficking](#)

Physician's conduct for alleged violations of Controlled Substances Act by distributing controlled substances outside usual course of professional practice and without legitimate medical purpose had to be evaluated based on objective standard, not subjective "good

faith" standard. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, [21 U.S.C.A. § 841\(a\)\(1\)](#).

[3 Cases that cite this headnote](#)

[88] Criminal Law 🔑 [Failure to instruct](#)

A district court's rejection of a proposed jury instruction is reviewed for an abuse of discretion.

[89] Criminal Law 🔑 [Failure or Refusal to Give Instructions](#)

A district court commits reversible error by rejecting a proposed jury instruction if: (1) the requested instruction was a correct statement of the law, (2) its subject matter was not substantially covered by other instructions, and (3) its subject matter dealt with an issue in the trial court that was so important that failure to give it seriously impaired the defendant's ability to defend himself.

[90] Controlled Substances 🔑 [Defenses](#)

Good faith is a defense to a Controlled Substances Act violation as long as the defendants' conduct also was in accordance with the standards of medical practice generally recognized and accepted in the United States; defendants must maintain at all times that they acted in good faith and in accordance with that standard. Comprehensive Drug Abuse Prevention and Control Act of 1970 §§ 401, 406, [21 U.S.C.A. §§ 841\(a\)\(1\), 846](#).

[2 Cases that cite this headnote](#)

[91] Controlled Substances 🔑 [Elements in general](#)

Acting as drug dealer or drug pusher as conventionally understood was not necessary for Controlled Substances Act conviction for distributing controlled substances outside usual course of professional practice and without legitimate medical purpose. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, [21 U.S.C.A. § 841\(a\)\(1\)](#).

[92] Criminal Law 🔑 Objections and disposition thereof**Criminal Law** 🔑 Statements regarding applicable law

Jury instruction at end of trial defining criminal standard adequately for Controlled Substances Act conviction for distributing controlled substances outside usual course of professional practice and without legitimate medical purpose cured any incorrect references to civil standard of care by experts or prosecution, or expert's failure to define standard to be applied, particularly where defendants presented expert to provide explanation of "usual course of professional practice," expert's definition was that medical malpractice was not outside usual course of professional practice, and defendants argued that malpractice was not enough to convict. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841(a) (1).

3 Cases that cite this headnote

[93] Criminal Law 🔑 Sentencing and Punishment

District court's statement that it would have imposed same sentence did not render alleged substantively unreasonable Sentencing Guidelines errors harmless, since defendant's offense level would have been 25 if he succeeded on his Guideline challenges, which, with criminal history score of I, resulted in lower guideline range of 57 to 71 months, and district court did not provide sufficient fact-finding or explanation to support upward variance from 71 to 252 months. 18 U.S.C.A. §§ 1956(h), 3553(a) (2); U.S.S.G. § 2S1.1(b)(2)(B).

[94] Criminal Law 🔑 Sentencing

On appeal, the substantive reasonableness of a sentence is examined under the totality of the circumstances.

[95] Sentencing and Punishment 🔑 Operation and effect of guidelines in general

In determining whether to sentence a defendant outside the sentencing guidelines, a district court must consider the extent of the deviation and ensure that the justification is sufficiently compelling to support the degree of the variance.

[96] Sentencing and Punishment 🔑 Sufficiency

In sentencing, a major departure from the sentencing guidelines range should be supported by a more significant justification than a minor one, and the district court must adequately explain the chosen sentence to allow for meaningful appellate review and to promote the perception of fair sentencing.

[97] Sentencing and Punishment 🔑 Nature, degree or seriousness of offense

District court did not clearly err in concluding that at least 10.6% of prescriptions written by defendant medical doctor were illegal, in sentencing him after he was convicted of violating Controlled Substances Act conviction for distributing controlled substances outside usual course of professional practice and without legitimate medical purpose, since two nurse practitioners at defendant's clinic credibly suggested that half of clinic's patients were over-medicated, and evidence at trial indicated that significant amounts of defendant's practice occurred outside usual course of professional practice. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841(a)(1).

1 Case that cites this headnote

[98] Criminal Law 🔑 Application of guidelines**Criminal Law** 🔑 Review De Novo**Criminal Law** 🔑 Sentencing

When reviewing a sentence for procedural reasonableness, the Court of Appeals considers legal issues de novo, reviews factual findings for clear error, and applies the sentencing guidelines

to the facts with due deference, which is akin to clear error review.

[99] **Criminal Law** 🔑 Sentencing

A district court's determination of the quantity of drugs used to establish a base offense level for sentencing purposes is reviewed for clear error.

1 Case that cites this headnote

[100] **Criminal Law** 🔑 Theory and Grounds of Decision in Lower Court

Criminal Law 🔑 Sentencing

The Court of Appeals may affirm a district court's determination of the quantity of drugs used to establish a base offense level for sentencing purposes for any reason supported by the record, even if not relied upon by the district court. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841(a)(1).

[101] **Criminal Law** 🔑 Questions of Fact and Findings

To be clearly erroneous, a factual finding must leave the Court of Appeals with a definite and firm conviction that a mistake has been committed.

[102] **Criminal Law** 🔑 Questions of Fact and Findings

A factual finding cannot be clearly erroneous when the factfinder is choosing between two permissible views of the evidence.

1 Case that cites this headnote

[103] **Criminal Law** 🔑 Sentencing

The Court of Appeals accords great deference to a sentencing court's credibility determinations of drug-quantity witnesses. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841(a)(1).

[104] **Sentencing and Punishment** 🔑 Factors enhancing sentence

At sentencing, the government bears the burden of establishing drug quantity by a preponderance of the evidence. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841(a)(1).

[105] **Sentencing and Punishment** 🔑 Burden of proof

At sentencing, a district court must ensure that the government carries its burden of establishing drug quantity by presenting reliable and specific evidence.

[106] **Sentencing and Punishment** 🔑 Nature, degree or seriousness of offense

When the drug amount that is seized does not reflect the scale of the offense, the district court at sentencing must approximate the drug quantity. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841(a)(1).

2 Cases that cite this headnote

[107] **Sentencing and Punishment** 🔑 Nature, degree or seriousness of offense

In estimating the drug quantity attributable to the defendant, a sentencing court may rely on evidence demonstrating the average frequency and amount of a defendant's drug sales over a given period; this determination may be based on fair, accurate, and conservative estimates of the quantity of drugs attributable to a defendant, but it cannot be based on calculations of drug quantities that are merely speculative. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841(a)(1).

2 Cases that cite this headnote

[108] **Sentencing and Punishment** 🔑 Obstruction of justice

District court's finding that defendant medical doctor testified falsely about knowing about forgery of prescriptions was not clearly erroneous, in applying obstruction of justice enhancement to defendant's sentence after he was convicted of violating Controlled Substances Act conviction for distributing controlled substances outside usual course of professional practice and without legitimate medical purpose, since defendant directed co-defendant medical doctor in e-mail to talk to nurse practitioner on cutting down on use of red flag drugs and other persons who worked both in and outside clinic testified that they were aware that nurse practitioner was writing prescriptions. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841(a) (1); U.S.S.G. § 3C1.1.

[109] Criminal Law 🔑 Review De Novo
Criminal Law 🔑 Sentencing

In reviewing the district court's imposition of the obstruction-of-justice sentencing enhancement, the Court of Appeals reviews a district court's factual findings for clear error and its application of those findings to the Sentencing Guidelines de novo. U.S.S.G. § 3C1.1.

[110] Criminal Law 🔑 Sentencing

The Court of Appeals accords great deference to a district court's credibility determinations when applying the obstruction-of-justice sentencing enhancement based on perjury. U.S.S.G. § 3C1.1.

[111] Sentencing and Punishment 🔑 Obstruction of justice

Perjury occurs, within the meaning of the obstruction-of-justice sentencing enhancement, where a witness gives deliberately false testimony regarding a material matter, which is not caused by confusion, mistake, or faulty memory. U.S.S.G. § 3C1.1.

[112] Sentencing and Punishment 🔑 Necessity

If a defendant objects to an obstruction-of-justice sentencing enhancement resulting from his trial testimony, a district court must review the evidence and make independent findings necessary to establish a willful impediment to or obstruction of justice. U.S.S.G. § 3C1.1.

[113] Sentencing and Punishment 🔑 Necessity

To apply the obstruction-of-justice sentencing enhancement, a district court must make a factual finding that the defendant gave perjured testimony on a material matter. U.S.S.G. § 3C1.1.

[114] Criminal Law 🔑 Sentencing and Punishment

District court's error in applying two-level sentencing enhancement for money laundering when it should have applied one-level enhancement did not affect defendant's substantial rights, since defendant's original offense level was 44, which was treated as 43 because that was maximum offense level used by Sentencing Guidelines, and applying correct enhancement would not have changed calculation of Guideline range because it would have reduced his offense level only to 43. 18 U.S.C.A. § 1956(h); U.S.S.G. § 2S1.1(b)(2)(B).

2 Cases that cite this headnote

[115] Criminal Law 🔑 Sentencing proceedings in general

A failure to preserve a procedural objection at sentencing means that the Court of Appeals reviews only for plain error.

[116] Criminal Law 🔑 Necessity of Objections in General

Under plain error review, the Court of Appeals considers whether (1) an error occurred, (2) the error was plain, and (3) the error affects substantial rights, and when those factors are met, it may exercise discretion and correct the

error if it seriously affects the fairness, integrity or public reputation of judicial proceedings.

[117] Criminal Law 🔑 Sentencing

A district court's factual finding as to the specific amount of restitution is reviewed for clear error.

[118] Criminal Law 🔑 Restitution

A district court's decision with regard to restitution to allow an estimate of a victim's loss in a particular case is reviewed for abuse of discretion.

[119] Sentencing and Punishment 🔑 Actual loss

The amount of restitution ordered by a district court under the Mandatory Victims Restitution Act (MVRA) must be based on the amount of loss actually caused by the defendant's conduct. 18 U.S.C.A. § 3663A(a)(1).

[120] Sentencing and Punishment 🔑 Degree of proof

The government's burden in seeking restitution under the Mandatory Victims Restitution Act (MVRA) to establish the loss amount by a preponderance of the evidence simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence. 18 U.S.C.A. § 3664(e).

[121] Sentencing and Punishment 🔑 Degree of proof

Because criminals rarely keep detailed records of their lawless dealings, totaling up every column and accounting for every misbegotten dollar, the preponderance standard for establishing the amount of restitution under the Mandatory Victims Restitution Act (MVRA) must be applied in a practical, common-sense way. 18 U.S.C.A. § 3664(e).

[122] Sentencing and Punishment 🔑 Actual loss

As the determination of the restitution amount under the Mandatory Victims Restitution Act (MVRA) is an inexact science, the government need not calculate the victim's actual loss with laser-like precision, but may instead provide a reasonable estimate of that amount. 18 U.S.C.A. § 3664(e).

[123] Sentencing and Punishment 🔑 Burden of proof

Notwithstanding the government's burden under the Mandatory Victims Restitution Act (MVRA) to prove the restitution amount, the defendant bears the burden to prove the value of any goods or services he provided that he claims should not be included in the restitution amount. 18 U.S.C.A. § 3664(e).

[124] Sentencing and Punishment 🔑 Findings and statement of reasons

When a district court orders restitution under the Mandatory Victims Restitution Act (MVRA), it must explain its findings with sufficient clarity to enable the Court of Appeals to adequately perform its function on appellate review; to that end, the district court must specifically find whether the victim suffered a loss and the amount of those actual losses. 18 U.S.C.A. § 3663A.

[125] Sentencing and Punishment 🔑 Measure of valuation

Restitution to healthcare insurers under Mandatory Victims Restitution Act (MVRA) for 85% of payments each insurer made for transmucosal immediate-release fentanyl (TIRF) medications that defendant medical doctors prescribed during indictment period was not clearly erroneous, after defendants were convicted of violating Controlled Substances Act by knowingly or intentionally prescribing controlled substances outside usual course of professional practice or without legitimate medical purpose, since defendants prescribed

millions of doses of TIRFs for their own financial gain, rather than for legitimate needs of their patients, determining which of thousands of TIRF prescriptions were illegal would have been impractical, and defendant did not show value of TIRF prescriptions he wrote that he claimed were medically necessary. 18 U.S.C.A. §§ 3663A(a)(1), 3664(e).

[126] Sentencing and Punishment 🔑 Measure of valuation

Restitution to healthcare insurers under Mandatory Victims Restitution Act (MVRA) for 50% of each insurer's payments for Schedule II prescriptions dispensed by clinic was not clearly erroneous, after defendant medical doctors were convicted of violating Controlled Substances Act by knowingly or intentionally prescribing controlled substances outside usual course of professional practice or without legitimate medical purpose, since nurse practitioners who had firsthand knowledge of clinic's patients for years testified that at least half of clinic's patients were over-medicated or had received prescriptions for larger doses of drugs than they needed, and defendants' prescribing habits were consistently outside usual course of professional practice during indictment period. 18 U.S.C.A. §§ 3663A(a)(1), 3664(e).

[127] Sentencing and Punishment 🔑 Measure of valuation

Sentencing and Punishment 🔑 Degree of proof

The Mandatory Victims Restitution Act (MVRA) justifies the use of approximation provided the estimate is reasonable and based on a preponderance of the evidence. 18 U.S.C.A. §§ 3663A(a)(1), 3664(e).

[128] Sentencing and Punishment 🔑 Findings and statement of reasons

District court explained its findings with sufficient clarity to enable Court of Appeals to perform its duty on appellate review of

restitution order under Mandatory Victims Restitution Act (MVRA), after defendant medical doctor was convicted of violating Controlled Substances Act by knowingly or intentionally prescribing controlled substances outside usual course of professional practice or without legitimate medical purpose, where defendant's judgment of conviction broke down amount of restitution that was owed individually by defendant to each insurer and the amount defendant owed jointly and severally with co-defendant medical doctor to each insurer, and defendant never objected to actual losses sustained by any insurer, instead objecting only generally to method of calculating losses. 18 U.S.C.A. §§ 3663A(a)(1), 3664(e).

[129] Criminal Law 🔑 Points and authorities

A party seeking to raise a claim or issue on appeal must raise it plainly and prominently or otherwise the issue is deemed abandoned.

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Appeals from the United States District Court for the Southern District of Alabama, D.C. Docket No. 1:15-cr-00088-CG-B-2

Before [WILSON](#) and [NEWSOM](#), Circuit Judges, and COOGLER, * District Judge.

Opinion

COOGLER, District Judge:

Following a seven-week trial in the United States District Court for the Southern District of Alabama, pain management physicians Xiulu Ruan (“Ruan”) and John Patrick Couch (“Couch”) (together, “the appellants”) were convicted by a jury of conspiring to run a medical practice constituting *1120 a racketeering enterprise in violation of the Racketeer Influenced and Corrupt Organizations Act (“RICO”), [18 U.S.C. § 1962\(d\)](#); conspiring to violate the Controlled Substances Act, [21 U.S.C. §§ 846 & 841\(a\)\(1\)](#), by dispensing Schedule II drugs, fentanyl, and Schedule III drugs outside the usual course of professional practice and without a legitimate medical purpose; conspiracies to commit health care fraud and mail or wire fraud in violation of [18 U.S.C. §§ 1347\(a\) & 1349](#); and conspiracies to receive kickbacks in relation to a Federal health care program in violation of [18 U.S.C. § 371](#) and [42 U.S.C. § 1320a-7b\(b\)](#). In addition, Ruan and Couch were individually convicted of multiple counts of substantive drug distribution in violation of the Controlled Substances Act, [21 U.S.C. § 841\(a\)\(1\)](#). Ruan was further convicted of a money laundering conspiracy in violation of [18 U.S.C. § 1956\(h\)](#) and two counts of substantive money laundering in violation of [18 U.S.C. § 1957](#). Ruan was sentenced to 252 months’ imprisonment, to be followed by four years of supervised release, and ordered to pay over \$15 million in restitution. Couch was sentenced to 240 months’ imprisonment, followed by four years of supervised release, and ordered to pay over \$16 million in restitution.

In this broad-sweeping appeal, Ruan and Couch challenge their convictions, various evidentiary rulings at trial, and the district court’s jury instructions. Ruan also challenges his sentence and the district court’s order of restitution. After thorough review and having had the benefit of oral argument, we affirm in large part the decisions of the district court, but we reverse the district court’s ruling that sufficient evidence supported one of the illegal kickback conspiracy convictions. We thus remand the cases for resentencing.

I. Background

A. Procedural History

A Southern District of Alabama grand jury indicted Ruan and Couch on April 30, 2015, charging conspiracy to distribute controlled substances, [21 U.S.C. § 846](#), and conspiracy to commit health care fraud, [18 U.S.C. § 1347\(a\)](#). After a raid of their medical clinic and pharmacy by the Federal Bureau of Investigation (“FBI”), a Superseding Indictment issued on April 28, 2016, charging 22 counts. The Superseding Indictment alleged that Ruan and Couch’s medical clinic was essentially a “pill mill,” which prescribed controlled substances for no legitimate medical purpose or outside the usual course of professional practice. Ruan and Couch were both charged with one count of conspiracy to commit racketeering, [18 U.S.C. § 1962\(d\)](#) (Count 1); three counts of conspiracies to violate the Controlled Substances Act by dispensing Schedule II and III controlled substances and fentanyl outside the usual course of professional practice and without a legitimate medical purpose, [21 U.S.C. §§ 841\(a\)\(1\) & 846](#) (Counts 2–4); one count of conspiracy to commit health care fraud, [18 U.S.C. § 1347\(a\)](#) (Count 15); three counts of conspiracy to violate the Anti-Kickback statute, [18 U.S.C. § 371](#) (Counts 16–18); and one count of conspiracy to commit wire and mail fraud, [18 U.S.C. § 1349](#) (Count 19). Couch was charged with five additional counts of illegal drug distribution involving prescribing controlled substances to named individuals, [18 U.S.C. § 2\(a\)](#) and [21 U.S.C. § 841\(a\)\(1\)](#) (Counts 5–7 and 13–14). Ruan was charged with five additional counts of illegal drug distribution involving prescribing controlled substances to named individuals, [21 U.S.C. § 841\(a\)\(1\)](#) (Counts 8–12), and three counts of conspiracy to commit money laundering and substantive money laundering, [18 U.S.C. §§ 1956\(h\) & 1957](#) (Counts 20–22). *1121 The Superseding Indictment also contained numerous forfeiture provisions.

Ruan and Couch pled not guilty. Their joint trial commenced in Mobile, Alabama, on January 6, 2017, and lasted 31 days. The government called more than 50 witnesses, including 15 of their former patients or their relatives; 12 of their former staff members, including nurse practitioners with whom they had worked closely; four pharmaceutical company employees; seven representatives from various medical insurance companies; three medical experts; the director of the Alabama Department of Public Health; and 12 law enforcement agents and analysts. The government also introduced numerous charts from insurers and the Drug Enforcement Administration (“DEA”) reflecting the

volume and cost to insurers of prescriptions for controlled substances that Ruan and Couch had written, compared to other physicians in Alabama and nationally. Both Ruan and Couch testified in their defense, and they also called five former patients, 11 additional former employees, and three medical experts of their own. The government dismissed Count 18 at the close of its case. Ruan and Couch moved for judgments of acquittal under [Federal Rule of Criminal Procedure 29](#) at the close of the government's case, and again at the close of all the evidence, and the district court denied their motions.

On February 23, 2017, the jury convicted Couch on all counts against him. Ruan was acquitted on Count 10 but convicted on all other counts. Ruan and Couch renewed their motions for judgment of acquittal or new trial, and the district court denied the motions.

On May 25 and 26, 2017, the district court imposed below-guidelines sentences of 252 (Ruan) and 240 (Couch) months of imprisonment, each to be followed by four years of supervised release. Ruan was ordered to pay \$15,239,369.93 in restitution and Couch \$16,844,569.03. Ruan and Couch are currently incarcerated. This appeal followed.¹

B. Trial Evidence²

1. The Appellants' Clinic and Pharmacy

The appellants were board-certified doctors specializing in pain management. They co-owned a medical clinic, Physicians Pain Specialists of Alabama ("PPSA"), and a pharmacy, C&R Pharmacy ("C&R"). PPSA had two locations in Mobile, Alabama, one on Springhill Avenue and one on Airport Boulevard. C&R was connected to PPSA's Airport Boulevard location, and its sole business was dispensing drugs prescribed at PPSA. The Springhill office contained an in-office dispensary for workers' compensation patients. Ruan worked primarily at the Airport location and Couch primarily at Springhill, but once a week they would switch locations. In May 2015, when an FBI raid shut down PPSA and C&R, they had 57 employees and served over 8,000 patients.

The appellants' medical practice was lucrative. From January 2011 to May 2015, the period covered by the Superseding Indictment, Couch made over \$3.7 million from PPSA, and Ruan made over \$3.9 million. C&R received a service fee

for each prescription it filled—more than 70,000 during those years—netting Ruan and *1122 Couch each more than \$555,000 from their pharmacy.

2. The Controlled Substances Act

On the first day of trial government witnesses told the jury that the Controlled Substances Act categorizes controlled substances into five schedules, based on their abuse potential and medical value. The Act makes it a crime for anyone to, among other things, dispense a controlled substance, with the exception that licensed health care professionals may dispense Schedule II, III, and IV controlled substances with a prescription. *See* [21 U.S.C. §§ 841\(a\)\(1\), 828](#). However, such prescriptions are only lawful if they are issued for a legitimate medical purpose in the usual course of the licensed health care professional's professional practice. *See* [21 C.F.R. § 1306.04](#).

From January 2011 to May 2015, the appellants wrote nearly 300,000 prescriptions for controlled substances, over half of which were Schedule II drugs. Schedule II drugs are the most powerful and dangerous drugs that can be lawfully prescribed, and they include many pharmaceutical opioids such as [fentanyl](#), [hydrocodone](#), [morphine](#), [oxycodone](#), [methadone](#), [hydromorphone](#), and [oxymorphone](#). Opioids are dangerous because, while they can help mask pain, their use can create physical and psychological dependence that can lead to addiction. Side effects from opioid use include lethargy, confusion, falls, and depressed breathing.

Opioids can be particularly dangerous when combined with two Schedule IV controlled substances: benzodiazepines and [carisoprodol](#). Benzodiazepines, such as [Xanax](#) and [Valium](#), are psychoactive drugs that treat a wide range of conditions including insomnia or anxiety. [Carisoprodol](#) is a muscle relaxant marketed under the brand name Soma. The combination of these three types of drugs—which the government referred to as the "Holy Trinity" at trial—is popular among substance abusers because of its euphoric effect, yet it is highly addictive and can increase the chances of the user's death. Together, the appellants prescribed nearly 12.5 million units of Schedule II opioids, and opioid prescriptions accounted for nearly 75% of their total controlled-substance prescriptions. Most of the rest of their controlled-substance prescriptions were for benzodiazepines and Soma, the other components of the "Holy Trinity."

3. Ruan and Couch Prescribed Millions of Doses of Opioids Based on Their Financial Interests

The government sought to prove that Ruan and Couch prescribed millions of doses of opioids and other controlled substances outside the usual course of professional practice and, thus, illegally. Over Ruan and Couch's objection, the government used Alabama's Prescription Database Monitoring Program ("PDMP"), a database of all controlled substance prescriptions dispensed statewide that is available to doctors and other health personnel, to pull Ruan and Couch's prescribing data. The government focused especially on Ruan and Couch's frequent prescribing of a version of [fentanyl](#) called transmucosal immediate-release [fentanyl](#) ("TIRF"), which the Food and Drug Administration ("FDA") had approved in 2011 to treat "breakthrough pain in adult [cancer](#) patients who are already receiving and who are tolerant to around-the-clock opioid therapy." The two types of TIRFs that Ruan and Couch prescribed were Subsys, manufactured by Insys Therapeutics ("Insys"), and Abstral, manufactured by Galena Biopharma ("Galena"). Subsys is an under-the-tongue oral spray, and Abstral is an under-the-tongue dissolving tablet, but both penetrate the blood-brain barrier more quickly than medications absorbed ***1123** digestively, working in five minutes compared to 45 minutes for most other opioids. Not surprisingly, TIRFs are expensive, with average doses costing anywhere from \$3,000 to over \$20,000 per month. And although it is not illegal for a doctor to prescribe TIRFs "off-label" to patients who do not have [cancer](#), insurers would usually only pay for on-label uses of TIRFs. From January 2011 to May 2015, Ruan and Couch prescribed more than 475,000 doses of TIRFs to over 1,000 patients. From 2012 to 2014, they sharply increased both the number of patients receiving TIRF prescriptions and the dosages prescribed. This practice placed the appellants among the top TIRF prescribers nationwide: they often surpassed the next highest prescriber by more than double. Despite these high numbers of TIRF prescriptions, no more than 15% of PPSA patients had [cancer](#).³

One of the ways in which the government sought to prove that Ruan and Couch's prescribing of Abstral and Subsys deviated from the usual course of professional practice was that their prescribing habits tracked financial incentives rather than their patients' medical needs. One of the government's medical experts, Dr. Tricia Aultman ("Dr. Aultman"), testified that prescribing drugs based on one's own

financial interest is outside the usual course of professional practice.

i. The Appellants' Investments in Galena Stock

A DEA agent created a line chart showing the micrograms⁴ of Abstral prescribed by Ruan and Couch each month from January 2011 to May 2015. Ruan and Couch prescribed very little Abstral until late 2013—the most Couch prescribed was 76,800 mcg one month, and some months he did not prescribe any, and Ruan's prescriptions maxed out at 128,000 mcg per month. However, in April 2013, Galena initiated a study to gather data on how Abstral was working on patients. As former Galena sales representative David Corin ("Corin") testified, Galena offered doctors \$500 per patient to enroll in the study but limited it to 25 patients per doctor. Couch negotiated with Galena for an exception to enroll up to 75 of his patients for a fee of \$2,500 per patient. Immediately after Galena approved that arrangement, Couch began prescribing over 1.5 million mcg of Abstral per month.

Similarly, in September 2013, Ruan prescribed only 25,600 mcg of Abstral. But in October 2013, his prescriptions rose to 192,000 mcg. Around that time, a Galena sales representative visited PPSA in Mobile. Shortly thereafter, Couch and Ruan began purchasing Galena stock. Between November 2013 and January 2014, they purchased more than \$1.3 million of stock, both individually and through PPSA. In a February 2, 2014, email to Couch, Ruan wrote that they could "play a big role" in increasing the value of Galena stock. A few days later Ruan emailed another doctor, writing that although he had never purchased stock before, he decided to invest in Galena to help "generate enough profit to pay for [his] divorce settlement." And in a February 17, 2014, email between Ruan and a colleague, Ruan indicated that he ***1124** suspected Galena would have a "substantial market share growth at the end of March." Ruan's prescribing of Abstral greatly increased during this time. For example, in January 2014, Ruan prescribed over 1.4 million mcg; in February he prescribed over 2.3 million mcg; and in March his prescriptions rose to over 2.6 million mcg. Galena's stock price increased dramatically from October 2013 to the start of 2014, more than tripling in price.

However, Corin testified that in January 2014, members of Galena's board of directors were given a "blackout period" in which they were briefly permitted to sell their stock; they did so—"millions of dollars' worth"—and the price "dropped

dramatically.” Ruan and Couch “were very upset,” and a Galena representative flew to Mobile in February 2014 to calm them down because they were “important individuals for Galena” and the company’s “highest Abstral prescribers.” Ruan and Couch demanded that Galena fire its CEO and board. Between March and October 2014, their Abstral prescribing plummeted. Ruan reached a low of 624,000 mcg in August 2014, but that month, Galena fired its CEO, and in November, the new CEO came to Mobile to meet Ruan and Couch at Ruan’s demand. After that visit, their Abstral prescriptions again spiked, with Couch prescribing over 2 million mcg and Ruan prescribing over 1.8 million mcg in November. A similar dip in Ruan and Couch’s Abstral prescribing in February 2015 matched a significant dip in Galena’s stock price in February 2015, followed by another visit by the CEO to Mobile, and a rebound in Ruan and Couch’s prescribing.

Corin also explained that Galena initiated a voucher program in August 2013, where patients could receive up to three vouchers for 32 tablets of Abstral. Because TIRFs were so expensive, the purpose of the program was to help patients afford the drugs while they awaited insurance approval and to allow doctors to titrate patients onto the medication, with one voucher being issued at a time until an appropriate dose was found for a full prescription. However, Ruan and Couch would use all three prescriptions at once. Galena started losing money as a result of this practice because Galena would pay for all 96 pills instead of whatever vouchers were needed to titrate the patients, and Couch and Ruan were the top two prescribers in the country, accounting for 30% of the total prescriptions for Abstral. Under the voucher program, the pharmacy filling the prescriptions got paid the same as if the prescription was fully covered by insurance. And 91% of the Subsys and Abstral prescriptions Ruan and Couch wrote were filled by their patients at their own pharmacy, C&R. Galena had to abandon the voucher program in March 2014, and Ruan and Couch slowed their prescribing of Abstral in response to the cessation of the voucher program.

When PPSA was shut down in May 2015, national Abstral sales dropped “significantly.” In fact, Galena was forced to sell its license for Abstral because it could not make up the lost revenue.

ii. The Appellants’ Participation in Insys’s Speaker Program

Natalie Perhacs (“Perhacs”), a former sales representative for Insys, testified that Insys also sought to influence Ruan and Couch’s prescribing with money. Perhacs first met Ruan and Couch when she was a sales representative for a respiratory equipment company. Eventually, Ruan recommended Perhacs for a job at Insys. Perhacs became the Insys drug representative for Ruan and Couch. She explained that Insys had created a speaker program in August 2012 in which it paid doctors to talk about Subsys to other doctors, usually over a meal at a restaurant. Pharmaceutically-funded *1125 speaker programs are lawful, but payments made to doctors are required to be disclosed to the public. Both Ruan and Couch had been speakers for Insys since before she started. The stated goal of the speaker program was to educate doctors and get them to write more prescriptions, but Perhacs stated that Ruan and Couch would do speaker programs when no other prescribers showed up. She stated that PPSA was one of the top ten prescribers of Subsys, and Ruan and Couch were “whales” (the top prescribing doctors). She indicated that the actual purpose of the speaker program was to influence Ruan and Couch into continuing to prescribe Subsys, and Ruan and Couch were paid for their involvement in these dinners. In 2013, Ruan and Couch were each paid to host one program per week, and although no prescribers, or the same prescribers, would show up to speaking programs, they were rarely canceled because the point was not to educate others but to “influence how many prescriptions [the appellants] write.” If a program was canceled, Perhacs could be fired or face a financial penalty.

In November 2013, Ruan approached a Galena sales representative about becoming a speaker for Abstral because of his high-prescribing of TIRF medications, generally. However, Galena decided it would not make sense to have Ruan be a speaker because there were no other doctors in the area prescribing TIRF medications, and the purpose of the speaker program was to educate other doctors.

In early 2014, after the appellants started prescribing more Abstral, the competing TIRF medication, Insys employees grew concerned about losing market share. On an email including top Insys executives, the Vice President of Sales said that “Dr. Ruan and Dr. Couch are killing us.” In April 2014, Insys reduced, but did not stop, the appellants’ speaking programs.

A few months later, in June 2014, Ruan learned that a Michigan doctor, the top national Subsys prescriber, had been indicted for receiving kickbacks from Insys in part

related to his acceptance of honoraria received from the speaker program. In that criminal complaint, which Ruan saw, Ruan and Couch are identified by prescriber number as the number three and five prescribers, respectively. The next day, Ruan began planning for Insys to donate all of his subsequent speaker fees to universities, in one case establishing a scholarship in his name.

Nonetheless, Insys paid Couch more than \$100,000 and Ruan over \$166,000 for speaking engagements from 2013 until the FBI raided PPSA in May 2015. In 2016, Perhaps pled guilty to conspiracy to violate the Anti-Kickback statute by paying kickbacks to the appellants to prescribe Subsys through the speaker program.

iii. The Appellants Ordered Unnecessary Drug Tests and Used Their Pharmacy Inappropriately

Prescribing certain drugs when they had a financial self-interest to do so was not the only example of illegal conduct by Ruan and Couch: the government also sought to prove that they ordered unnecessary drug tests for patients solely because they would generate revenue. Government expert Dr. Rahul Vohra (“Dr. Vohra”) explained that in pain management, drug testing patients can be a valuable clinical tool because it can tell a doctor whether the patients are not taking the drugs prescribed or are taking other drugs that they should not be. This testing comes in two forms: an in-office “cup” screening, which is instantaneous but less accurate, and an off-site test with [gas chromatography](#) and [mass spectroscopy](#) (GC-MS), which takes longer but is more accurate. In 2013, Ruan began ordering off-site GC-MS testing for every patient because, in ***1126** his words, off-site testing “generates revenue,” while in-office urine tests “pays nothing.” Ruan negotiated with the off-site drug testing company, threatening to work with a competitor unless the company could start immediately because he was “losing about \$8,000 a day from not testing and ... cannot just wait.” Later that year, when PPSA switched to an electronic medical records system, and nurses forgot to order the GS-MS tests in the system for every patient, Ruan forwarded to Couch a discussion from the testing company about the missing orders, estimating an annual lost profit of over \$800,000. He told Couch, “[I]f we do not run GC-MS, there is no revenue.”

Dr. Aultman and Dr. Vohra also explained that the proper way for a doctor to use drug screening is to counsel patients whose tests are inconsistent, indicating potential diversion or

abuse of drugs, or to eventually “fire” them as patients. Yet the government presented evidence that Ruan and Couch rarely fired patients whose drug screens were inconsistent because they would lose the revenue. For example, a patient who was selling his medications was released from the practice only after his sixth or seventh inconsistent drug test using his five-year-old son's urine. Another patient, a former felon with numerous drug screens not showing prescribed drugs, was also continuously prescribed more opioids. An email Ruan wrote to a medical student was introduced, in which Ruan stated that “[i]n private practice the more you fire, the more revenue you lose.” Instead, he opined, “when one patient tests positive for street drugs, that gives you more reason to do more frequent urine drug screens, which pays three times more than an office visit.” While Ruan and Couch did not often fire patients with inconsistent drug screens, they did fire patients whose insurance would no longer pay for their TIRFs. For example, despite a history of drug abuse and three trips to the emergency room caused by her overusing TIRFs, Ruan dismissed patient Kathleen Burns only after her insurance stopped covering Subsys.

The government also put on evidence that Ruan and Couch used their pharmacy, C&R, inappropriately. Insys helped them prescribe more Subsys by ensuring it would be in stock at C&R. C&R was “having trouble filling [Subsys] as often as it was written.” This was even though, in 2014, C&R was ordering from wholesalers more than 42 times as much Subsys as the average U.S. pharmacy. Insys's owner and its CEO came to Mobile, and it was arranged that C&R would purchase Subsys directly from Insys, cutting out the wholesalers. Ruan and Couch also asked Galena to cut out the wholesalers and ship Abstral directly to C&R, but it refused. However, Galena did offer a rebate program under which C&R received 8.75% of the purchase price for all Abstral it dispensed. C&R dispensed nearly \$13 million of Abstral, approximately half of which occurred after the rebate agreement, making its rebate to C&R more than half a million dollars.

Additionally, Ruan and Couch often prescribed medications based solely on what was in stock at C&R, rather than on the patient's medical needs. Nurse practitioners testified that Ruan “strongly encouraged” patients to use C&R and that staff took patients’ prescriptions directly to C&R. One testified that Ruan “wanted to know what we [C&R] had in stock” before writing prescriptions. Dr. Greenberg opined that Ruan and Couch should have disclosed to patients that they owned C&R, but they rarely did.

4. Ruan and Couch Often Prescribed Opioids Without Seeing Patients, Obtaining Informed Consent, or Keeping Accurate Records

Another way that the government sought to establish that PPSA operated *1127 outside the usual course of professional practice was to show that Ruan and Couch prescribed powerful opioids without actually seeing patients. The government's medical experts testified that before prescribing controlled substances, a doctor should see the patient, take a medical history, and do an exam. A doctor who conducts a thorough evaluation of each patient can normally see 20 to 25 patients per day, but PPSA routinely processed 150 to 200 patients daily, often quadruple-booking patients for the same time. This worked because many PPSA patients never saw Couch and rarely saw Ruan. In fact, one patient for whom Couch signed multiple prescriptions and another patient's wife who came to half of her husband's appointments could not identify Couch in court because they had never met him. Others said they had met him only once, despite multiple PPSA visits during which he signed prescriptions for them. Instead, patients were seen by nurse practitioners who were not doctors, namely Justin Palmer, Stacy Madison, Bridgette Parker, Matt Bean, and Sharon Noland.

The jury was able to see this practice firsthand as DEA task force officer Patrick Kelley ("Kelley" or "Officer Kelley") went undercover to PPSA as a patient under the alias "Shawn Brennan" in August 2014. Kelley testified, and undercover videos of his PPSA office visits were played for the jury. The DEA arranged for a local chiropractor to refer Kelley to Couch with medical records, including normal MRI results. Although Kelley was first turned away from PPSA because he did not have insurance, he was admitted later that same day after the chiropractor called PPSA to vouch for him. Rather than see Couch, Kelley saw a nurse practitioner, Stacy Madison ("Madison"), who took a brief medical history from Kelley but did not question him about his pain levels, even though he had deliberately left that question blank on the new patient form. Kelley was asked to bend forward as far as he could without pain, and he was able to touch the floor. Nonetheless, he was asked whether he had previously taken anything that helped with his pain. Kelley started his answer with the caveat that he was "going to have to admit to some criminal activity" and said that he had "blue" pills called "Roxy"—purposefully using street names for [Roxicodone](#) 30 mg, an "immediate release" version of oxycodone that

is popular among substance abusers. Couch made a 42-second appearance at the end of that visit and signed a 90-pill prescription for [Roxicodone](#) 30 mg. Kelley returned for four more visits, never saw Couch again, and received [Roxicodone](#) prescriptions each time. At his third visit, the nurse practitioner, now Bridgette Parker ("Parker"), increased his dose to 110 pills. Kelley never filled the prescriptions, which a check of Alabama's PDMP would have revealed, and urine tests did not show the drugs in his system, but no one at PPSA ever discussed that with him. Parker also gave Kelley signed prescriptions, dated for a month later than his visit, although regulations provide that physicians must write a separate prescription for each 30-day supply of a Schedule II drug and prohibit a single prescription with refills. The prescriptions Kelley received at three of these visits to PPSA were the basis for Couch's convictions for illegal drug distribution on Counts 5–7.

Two undercover DEA agents posed as patients of Ruan's as well, but Ruan never prescribed either patient opioids. The government moved *in limine* to exclude videos of these visits, arguing that they did not show anything illegal and Ruan was merely trying to prove that he practiced "good medicine." The district court agreed, so the jury never saw them.

Nurse practitioner Justin Palmer ("Palmer") also offered extensive testimony *1128 for the government, particularly about Couch's practice. Palmer had worked at PPSA since July 2010, first working with both Couch and Ruan but after about a year working almost exclusively with Couch. Palmer stated that he would see roughly 30 patients a day on Couch's behalf, often starting hours before Couch arrived at the office. Some patients believed Palmer was a doctor, referring to him as "Dr. Justin." Palmer's visits were billed to insurance as if Couch was the one seeing the patients. Palmer also wrote prescriptions for opioids under Couch's signature, even though Palmer was not authorized to prescribe Schedule II drugs. When Couch went on vacation, "he would leave prescription pads that were presigned so [Palmer] could write what [he] needed to." Couch continued doing this even after PPSA's practice administrator told him it was illegal and risky. In time, Palmer began forging Couch's signature on prescriptions. PPSA and C&R staff knew Palmer was doing this, and nurses and the pharmacist would ask him to sign Couch's name on prescriptions and records. At one point, Couch caught Palmer forging his name on a prescription for Adderall, a Schedule II drug, and fired him—but only for "10 minutes"—before deciding to give him a second chance and rehiring him. Palmer stated that he believed that Couch

continued to be aware of his forgery because Palmer was seeing patients when Couch was on vacation or out of the office. Palmer estimated that, between 2011 and 2012, he had forged Couch's signature 15 to 20 times a day.

Palmer also purchased Galena stock when Ruan and Couch did. After that, he and Couch discussed candidates that they believed could be suitable for Abstral, and it was suggested that Palmer find people to put on the drug. Palmer also confirmed that he prescribed TIRF drugs to non-cancer patients for breakthrough pain, such as migraines that did not respond to other medication.

Palmer testified that, while at PPSA, he observed what he believed to be drug-seeking behavior from patients, such as patients needing more and more medication, saying that they had lost medication, coming back early for refills, or saying that they had new pain. He stated that he would often have to argue with patients because he believed that their pain was not as severe as they were reporting. The government asked:

Q: Did you feel like you were overwriting?

A: I did.

Q: Approximately what percentage of the patients did you feel like were overwritten?

A: At least—at least half, half to maybe more.

Palmer also stole and abused medications from PPSA while working there. After a PPSA employee caught Palmer actively injecting drugs while at work, Couch suspended him with pay for two weeks. According to Palmer, nurse practitioners Parker and Madison also used drugs while working for Couch. Prior to trial, Palmer pled guilty in this action to conspiracy to distribute controlled substances outside the usual course of professional practice and without a legitimate medical purpose.

Nurse practitioner Sharon Noland (“Noland”) also testified for the government. She had worked at PPSA since November 2011, working solely for Ruan until May 2014. She testified that Ruan would prescribe certain drugs—which Noland called the “flavor of the day”—based on what speaker programs he was doing and what was being pushed by “drug reps,” even if the patient's pain was controlled on an existing regimen. She described that Ruan *1129 was “very involved with the practice,” agreeing with the government's characterization that he tended to “micromanage.” Noland

said that she witnessed Palmer signing prescriptions as Couch.

Nurse practitioner Parker also testified. She had worked at PPSA from September 2012 to January 2015, working solely for Couch since December 2013. Parker testified that although TIRF medications were indicated for cancer, Ruan used it off-label “for anything we could use it on.” Parker also testified that Ruan would change patients’ medications, adding TIRF medications to their regimen, when their prior medications were working. Ruan would also change patients from one TIRF medication to another without explanation. Parker confirmed that Palmer would sign Couch's name on prescriptions, and she stated that she believed that half of the patients at PPSA were overmedicated, basing her opinion on the fact that the patients “looked ... overmedicated, wanted more medication.” Parker also abused prescription drugs while at work, even going into withdrawal, and Couch agreed to help pay for her treatment. Like Palmer, Parker pled guilty prior to trial in this case to conspiracy to distribute controlled substances.

Ruan was aware of Couch's practice of permitting Palmer and others to see patients and write prescriptions on Couch's behalf. In July 2014, for example, Ruan sent an email to Couch asking Couch to “talk to Justin [Palmer] on cutting down” the amount of Roxicodone 30 mg he prescribed in light of news reports that Alabama had the most opioid prescriptions in the country, which Ruan feared could increase regulatory scrutiny of PPSA.⁵ Couch responded that “[w]e,” meaning he and Palmer, would not “write triple digit dispensations [sic] of short acting opioids.” And although Ruan usually signed his own prescriptions, he often did so without seeing patients. Several nurse practitioners testified that they would line up at Ruan's office for him to sign prescriptions. One patient testified that he did not meet Ruan until his “fourth or fifth visit” when Ruan “stuck his head in the door” to introduce himself.

The government's experts also explained to the jury that the usual course of professional practice is to obtain patients’ informed consent before administering drugs and to have accurate records supporting every prescription. But there was evidence presented that many patients received no warnings before receiving prescriptions for powerful opioids. And many PPSA records contained numerous errors, including not listing all prescriptions written or explaining why a prescription was changed. Patients *1130 testified that exams and tests listed in their medical records did not occur.

5. Specific Prescriptions Were Illegal

Aside from evidence pertaining to how Ruan and Couch operated PPSA, the government also put on evidence that Ruan and Couch treated approximately three dozen specific PPSA patients outside the usual course of professional practice or prescribed them medications for no legitimate medical purpose. Fourteen patients, or their family members, testified at trial, criticizing the care they received. The government's three medical experts, Dr. Aultman, Dr. Vohra, and Dr. David Greenberg ("Dr. Greenberg"), reviewed other patients' files and offered their opinions that the appellants' treatment of those individuals did not meet the usual course of professional practice standard. Evidence was presented that Ruan and Couch rapidly increased patients' opioid dosages beyond the minimum necessary for pain control and failed to refer patients for mental-health treatment, surgery, or physical therapy that their records indicated would have been appropriate. They prescribed powerful opioids to people displaying red flags for diversion and abuse, like criminal records, inconsistent drug screens, and drug-seeking behavior. Some patients testified that they were overmedicated on opioids, making their lives worse.

For example, patient Randall Blackmon ("Blackmon") testified that he saw Couch on his first visit to PPSA but only saw Palmer on subsequent visits. Blackmon was prescribed [morphine](#), [methadone](#), and Subsys, even though he did not have [cancer](#); a physical examination was never conducted; and no one warned him that Subsys could interact negatively with his existing medications. He took 1600 mcg of Subsys four times a day for eight months, and he claimed that it made him lethargic and ruined his quality of life. Towards the end of the eight months, he presented to his primary care physician in such a dire state on Subsys that he was taken directly to the emergency room. At that point he learned that Subsys was only recommended for [cancer](#) patients, and his insurance stopped covering it. By that time his insurance had paid over \$21,500 per month for his Subsys.

Similarly, patient Joyce Barber ("Barber") was never treated by Couch, only Madison. She was prescribed Subsys with no warnings of the risks, and although she did not have [cancer](#), PPSA staff reported to her insurer that she had uterine [cancer](#) so that her Subsys prescription would be covered. Barber testified that Subsys made her feel like she was in a fog, and when Madison increased her prescription from 200 mcg

to 400 mcg, she became addicted, slept all day, and had no quality of life.

Patient Tina Goellner never saw Couch as a patient of PPSA. She recounted that, although she told staff at her first visit that she did not want to be prescribed narcotics for her pain because she was worried about becoming addicted, she was prescribed Subsys anyway and told that she should not worry because she did not have an "addictive personality." Subsys made her sleepy within two minutes of taking it, and when her dosage was increased rapidly from 200 mcg four times a day, to 400 mcg four times a day, to 800 mcg four times a day, she began sleeping all day.

Patient Tamison Blanks("Blanks") testified that she saw Couch once for five minutes despite going to regular appointments at PPSA for over 11 months. Although she was already taking Soma and [hydrocodone](#) (brand name [Norco](#)), she was prescribed 600 mcg of Subsys to use four times a day on her first visit, with no warnings. She described her dosage as "very strong" and said that she became a "monster" on Subsys. *1131 She described an instance where the Subsys numbed her to the point that she lay on a heating pad for so long that it burnt her breast, requiring a visit to the emergency room. She also said that at one of her appointments at PPSA, nurse practitioner Parker had abused opioids to the point that she was talking incoherently and fell asleep for about 10 minutes. Blanks commiserated with Parker's predicament because she had been in the same situation, and left that appointment and immediately checked in to a rehabilitation center.

In an attempt to contrast testimony like the foregoing, Ruan and Couch sought to call patients who would have testified that they approved of their treatment by Ruan and Couch and that their treatment enabled them to have a better quality of life. However, the district court ruled that because the appellants were not charged with illegally prescribing medication to all of their patients, and the government acknowledged that they had many patients to whom they provided legitimate care,⁶ this "good patient" evidence was irrelevant to the charges and would waste time in an already lengthy trial. They were thus prohibited from calling patients not identified in the Superseding Indictment or otherwise presented throughout the government's case, but they were, however, able to call as witnesses patients whose files were discussed by the government's experts.

6. The Appellants Engaged in Fraud, Accepted Kickbacks, and Ruan Laundered the Proceeds

Aside from violating the Controlled Substances Act, the government also presented evidence that the appellants engaged in fraud. Ruan and Couch lied to insurers, telling them that some patients had **cancer** so that insurers would pay for their TIRF prescriptions. BlueCross BlueShield of Alabama (“BCBS”), which insured a large portion of PPSA’s patients, paid less for nurse practitioner visits than for doctor visits and had a policy requiring a physician to actually see a patient before billing for services under the physician’s name, yet Ruan and Couch routinely billed BCBS for office visits conducted entirely by nurse practitioners under the doctor’s identification number. The appellants also billed for more complex office visits than they actually conducted, resulting in more revenue.

To support the charges alleging conspiracies involving kickbacks, Perhaps testified that the fees Ruan and Couch received from the Insys speaking engagements were solely to induce them to prescribe more Subsys. Separately, the government sought to prove that the company that managed PPSA’s in-house workers’ compensation dispensary gave illegal kickbacks to Ruan and Couch in exchange for referring their patients. Christopher Manfuso (“Manfuso”) testified that Ruan and Couch treated patients with work-related injuries covered by workers’ compensation insurance, which most workers get through a state program. For patients’ convenience, Alabama’s workers’ compensation program permits doctors to have an in-office dispensary for workers’ compensation patients. Unlike a pharmacy, a dispensary provides only prepackaged medication. Insurers, including the workers’ compensation program, “apply a steep discount” to medication dispensed at a pharmacy and billed electronically. But in a dispensary, the state sets the prices for medications, and Alabama’s fee schedule is “quite generous compared to commercial insurance.” Accordingly, “there’s more ***1132** money to be made” with a dispensary than sending workers’ compensation patients to a pharmacy, even one owned by the doctor; the revenues can be “about a hundred percent higher.”

The appellants ran such a dispensary at PPSA’s Springhill location to dispense drugs to patients covered by workers’ compensation insurance. In 2011, Industrial Pharmacy Management (“IPM”) approached the appellants about taking over the management of their dispensary. When working with

an outside company like IPM to manage a dispensary, the management company usually fronts the money to purchase the medications under the doctor’s DEA number and then reimburses itself from the gross receipts. The management company then deducts its management fee, usually 30%, and any additional costs, and the doctor is left with the remaining profit. With their previous management company, Ruan had been receiving around \$40,000 a month in profit from PPSA’s dispensary. To “induce [the appellants] to sign up with” IPM, Manfuso, an IPM representative, offered to deviate from the standard payment model and guarantee Ruan \$45,000 a month—regardless of how much or how little the dispensary actually profited—because it was “the only way [he] could get the business.” Over the next two years, Ruan executed several variations of this contract with IPM, negotiating on behalf of both himself and Couch. Ruan’s guarantees fluctuated between \$45,000 and \$53,000 a month. Couch received guaranteed payments in the \$15,000-to-\$20,000 range. To hide this difference from Couch, Ruan insisted that Manfuso send the checks to his house, not to PPSA.

After several years, the FBI raided and shut down IPM for paying kickbacks, and Michael Drobot, Manfuso’s direct boss at IPM, pled guilty to providing kickbacks in a California prosecution. Manfuso then opened his own company, Comprehensive RX Management (“CRM”). Ruan demanded even higher guarantees from CRM, upwards of \$80,000 a month at one point. All told, Ruan received more than \$2.4 million and Couch received nearly \$1 million from IPM and CRM.

Manfuso recalled that his interactions with Ruan were “[e]xtremely atypical” of the hundreds of other doctors with whom Manfuso worked. In determining how to stock the formulary (the dispensary’s inventory of drugs), Ruan was interested in the profit margins of various drugs, not clinical information. Manfuso also ultimately pled guilty to violating the Anti-Kickback statute.

Finally, to support the three money laundering counts, the government presented evidence that Ruan had 23 different bank accounts and used proceeds from illegal activities to purchase two luxury cars, worth over \$100,000 each.

7. The Defense Case

Ruan and Couch testified in their defense, both stating that their various policies and practices were within the usual

course of professional practice. Couch denied ever giving Palmer permission to sign his name on a prescription. On cross-examination, the government asked Ruan about the email that he sent to Couch regarding Palmer writing fewer [Roxicodone](#) prescriptions. The following exchange occurred:

Q: Okay. Now, is this one of the things you told [Couch] is: Please remind [Palmer] about this stuff.

A: That's what it said.

Q: Because you knew that [Palmer] was writing [prescriptions for [Roxicodone](#)]; correct?

A: He was initiating, I thought, not that he was—he saw the follow up and he initiated it. Dr. Couch had to approve. So if he initiated it, Dr. *1133 Couch do [sic] not want to turn it down.

Q: But you had knowledge that [Palmer] was—you wanted [Palmer] to cut down the [[Roxicodone](#)]; is that correct?

A: Initially, yes. That's my intention; that's right.

Q: And Dr. Couch told you back that he reviewed it with [Palmer] and it says: We do not write triple digits; is that correct?

A: Yes, that's what it says.

Q: It says “we?”

A: Right.

Ruan and Couch also called various PPSA employees and five patients identified by the government who testified favorably as to their course of treatment at PPSA. They called three experts, Dr. Carol Warfield (“Dr. Warfield”), Dr. Christopher George Gharibo, and Dr. Jeffrey A. Gudin. Dr. Warfield opined that Dr. Couch's prescribing habits were within the usual course of professional practice and for a medical purpose. Specifically, Dr. Warfield reviewed files for five of Couch's patients, and she testified that the medications Couch prescribed were in the usual course of medical practice and for a legitimate purpose. The other experts testified similarly.⁷

C. Forfeiture and Ruan's Sentence

Immediately following the verdict, Ruan signed a forfeiture agreement, stipulating that he “w[ould] not oppose the entry of a Preliminary Order of Forfeiture, forfeiting the above-listed assets and sums of money.” He agreed to forfeit various

bank accounts, two real properties, and 18 cars, and to the entry of a money judgment “for a sum of money of at least \$5,000,000.” The following week, the district court entered a Preliminary Order of Forfeiture pursuant to this agreement. This order became final at sentencing.

In Ruan's presentence investigation report (“PSR”), the probation officer applied a base offense level of 38 under [U.S.S.G. § 2S1.1](#), based on an underlying offense of drug conspiracy for which the government asserted that Ruan was accountable for the equivalent of 309,872 kilograms of marijuana. Ruan then received a two-level enhancement under [U.S.S.G. § 2S1.1\(b\)\(2\)\(B\)](#) because he had been convicted of violating [18 U.S.C. § 1956](#). He received another two-level enhancement for abusing a position of public trust, pursuant to [U.S.S.G. § 3B1.3](#). Finally, Ruan received a two-level obstruction-of-justice enhancement for testifying falsely at trial pursuant to [U.S.S.G. § 3C1.1](#). The PSR calculated the adjusted offense level as 44, but because the offense level exceeded the maximum level used in the guidelines, which is 43, the PSR treated Ruan's total offense level as 43. Because Ruan had no criminal history, he was attributed a criminal history category of I.

Based on an offense level of 43 and a criminal history category of I, the PSR noted that the guideline imprisonment range was simply “life.” However, the statutorily-authorized maximum sentences for each of the convictions were less than the applicable range. Specifically, the PSR noted that the maximum term of imprisonment was: (1) 20 years for each of Counts 1, 2, 4, 8, 9, 11, and 12; (2) 40 years for Count 3; (3) 10 years for each of Counts 15, 18, 19, 20, 21, and 22; and (4) 5 years for each of Counts 16 and 17. Pursuant to [U.S.S.G. § 5G1.2\(b\)](#), the probation officer converted the statutory maximum penalties to months and added them together, arriving at a guideline range of 3,000 months. The probation officer also determined that Ruan owed restitution totaling *1134 \$17,261,859.14 to various insurance companies that had paid for illegal prescriptions.

Ruan objected to the PSR and filed a sentencing memorandum, and the government responded to his objections. Ruan first objected that the government's drug-quantity calculation grossly overestimated the number of relevant prescriptions. The government responded that the district court needed only to approximate the quantity of controlled substances that were within the scope of the criminal activity that Ruan jointly undertook. The government explained that to reach that total drug quantity,

the government requested data of all controlled substances that PPSA prescribed during the relevant period, and then reduced the list to only morphine, oxycodone, methadone, hydromorphone, oxymorphone, and fentanyl. The government then calculated the total number of grams prescribed of each individual drug by first multiplying the number of units of the drug prescribed by its strength and converting that result to grams. Then, the government calculated the total amount of each drug and converted these totals to their marijuana equivalents. In determining how many of those prescriptions were illegal, the government acknowledged that not all prescriptions were illegal. However, the government noted that there was testimony from several witnesses, including nurse practitioners Palmer and Parker, who roughly estimated that 50% of the patients were illegally prescribed controlled substances. However, the government also stated that the ascribed offense level would still have been appropriate even if only 10.6% of the prescriptions written by Ruan and Couch were illegal. The government argued that sufficient evidence at trial was presented for the court to find that at least 10.6% of the prescriptions were written outside the usual course of professional practice, including: the manner in which Ruan and Couch prescribed opioids was consistent across time and patients; Couch rarely saw patients during follow up office visits; prescriptions were written in Couch's name by Palmer, which both doctors knew about; 5,793 prescriptions were written in Couch's name when he was out of the state or country; patients were seen and prescribed opioids before Couch would arrive to work at PPSA; and Couch and Ruan prescribed medication when they had a financial self-interest to do so.

Ruan disagreed, contending that the drug quantity should have been based on what was proven at trial through expert or patient testimony, and he argued that any reliance on Palmer's or Parker's statements as to 50% of the prescriptions being unlawful would be improper because (1) there was no established basis for their opinions, (2) they worked at a different location than Ruan, and (3) they lacked the ability or expertise to reach their conclusions. Ruan also offered DEA publications, which he stated showed that the average sentence for cases with between 1 and 5 distribution counts was 83.4 months.

Ruan also adopted Couch's arguments at sentencing, among them that other circuits followed a more nuanced approach in calculating drug quantities attributed to physicians because doctors' prescriptions were presumed to be legal. He also

asserted that courts should exclude any prescriptions that merely breach the civil malpractice standard because that standard did not establish criminality. He noted that, despite the government having Palmer on the stand for several hours, the reference to the 50% figure lasted mere seconds, and the government could have elicited more details from Palmer, such as explaining whether the term "overmedicated" referred to a breach of the civil standard of care or to prescriptions outside the usual course of professional practice.

***1135** Ruan's second objection to the PSR was to the restitution calculation. The government explained that it calculated restitution by taking the total paid for medications by insurers BCBS, United Healthcare, Medicare, and Tricare, and first deducted the payments each made for non-controlled substances and Schedule IV and V controlled substances. Then, the government deducted 15% of the total each insurer paid for TIRF prescriptions, based on testimony that no more than 15% of PPSA patients were cancer patients. The government finally deducted 50% from the amounts each insurer paid for the remaining Schedule II prescriptions based on the testimony that 50% of PPSA patients were overmedicated. Ruan responded, with regard to the illegal TIRF prescription percentage of 85%, that off-label TIRF prescriptions were not inherently illegal. He pointed out that insurance companies, including BCBS, sometimes approved such prescriptions, and that Dr. Aultman had agreed that prescribing off-label is not illegal. He also argued that the 50% figure as to the remaining Schedule II drugs was speculative, and the government should provide specific evidence as to why each prescription paid for by each insurer was fraudulent.

Ruan's third objection was to the obstruction-of-justice enhancement. In response, the government stated that Ruan testified falsely when he stated that he was unaware that Palmer was forging Couch's prescriptions. In an email, Ruan reminded Couch to talk to Palmer about not prescribing "red flag" drugs, and testimony from other PPSA employees and patients established that nearly everyone was aware that Palmer was prescribing controlled substances in Couch's name. The government pointed out that Ruan had a financial interest in that activity because prescriptions forged by Palmer could be filled at C&R.

At sentencing, Ruan reiterated these arguments.⁸ He also argued that: (1) he prescribed half the number of drugs that Couch did; (2) he exercised greater oversight over his nurse practitioners than Couch had; (3) he had an excellent national reputation; and (4) despite some mistakes, he practiced good

medicine and legitimately helped patients. The government responded that: (1) Ruan was the leader of PPSA and that every aspect of the illegal activity was led and directed by him; (2) he made a variety of decisions in his practice based on whether he would make money off of them rather than whether it would benefit the patient being treated; and (3) he had a variety of valuable assets that he attempted to hide.

The district court found that Ruan was the leader of the fraud offenses and racketeering enterprise. The court noted that Ruan was the “better doctor”—insofar as he had more board certifications and degrees—but it was his making the business decisions that necessitated a higher sentence. The district court stated that it recalled testimony that 50% of the prescriptions written were not for a legitimate medical purpose and stated that using this testimony was a reasonable way for the government to calculate the drug-quantity and restitution amounts. The court found that the government had showed that at least 10.6% of the prescriptions were written outside the usual course of professional practice, and it concluded that the appropriate base offense level was 38. The district court also found that the obstruction-of-justice enhancement was appropriate ***1136** because it concluded that the email from Ruan to Couch about Palmer was a clear indication that Ruan was aware of Palmer forging prescriptions. The court sentenced Ruan to 252 months’ imprisonment, varying downward because Ruan did not have a criminal history and because the court believed that the sentence reflected the seriousness of the offense and the need for punishment, deterrence, and incapacitation. It also ordered Ruan to make restitution as described in the PSR. Lastly, the district court finalized a preliminary order of forfeiture as to Ruan.

II. Discussion

A. Sufficiency of the Evidence

Ruan challenges the sufficiency of the evidence on all counts against him. Couch joins Ruan's arguments as to their joint convictions—Counts 1–4, 15–17, and 19.⁹

[1] [2] This Court “review[s] the sufficiency of the evidence *de novo*, viewing the evidence and all reasonable inferences and credibility choices in favor of the government and the jury's verdict.” *United States v. Ignasiak*, 667 F.3d 1217, 1227 (11th Cir. 2012). “A conviction must be affirmed unless there is no reasonable construction of the evidence from which the jury could have found the defendant guilty beyond a reasonable doubt.” *Id.* As we explain below, we

conclude that the evidence presented at trial was sufficient to convict the appellants on all of the counts that are challenged, except Count 16 charging both appellants with conspiring to violate the Anti-Kickback statute based on their operation of PPSA's in-house workers’ compensation dispensary.

1. Counts 8, 9, 11, and 12: Substantive Drug Distribution Against Ruan¹⁰

[3] [4] [5] Counts 8, 9, 11, and 12 of the Superseding Indictment alleged that Ruan's prescribing of opioids to four specific patients violated 21 U.S.C. § 841(a)(1), and 18 U.S.C. § 2. In the medical context, drug distribution in violation of § 841(a)(1) requires proof that either “(1) the prescription was not for a ‘legitimate medical purpose’ or 2) the prescription was not made in the ‘usual course of professional practice.’” *United States v. Joseph*, 709 F.3d 1082, 1102 (11th Cir. 2013) (quoting *United States v. Tobin*, 676 F.3d 1264, 1282 (11th Cir. 2012)). “The mens rea required for a conviction under section 841(a)(1) is ‘knowledge, not willfulness.’” *Id.* (quoting *Tobin*, 676 F.3d at 1279–80). Ruan was charged and convicted as both a principal, 21 U.S.C. § 841(a)(1), and an aider and abettor, 18 U.S.C. § 2. To sustain a conviction under 18 U.S.C. § 2, “the prosecution must show that ‘the defendant associated [him]self with a criminal venture, participated in it as something []he wished to bring about, and sought by [his] actions to make it succeed.’” *Id.* (quoting *United States v. Pantoja-Soto*, 739 F.2d 1520, 1525 (11th Cir. 1984)).

i. Count 8: Prescriptions Ruan Wrote on February 26, 2015 for Diane Greathouse

[6] [7] [8] Count 8 charged that six prescriptions Ruan wrote for patient Diane Greathouse (“Greathouse”) on February 26, 2015—two for 400 mcg each of the TIRF medications Abstral and Subsys, one for 40 mg of OxyContin (an extended release oxycodone), and one for 10 mg of ***1137** Norco—amounted to unlawful drug distribution. Government expert witness Dr. Greenberg reviewed Greathouse's file and testified at trial that those prescriptions were not for any legitimate medical purpose and that Ruan's overall treatment of Greathouse, including prescribing them, was outside the usual course of professional practice. In support, Dr. Greenberg stated that Ruan prescribed Greathouse Abstral and Subsys, two TIRF medications that are intended for cancer treatment, although she did not have cancer. Additionally, in his

opinion, Ruan's choice to prescribe both Abstral and Subsys, different formulations of the same drug, "makes no sense." Dr. Greenberg further explained that Ruan was already prescribing Greathouse such high doses of opioids that she could be "in a stupor and ready to fall into a coma", but then had tried to counteract those effects, not by discontinuing the opioids but by improperly prescribing [Provigil](#), an [amphetamine](#), to the mixture of drugs. He also noted that Ruan had previously prescribed Greathouse a [naloxone](#) (brand name [Narcan](#)) injector, which is used as an antidote for [fentanyl overdoses](#), without her informed consent and without ensuring that her family members, who would be the ones using it in case of her overdose, had CPR or other relevant training.

Ruan's principal argument in support of his claim that the evidence was insufficient to convict him on Count 8—as well as on Counts 9, 11, and 12—is that Dr. Greenberg's testimony was unreliable. Ruan draws our attention to the fact that on the Monday following Dr. Greenberg's testimony at trial, which had concluded the previous week, government counsel alerted the district court and defense counsel, through a motion filed under seal, that Dr. Greenberg had notified them over the weekend that he thought he had early-onset dementia and was consulting a neurologist. During a hearing outside the presence of the jury, government counsel expressed misgivings about some of Dr. Greenberg's testimony, represented that he had offered to refund monies and not charge for his trial testimony and that the government intended to accept his offer, but indicated that the government wanted to gather more information before deciding whether to ask for a specific jury instruction on the issue.

Despite this troubling circumstance, Ruan cannot succeed on his insufficiency of the evidence argument. Neither Ruan nor Couch asked the district court to provide the jury with the government's disclosure concerning Dr. Greenberg's mental health. Rather, at the in-chambers hearing, Couch's attorney noted that the standard for competency is "fairly liberal," recounted that Dr. Greenberg had been cross-examined, and mentioned that "we don't think that there's anything there." Ruan's attorney said nothing. The district judge stated, "I don't think there's any question that he was competent to testify," suggested that the issue merely related to Dr. Greenberg's credibility, and decided to await more information from the government, if any materialized. No further information was presented by the end of trial.

Considering the foregoing, to the extent Ruan asserts that the jury should have been made aware that Dr. Greenberg thought he may have a mental health issue, our review of that claim is limited to plain error because Ruan never preserved the issue. See [Fed. R. Crim. P. 52\(b\)](#) ("A plain error that affects substantial rights may be considered even though it was not brought to the court's attention."). And although Dr. Greenberg was the sole government expert witness relating to the four substantive drug distribution counts charged against Ruan, defense counsel rigorously cross-examined him, during which time, as discussed in further detail below, ***1138** he admitted to several errors and omissions in his testimony and even changed his opinion on several points. Thus, the jury was aware that Dr. Greenberg's testimony was not infallible. We thus cannot say that, even if the jurors had known of Dr. Greenberg's disclosure to government counsel, they "could not have found [Ruan] guilty under any reasonable construction of the evidence." [Ignasiak](#), 667 F.3d at 1229 (quoting [United States v. Merrill](#), 513 F.3d 1293, 1299 (11th Cir. 2008)).

Aside from Dr. Greenberg's credibility, Ruan also argues that the evidence was insufficient to convict him on Count 8 because the jury heard during Dr. Greenberg's cross-examination that (1) the medications Ruan prescribed Greathouse alleviated her pain and enabled her to continue working, (2) the Centers for Disease Control and Prevention recommend [Narcan](#) when a patient is at risk for opioid overdose, and (3) the FDA authorizes the manufacture of larger doses of Subsys and Abstral than what Ruan prescribed. We are not persuaded that reasonable jurors could not have found guilt after hearing this evidence. Dr. Greenberg testified that if Greathouse was able to work it would only be because of the amphetamines Ruan prescribed her and prescribing those was "simply way below the rational standard of care for dealing with people who are in a near overdose state." He further explained that subsequent studies had shown that [Narcan](#) did not always work as intended when given by a family member instead of a medical professional and would not help a patient, like Greathouse, who was also taking other drugs with sedative effects, including benzodiazepines. The jury was entitled to credit Dr. Greenberg's testimony. Sufficient evidence supports Ruan's conviction on Count 8 for drug distribution.

ii. Count 9: Prescriptions Ruan Wrote on April 27, 2015 for Kim Lowe

[9] Count 9 was based on three prescriptions Ruan wrote on April 27, 2015, to patient Kim Lowe (“Lowe”) for 600 mcg of [Fentora](#), which is a [fentanyl](#) lozenge, and 80 mg and 15 mg of the opioids [OxyContin](#) and oxycodone, respectively. Dr. Greenberg reviewed Lowe's file and testified at trial that those prescriptions were not for any legitimate medical purpose and that Ruan's overall treatment of Lowe since January 2009 was outside the usual course of professional practice. Dr. Greenberg specifically stated that Ruan acted outside the usual course of professional practice when he: (1) failed to take down Lowe's history of illnesses and medications; (2) failed to refer her for mental health treatment despite her general complaints of “severe pain over her entire body” lasting more than 20 years, which Dr. Greenberg opined was a “red flag” for a psychiatric problem given that there are few diseases that can cause such symptoms; (3) failed to obtain Lowe's informed consent prior to prescribing her a combination of [oxymorphone](#) (brand name [Opana](#)), [OxyContin](#), [Xanax](#), [oxycodone](#) (brand name [Percocet](#)), [Lunesta](#) sleeping pills, and Soma; (4) prescribed Lowe, who did not have [cancer](#), the [fentanyl](#) lozenge, which Dr. Greenberg described as an “end-of-life drug that is only approved by the FDA for people who are in the last stages of their lives with [cancer](#)”; (5) failed to counsel her when she ran out of medications prematurely, which suggested that she was either taking more than what was prescribed or diverting medications; and (6) ignored positive urine screening test results for [hydrocodone](#) and [fentanyl](#) at a time when Ruan was not prescribing her those medications.

Ruan points out that on cross-examination, Dr. Greenberg was shown a part of Lowe's medical file dating back to 2008 *1139 that he had never seen before that revealed that Ruan did in fact do an initial exam, record Lowe's medical history, and review information from her referring physician when he first saw her as a patient. Dr. Greenberg was also shown where Lowe kept a pain diary and communicated her perceived levels of pain to Ruan. Additionally, Lowe herself testified for the defense, stating that Ruan did more than just prescribe opioids; his treatment of her included a [back brace](#), various nerve and facet blocks, injections, epidurals, physical therapy, and ointments. Although Lowe believed that the medications Ruan prescribed medically benefited her, she also had trouble remembering that she had been a patient of Ruan's since 2009, believing instead that she had only seen him for the past three years. The jury was entitled to credit Dr. Greenberg, a physician, over Lowe, and even if Lowe felt that she benefitted from the medications Ruan prescribed, a reasonable jury could nonetheless conclude that the manner

in which Ruan prescribed them was outside the usual course of professional practice. Sufficient evidence supports Ruan's conviction on Count 9 for drug distribution.

iii. Count 11: Prescription Ruan Wrote on November 25, 2014 for Deborah Walker

[10] Count 11 addressed a prescription for the opioid [Opana](#) that Ruan wrote for patient Deborah Walker (“Walker”) on November 25, 2014. Dr. Greenberg testified that Walker came to Ruan 11 months earlier, in January 2014, seeking pain medication shortly after completing a 19-month prison sentence. Dr. Greenberg considered prison time a “giant red flag” for drug-seeking behavior but noted that he did not see any indication that Ruan had asked Walker whether she was incarcerated due to a drug-related crime. He also criticized Ruan's failure to refer Walker to a psychiatrist when it was noted in her file that she had [bipolar disorder](#) with schizophrenic features. Dr. Greenberg also opined that Ruan should have suspected diversion and counseled Walker on such matters when a urine test performed during that January 2014 visit did not detect Soma and [hydrocodone](#), drugs that he thought Ruan had recently prescribed her. In Dr. Greenberg's view, it was improper for Ruan to have prescribed [Opana](#) because it is the “most sought[] after prescription drug by people who are heroin addicts or other I.V.-type abusers of I.V. opioid drugs.” He also condemned Ruan's addition of prescriptions for Soma and [hydrocodone](#) at subsequent visits.

During a visit to Ruan in April 2014, Walker tested positive for several drugs, including [hydromorphone](#), that Ruan had not prescribed, which suggested to Dr. Greenberg that Walker was receiving opioids from other doctors or off the street. Dr. Greenberg testified that he did not believe that Ruan was checking the PDMP, which would have revealed that Walker was indeed receiving pain medications from 12 or 13 different doctors. Dr. Greenberg opined that the prescription Ruan wrote for Walker for [Opana](#) in November 2014 was merely the last in a long line of medically illegitimate prescriptions that were written by Ruan outside the usual course of professional practice.

Dr. Greenberg was subject to extensive cross-examination related to his review of Walker's file. He admitted that he had missed that Walker had been a patient of Ruan's in 2011, before going to prison, and that Ruan had prescribed the Soma and hydrocodone before her period of incarceration, which could have explained why those drugs were not present

in the drug screen in January 2014, after she had been incarcerated for 19 months. Dr. Greenberg was also shown portions of Walker's physical file from 2008, before PPSA migrated *1140 to electronic record-keeping, showing that she had been advised about the dangers of developing a dependency on opioids and mixing opioids with alcohol. Dr. Greenberg admitted that such warnings and informed consent were within the scope of professional medical practice.

The jury also heard from Walker's husband,¹¹ who testified that his wife had a drug addiction and served time for burglary and stealing to support her drug habit. He described how Ruan rapidly increased her opioid dosages beyond the minimum necessary for pain control, stating that her prescribed medications would put her in an “almost comatose” state, that the dosages were so great that she would immediately fall asleep after taking the medications, and that she routinely fell asleep while cooking and he would come home from work to find their home filled with smoke. Given this testimony, we find that the totality of the evidence was sufficient for the jury to determine that Ruan dispensed controlled substances to Walker outside the usual course of professional practice as charged in Count 11.

iv. Count 12: Prescription Ruan Wrote on October 10, 2012 for John Bosarge

[11] Count 12 alleged that a prescription Ruan wrote for morphine sulfate (brand name MS-Contin) on October 10, 2012, to patient John Bosarge (“Bosarge”) was for no legitimate medical purpose and outside the usual course of professional practice. Dr. Greenberg considered Bosarge, who was an opioid-dependent 50-year-old, a “high risk” patient because he suffered from psychiatric and cardiac problems as well as high blood pressure. Dr. Greenberg opined that Ruan's treatment of Bosarge was outside the usual course of professional practice because, rather than prescribe the “absolute minimum” dose of opioids that would have helped his pain yet addressed his opioid dependence, he combined the opioid prescriptions with prescriptions for Xanax, a “sedative-hypnotic” drug, which created a risk of an “accidental respiratory arrest,” and butorphanol, an “agonist-antagonist” drug, which could cause, if a patient is not detoxed from opioids first, the patient to go into a painful withdrawal. Dr. Greenberg emphasized that the warning labels on those medications warned against prescribing them together.

Ruan argues that the charged prescription was merely a continuation of Bosarge's prior treatment with his referring physician, but the jury heard evidence that morphine like Ruan prescribed Bosarge is a stronger opioid than the hydrocodone he was previously taking before the referral to Ruan. The jury was entitled to credit Dr. Greenberg's opinion that Ruan's treatment of Bosarge fell outside the usual course of professional practice, and sufficient evidence supports Count 12.

2. Counts 2, 3, and 4: Drug Distribution Conspiracies Against Couch and Ruan

[12] [13] [14] Counts 2, 3, and 4 charged the appellants with conspiracies to dispense Schedule II drugs, fentanyl, and Schedule III drugs, respectively, in violation of 21 U.S.C. §§ 846 and 841(a)(1). “In order to secure a conviction for unlawful dispensation under § 841(a)(1), the government must prove that the defendant ‘dispensed controlled substances for other than legitimate medical purposes in the usual course of professional practice, and that he did so knowingly and intentionally.’ ” *1141 United States v. Azmat, 805 F.3d 1018, 1035 (11th Cir. 2015) (quoting Ignasiak, 667 F.3d at 1227). “To establish a conspiracy in violation of § 846,” the government must prove that: “(1) there was an agreement between two or more people to commit a crime (in this case, unlawfully dispensing controlled substances in violation of § 841(a)(1)); (2) the defendant knew about the agreement; and (3) the defendant voluntarily joined the agreement.” *Id.* (footnote omitted). “A conspiracy conviction will be upheld if ‘the circumstances surrounding a person's presence at the scene of conspiratorial activity are so obvious that knowledge of its character can fairly be attributed to him.’ ” *Id.* (quoting *United States v. Figueroa*, 720 F.2d 1239, 1246 (11th Cir. 1983)).

i. Counts 2 and 4: Schedule II and III Drugs

[15] The appellants argue that the prescriptions they wrote for these drugs were legitimate, but the evidence at trial indicated significant activities by Ruan and Couch that were outside the course of professional practice. They altered their prescribing habits where they had a financial interest, like when they increased their Abstral prescriptions after purchasing stock in the company, decreased their Abstral prescriptions after a drop in stock price and a change in voucher rules, and increased them again after C&R entered

a rebate agreement with Galena. Insys maintained Ruan and Couch as weekly speakers in order to influence their prescription habits. Palmer was forging prescriptions with Couch's signature, and he did this for his patients and for those of other PPSA nurses, something that Ruan was aware of and acquiesced to. Couch and Ruan would leave blank prescription pads, which sometimes only had the doctors' signatures on them, for use by the nurses when the doctors were out of the office. Additionally, the patient files examined for trial by the government's experts suggested that there were serious gaps in patients' quality of care, including taking insufficient steps to safeguard high-risk patients, ignoring signs of potential drug diversion, and failing to get adequately informed consent before prescribing drugs, including for off-label use. The jury was free to disbelieve Ruan and Couch and reasonably could infer that the appellants were participating in a conspiracy to unlawfully distribute controlled substances.

ii. Count 3: Fentanyl

[16] Count 3 charged a conspiracy to distribute fentanyl, also a Schedule II drug.¹² The jury was asked to find whether the conspiracy involved more than 40 grams, a quantity triggering a 5-year mandatory minimum sentence under 21 U.S.C. § 841(b)(1)(B)(vi). The only argument the appellants raise regarding this count is that there was insufficient evidence to support the jury's finding that they prescribed over 40 grams of fentanyl in a manner outside the usual course of professional practice or for no legitimate medical purpose.

The government's chart listing the appellants' top 28 patients receiving the most Subsys or Abstral prescriptions without a cancer diagnosis showed that the appellants prescribed a total of 67.311 grams of fentanyl to those patients off-label. The appellants claim that the jury could not consider the full 67.311-gram amount because the government only presented testimony specifically addressing 10 of those patients, who were prescribed a total of 33 grams. More specifically, government expert Dr. Greenberg testified about five *1142 patients who were prescribed a total of 14.958 grams, the fentanyl prescribed to the patients who testified was 16.621 grams, and the fentanyl prescribed to patients whose relatives testified was 1.487 grams. However, government experts Dr. Aultman and Dr. Vohra testified about an additional five patients who were prescribed fentanyl not included in the chart and testified that the appellants' treatment of them was outside the usual course of professional practice. The government points to PDMP data showing that these five

patients received 8.83 grams of fentanyl, which, combined with the 33 grams, surpasses the 40-gram threshold.

While the jury was shown PDMP data throughout the trial, we do not think that they were sufficiently presented with the specific data showing that these five patients received 8.83 grams of fentanyl. But even if the jury erred in finding that over 40 grams was prescribed, the error was harmless because the 5-year mandatory minimum sentence was well below the sentences the appellants received. We find no error with the jury's guilty verdict with regard to Count 3.

3. Count 15: Health Care Fraud Conspiracy Against Couch and Ruan

[17] [18] [19] [20] Count 15 alleged that the appellants engaged in a conspiracy to fraudulently obtain money from a health care benefits program in violation of 18 U.S.C. § 1347(a). A health care fraud conspiracy exists when defendants agree to submit false claims to health care benefit programs. *United States v. Gonzalez*, 834 F.3d 1206, 1214 (11th Cir. 2016). The defendants must have known that the claims submitted were actually false. *Id.* "A person makes a false claim if the treatments that were billed were 'not medically necessary[] or were not delivered to the patients.'" *Id.* (quoting *United States v. Medina*, 485 F.3d 1291, 1304 (11th Cir. 2007)). To sustain a conviction, the government "had to establish beyond a reasonable doubt that: (1) a conspiracy existed to commit health care fraud under 18 U.S.C. § 1347; (2) [the appellants] knew of the conspiracy; and (3) [the appellants] knowingly and voluntarily joined it." *Id.*

[21] The Superseding Indictment alleged and the government sought to prove at trial that the appellants agreed to commit health care fraud in four ways: (1) falsely certifying to insurers that some patients had cancer so that the insurers would pay for their TIRF prescriptions; (2) billing BCBS for office visits conducted by nurse practitioners using Couch's physician identification number; (3) billing insurers for drug tests that were medically unnecessary; and (4) billing insurers for PPSA office visits at which patients were prescribed medically unnecessary drugs. If sufficient evidence supports any one of these methods, we must uphold the health care fraud conspiracy conviction. See *United States v. Ross*, 131 F.3d 970, 984 (11th Cir. 1997).

First, the evidence was sufficient to convict the appellants of conspiring to defraud a health care benefits program by falsely certifying to insurers that some patients had [cancer](#) so that insurers would pay for their TIRF prescriptions. *See Gonzalez*, 834 F.3d at 1215–16 (submitting a false claim to an insurer encompasses lying about a patient's condition to the insurer). DEA Special Agent Michael Burt testified that Ruan signed a letter to Cigna confirming that his patient Kathleen Burns's prescription for Subsys had been “for breakthrough [cancer](#) pain,” when she did not have [cancer](#).¹³ Similarly, Perhaps, the *1143 former pharmaceutical sales representative for Insys, testified that Couch signed a form sent to Insys to get insurance approval for Abstral,¹⁴ listing patient Ronald Ivy's diagnosis as bladder [cancer](#), yet his medical file had no mention of any [cancer](#). Several witnesses, including DEA Diversion Investigator Michelle Penfold and Couch's nurse practitioner Palmer, discussed how a Subsys prescription for Joyce Barber listed a diagnosis of “[u]terine [cancer](#).” Barber herself testified that when her insurance company later called her to verify that she had [cancer](#) and she told them truthfully that she did not, they stopped covering Subsys. And Dr. Aultman, when testifying regarding her review of several patient files, noted that a prescription Couch wrote for Brenda Ward had “[cervical cancer](#)” written on it even though her medical record contained no verification of that diagnosis.

[22] We also find that the evidence was sufficient to convict the appellants for conspiring to defraud BCBS. Cindy McKenzie, a BCBS employee who oversees and manages fraud activities, testified that the appellants routinely billed for office visits conducted entirely by nurse practitioners, like Palmer, under Couch's identification number. This practice is called incident to billing, and while some insurers allow it,¹⁵ BCBS did not. Rather, BCBS paid about 30% less for nurse practitioner visits than for doctor visits, and it expressly required a physician working with a nurse practitioner to also “see[] and render[] services to the patient” to bill BCBS under the doctor's name. In October 2014, BCBS clarified its policy, effective January 1, 2015, to permit only the “provider who is physically conducting or affirming the [patient's history] and performing an in-person examination” to submit a bill. BCBS notified providers of this change, and Ken Cross, PPSA's practice manager, testified that he told the appellants that they at least needed to see their patients every visit. Yet Palmer saw dozens of BCBS patients every day without Couch. BCBS found no records of PPSA visits billed under Palmer's name, only those billed under Ruan's and Couch's. McKenzie testified that “[t]hat's a false claim.”

[23] Although Ruan testified that he personally saw all of his patients, he acquiesced in Couch's practice of permitting Palmer and others to see patients independently. This is evidenced by the July 2014 email in which Ruan asked Couch to “talk to Justin [Palmer] on cutting down” the amount of [Roxicodone](#) 30 mg he prescribed in light of news reports that Alabama had the most opioid prescriptions in the country. Couch responded that “[w]e,” meaning he and Palmer, would not “write triple digit dispensations [sic] of short acting opioids.”

[24] We also find that the evidence was sufficient to convict the appellants for conspiring to defraud a health care benefits program by billing for expensive off-site urine screen tests that were medically unnecessary. Ruan ordered them for every patient because they generated more revenue than in-house tests. And the jury heard from several sources that the appellants rarely discussed inconsistent test results with patients, whether to counsel them into compliance or fire them as patients. *1144 Ruan himself had stated that “[i]n private practice the more you fire, the more revenue you lose.” Instead, he opined, “when one patient tests positive for street drugs, that gives you more reason to do more frequent urine drug screens, which pays three times more than an office visit.”

[25] Finally, because we have already found that the evidence is sufficient to convict the appellants of illegally prescribing drugs, like Abstral and Subsys, outside the course of professional practice, we find that their billing insurers for PPSA office visits at which patients were prescribed these drugs that C&R then dispensed, is an alternative object of the health care fraud conspiracy. Indeed, for Abstral and Subsys, the appellants were either the top or among the top billers of BCBS, Medicare, Tricare, and United Healthcare. While not all of these prescriptions were illegal, some were. In sum, the evidence was sufficient to convict Ruan and Couch for health care fraud conspiracy.

4. Counts 16 and 17: Conspiracies to Receive Kickbacks Against Couch and Ruan

[26] Counts 16 and 17 charged the appellants with conspiring, in violation of [18 U.S.C. § 371](#),¹⁶ to violate the Anti-Kickback statute in two different ways. The statute provides in part that:

Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind ... in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program ... shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b)(1).

i. Count 16: PPSA's Workers' Compensation Dispensary

Count 16 charged the appellants with violating the Anti-Kickback statute by conspiring together and with Michael Drobot and Manfuso to accept kickbacks in exchange for letting IPM and CRM run their in-office workers' compensation dispensary. The appellants argue that their convictions on Count 16 must be vacated because there was no "Federal health care program" associated with PPSA's workers' compensation dispensary. As we explain below, we agree.

As noted, to prove a violation of the Anti-Kickback statute, the government needed to prove that the appellants (1) knowingly and willfully (2) received remuneration (3) in return for referring individuals to a person for the furnishing of medication (4) paid for by a "Federal health care program." See 42 U.S.C. § 1320a-7b(b)(1). The statute defines a "Federal health care program"—Medicaid and Medicare are common examples—as "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly in whole or in part, by the United States Government." 42 U.S.C. § 1320a-7b(f) (emphasis added). Because the 42 U.S.C. § 1320a-7b(b) offense was alleged as an *1145 18 U.S.C. § 371 conspiracy, federal jurisdiction was premised on the existence of a "Federal health care program," in addition to that also being

an element of the substantive crime. In short, the government had to show that federal funds passed through PPSA's workers' compensation dispensary.

[27] [28] In determining whether federal jurisdiction exists, the court examines the sufficiency of the evidence offered by the government. *United States v. Key*, 76 F.3d 350, 353 (11th Cir. 1996) ("Whether the government proved the jurisdictional element is measured as a challenge to the sufficiency of the evidence."). "All evidence and inferences therefrom are viewed in the light most favorable to the verdict." *Id.* The relevant inquiry in making this determination is whether a reasonable jury could have found the jurisdictional element to have been satisfied beyond a reasonable doubt. *Id.*

In *United States v. Dennis*, 237 F.3d 1295 (11th Cir. 2001), this Court examined at length the amount of evidence sufficient to prove federally-insured status in a bank-fraud prosecution. In that case, a government agent testified that the two banks involved were federally insured. *Id.* at 1304. However, this Court found the testimony "equivocal," and although the jurisdictional nexus was established for one of the banks through an official bank document containing the phrase "MEMBER FDIC," there was no such evidence relating to the other bank. *Id.* Regarding the second bank, this Court found the agent's testimony alone insufficient to establish the element:

The agent's conclusion that the bank was federally insured appears to be premised upon his belief that because a bank is a 'national bank,' it is necessarily a 'federally insured bank.' This reasoning lacks legal support. A 'national bank' is not necessarily 'federally insured.' As demonstrated by pertinent statutory provisions, the two concepts are distinct and not synonymous.

Id. at 1305. This Court held that the evidence was insufficient to prove beyond a reasonable doubt that the bank in question was federally insured and vacated the conviction for bank fraud. *Id.*

The evidence here is similarly equivocal. The government relied on two items to satisfy the requirement that the kickbacks must have been paid in exchange for referring individuals for services paid for by federal funds. First, the government relied on exhibits showing that the U.S. Department of Labor paid for office visits for several workers' compensation patients. But the exhibits showed that the U.S. Department of Labor paid for physician *services*, not prescriptions.

Second, the government put on evidence that, while most of PPSA's workers' compensation patients were covered by state-funded insurance, at least some patients who received medications from PPSA's workers' compensation dispensary were longshoremen who were covered by an insurance provider by the name of "FARA." FBI Special Agent Amy White read into evidence a July 2012 email from Manfuso, in which he told Ruan:

FARA is a federal longshoreman insurance program that has requested that you no longer dispense to their patients. Since they are a federal program, and not an Alabama workers' comp state program, the laws and regulations that apply to their patients are different. ... Alabama workers' comp law supports that the patient has the right to choose where to get their medications. Alabama work comp insurance companies cannot legally tell you not to dispense to their patients. Federal law unfortunately does not state that the patient has the right to choose where to get their medication. *1146 The insurance company that covers an injured federal worker—in this case that's FARA—has the ability to direct the patient to a certain pharmacy service to get their medication. In other words, FARA is allowed to tell you that they don't want you to dispense to their patients and they would like you to send their patients to an outside pharmacy.

There were other subsequent emails from Manfuso to Ruan where Manfuso repeatedly instructed Ruan to "immediately stop dispensing to FARA patients" because FARA was refusing to cover their medications. The government claimed that FARA was a "Federal health care program." However, none of the documents offered by the government at trial contained any indication that federal monies actually passed through the dispensary. The appellants argue that FARA is merely an insurance program administrator that covered several patients at the dispensary. The only evidence at trial relating to FARA are the emails from Manfuso to Ruan, which do nothing more than note that FARA is an insurance company. Moreover, FARA is not named in 42 U.S.C. § 14402(d), the statute listing Federal health care funding programs, like Medicare and Medicaid. We find that this evidence was insufficient to establish beyond a reasonable doubt that FARA paid for prescriptions with federal funds or that federal monies otherwise passed through PPSA's workers' compensation dispensary. Because this element of the offense was not proven, the appellants' convictions for conspiracy to violate the Anti-Kickback statute charged in Count 16 cannot stand. Accordingly, we reverse and vacate the appellants' convictions on Count 16, and we vacate their sentences as to this count.

ii. Count 17: Insys's Speaker Program

[29] Count 17 alleged that the appellants conspired with each other, Perhacs, and others to violate the Anti-Kickback statute through their participation in Insys's speaker program. The evidence clearly showed that Insys was using its program as a cover to funnel money to its top prescribers—Couch and Ruan. In the words of Perhacs, Insys selected the appellants to speak because they were "whale[s]"—"in [Insys's] top 10 list"—and that the entire point of the speakers' program was "[t]o influence [the appellants] to keep prescribing a lot of Subsys." People outside of PPSA office staff rarely attended these dinners, and the ones who did were sometimes "the same prescriber, time and time again." In contrast, a representative for Galena, the pharmaceutical company manufacturing Subys's competitor, Abstral, testified that when Ruan requested to be a speaker for Abstral, Galena declined because "he was treating all of the patients in the area, it didn't make sense for him to be a speaker because there would be nobody to speak to."

The appellants contend that the government failed to prove that they acted willfully to violate the Anti-Kickback statute. “Willfully” means that the act was committed voluntarily and purposely, with the intent to do something the law forbids. *See United States v. Starks*, 157 F.3d 833, 837–38 (11th Cir. 1998). Ruan points to testimony by Perhacs that Insys selected him as a speaker because he was a respected pain management physician. He also argues that Perhacs testified against him in hopes of receiving a sentence reduction. But there was sufficient evidence for the jury to believe that the speaking program was a sham, and Insys only reduced them after the appellants had been prescribing more and more of the competitor product, Abstral, for months. Additionally, Ruan showed consciousness of guilt when he began to direct Insys to dispose of the money by donating his speaking fees to various universities. Sufficient evidence supports the conviction on Count 17.

***1147 5. Count 19: Mail or Wire Fraud
Conspiracy Against Couch and Ruan**

[30] [31] [32] Count 19 charged the appellants with conspiring with Perhacs, Palmer, and Parker to commit mail or wire fraud in violation of 18 U.S.C. § 1349. To prove such a conspiracy, “the government need not demonstrate an agreement specifically to use the interstate wires to further the scheme to defraud.” *United States v. Hasson*, 333 F.3d 1264, 1270 (11th Cir. 2003). Instead, “it is enough to prove that the defendant knowingly and voluntarily agreed to participate in a scheme to defraud and that the use of the interstate wires in furtherance of the scheme was reasonably foreseeable.” *Id.* “A scheme to defraud requires proof of material misrepresentations, or the omission or concealment of material facts” *Id.* at 1270–71.

[33] [34] The Superseding Indictment charged, and the government sought to prove at trial, that the appellants conspired to make three types of misrepresentations to insurers. The first misrepresentation was that they routinely billed BCBS for more expensive doctor visits when only a nurse practitioner saw the patient. As discussed in the previous section devoted to Count 15, the evidence was sufficient to convict the appellants of health care fraud conspiracy for these actions. And since the government established that PPSA submitted these bills electronically, the use of the mails or wires element is met. The second misrepresentation, also discussed in the section regarding Count 15 above, was that they lied to insurers about patients

being diagnosed with cancer to induce those companies to pay for TIRF prescriptions. The jury saw that PPSA and the insurers sent forms and letters related to coverage via fax and mail. The third misrepresentation was that Ruan selected the most lucrative controlled substances to stock at PPSA’s workers’ compensation dispensary, and then he and Couch prescribed those drugs, making their medical decisions based on profit, not the needs of patients. As discussed in the section devoted to Count 16 above, Manfuso testified that while he and Ruan frequently discussed the profit margin of various drugs for the formulary, Ruan never talked with him about the drugs’ clinical aspects. Because the evidence showed that these discussions occurred over email between Ruan in Alabama and Manfuso in Maryland, the element of the use of interstate mail in furtherance of the scheme was satisfied.

6. Count 1: RICO Conspiracy Against Couch and Ruan

[35] [36] [37] Count 1 charged the appellants with conspiring to violate RICO based on predicate acts of drug distribution and mail or wire fraud. To establish a conspiracy to violate RICO under 18 U.S.C. § 1962(d), “the government must prove that the defendants ‘objectively manifested, through words or actions, an agreement to participate in the conduct of the affairs of the enterprise through the commission of two or more predicate crimes.’” *United States v. Starrett*, 55 F.3d 1525, 1543 (11th Cir. 1995) (quoting *United States v. Russo*, 796 F.2d 1443, 1455 (11th Cir. 1986)). “A RICO conspiracy differs from an ordinary conspiracy in two respects: it need not embrace an overt act, and it is broader and may encompass a great variety of conduct.” *Id.* (quoting *United States v. Pepe*, 747 F.2d 632, 659 (11th Cir. 1984)).

The appellants first contend that the jury could not have reasonably found that PPSA was a RICO “enterprise” because they operated it as separate medical practices at two different locations. We disagree. Ken Cross, the appellants’ former *1148 practice manager, testified that PPSA, as well as C&R, were legal entities jointly owned by the appellants. The RICO definition of an “enterprise” is broad, including “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.” 18 U.S.C. § 1961(4). While Ruan and Couch generally saw their own patients and divided their income proportionate to revenues generated from patients that each treated, they also made financial and business decisions together, such as buying Galena stock with PPSA funds. Ruan also negotiated with

IPM and CRM on behalf of himself and Couch to manage the PPSA workers' compensation dispensary. They discussed practice-management issues, such as Palmer's prescribing habits, via email, shared in the profits of C&R, and even worked at each other's primary location once a week. The jury had abundant evidence to conclude that the appellants were members of an "enterprise" as RICO defines the term because not only were PPSA and C&R jointly owned but Ruan and Couch were also associated in fact.

[38] There was also sufficient evidence presented to establish the commission of two or more predicate crimes. As detailed in the previous sections, the jury reasonably concluded that the appellants committed least two of the 13 drug distribution and mail or wire fraud counts charged. We thus conclude that the jury reasonably determined that RICO's predicate acts requirement was satisfied.

7. Counts 20, 21, and 22: Money Laundering Conspiracy and Substantive Money Laundering Against Ruan

[39] [40] Count 20 charged Ruan with conspiring with Manfuso and others to commit money laundering in violation of 18 U.S.C. § 1956(h). "That section makes it a crime to conspire to commit money laundering in violation of 18 U.S.C. § 1956 or § 1957." *United States v. Moran*, 778 F.3d 942, 962 (11th Cir. 2015). "Under § 1956(h), 'only two elements of conspiracy need be proven: (1) an agreement between two or more persons to commit a money-laundering offense; and (2) knowing and voluntary participation in that agreement by the defendant.' " *Id.* (quoting *United States v. Broughton*, 689 F.3d 1260, 1280 (11th Cir. 2012)). Here, the government alleged that the object of the 18 U.S.C. § 1956(h) conspiracy charged in Count 20 was 18 U.S.C. § 1957 money laundering. That section prohibits "knowingly engag[ing] or attempt[ing] to engage in a monetary transaction in criminally derived property of a value greater than \$10,000 and is derived from specified unlawful activity." 18 U.S.C. § 1957(a). Additionally, Counts 21 and 22 charged Ruan with substantive money laundering in violation of 18 U.S.C. § 1957(a). For these counts, the "monetary transaction[s] in criminally derived property" were alleged to be Ruan's purchase of two expensive automobiles. The "specified unlawful activity" underlying all three counts was alleged to be health care fraud conspiracy in violation of 18 U.S.C. § 1347(a), conspiracy to violate the Anti-Kickback statute in violation of 18 U.S.C. § 371, and conspiracy to distribute controlled substances in violation of 21 U.S.C. § 846.

In support of these counts, evidence was submitted that Ruan had 23 different bank accounts, some under his own name and others in the names of various companies he controlled, such as XLR Exotic Autos, LLC. Ruan received millions in profits from PPSA and C&R as well as speaker payments from Insys. Some of this money made its way into XLR Exotic Autos' bank account. In August and September 2014, Ruan used Erin Bauer, his personal assistant, to arrange two car purchases for him. Ruan wired \$124,355.87 from XLR Exotic Autos' bank account to an auto dealer in Dallas to purchase a 2011 Audi R8 Spyder. The following month, he wired \$110,000 to a different dealer in San Diego as partial payment for a 1994 Lamborghini Diablo.

Ruan asserts that there was insufficient evidence to convict him of conspiring to commit money laundering because PPSA and C&R had legitimate income and the purpose of purchasing the vehicles was not to funnel money back into a criminal venture. He relies largely on *United States v. Miles*, 360 F.3d 472 (5th Cir. 2004), but that case is distinguishable because it involved money laundering *promotion* under 18 U.S.C. § 1956(a)(1)(A)(i), which criminalizes financial transactions involving funds that are derived from specified illegal activity, where the "transactions are intentionally aimed at promoting specified unlawful activity." *Id.* at 476. Here, the object of the money laundering conspiracy was 18 U.S.C. § 1957(a), which the Fifth Circuit in *Miles* recognized is different: it allows prosecutions for the "mere expenditure of unlawfully obtained funds" as long as the expenditure is more than \$10,000. *Id.* at 477–78 (citing *United States v. Brown*, 186 F.3d 661, 670–71 (5th Cir. 1999) (explaining that in § 1957(a), "Congress established a \$10,000 per transaction threshold for convictions for simply spending dirty money")). This Court has similarly noted that because there is no need to establish the intent to conceal or promote, and in light of the \$10,000 threshold, 18 U.S.C. § 1957 "prohibits a wider range of activity than money 'laundering,' as traditionally understood." *Moran*, 778 F.3d at 963 (quoting *United States v. Wetherald*, 636 F.3d 1315, 1325 n.2 (11th Cir. 2011)).

[41] Thus, all that was required of the government as to Counts 21 and 22 was to prove two elements: (1) Ruan knowingly engaged in a financial transaction greater than \$10,000 and (2) at least \$10,000 of that money came from a "specified unlawful activity." Ruan argues that there was insufficient evidence that he used funds from specified unlawful activity to purchase the cars. But to the extent that Ruan is guilty of conspiracy to commit

health care fraud, conspiracy to receive kickbacks, and distribution of controlled substances, his challenge to his money laundering convictions also fails. As detailed above, Ruan made millions from health care fraud and distribution of controlled substances. The government traced those proceeds to the XLR Exotic Autos bank account used to purchase the cars. No more was required.

Having concluded that the evidence was sufficient to convict the appellants on all of the counts challenged, except Count 16, we now turn to the appellants' challenges to various evidentiary rulings at trial.

B. Evidentiary Challenges

1. Admission of PDMP Data

[42] The appellants challenge the government's use of prescribing data pulled from Alabama's PDMP and similar databases from Florida and Mississippi. The PDMP is a database of all controlled substance prescriptions dispensed—dispensed meaning that the patient actually receives the medication—in Alabama. The Alabama Department of Public Health (“ADPH”) maintains the PDMP database, and the government called state pharmacy director Nancy Bishop, who oversees the PDMP, to explain the system and offer the records.

Alabama law established the PDMP to “materially assist state regulators and practitioners authorized to prescribe and dispense controlled substances in the prevention of diversion, abuse, and misuse of controlled substances prescription medication.” [Ala. Code § 20-2-210](#); *see also* [Miss. Code Ann. § 73-21-127](#); [Fla. Stat. § 893.055\(2\)\(a\)](#). Each doctor or pharmacist who dispenses controlled substances is required ***1150** by law to report the following information to the PDMP database: the patient's name, the prescriber's name, the medication prescribed, the dosage amount, the quantity of medication dispensed, the date the provider wrote the prescription, and the date the pharmacy filled the prescription. [Ala. Code § 20-2-213\(d\)](#). Similarly, federal law requires pharmacies to keep copies of filled controlled substances prescriptions for at least two years. [21 C.F.R. § 1304.04\(a\), \(h\)\(2\), \(h\)\(4\)](#); *see* [21 U.S.C. § 828](#).

Access to the PDMP database is limited. [Ala. Code § 20-2-214](#). Pharmacists and doctors can see information on their own dispensing and prescribing as well as their patients'

information; state and local law enforcement may access the database for investigation; and federal law enforcement may do so on a showing of probable cause. Additionally, data may be shared with other states' monitoring programs.

Bishop explained that pharmacists enter the prescription information into the database either directly or via software that automatically transmits it to the PDMP as they dispense the medication. The ADPH includes a disclaimer on each page of the printed PDMP report stating that it “does not warrant the above information to be accurate or complete” because the report is “based on the search criteria and the data provided by the dispensing entities.” Addressing this disclaimer, Bishop agreed that she could not guarantee that each pharmacist input the data correctly. But she testified that doctors and pharmacists throughout the state access the database on a daily basis. The appellants themselves accessed it in their practice. Bishop described the PDMP as a “tool for the prescribers and the dispensers to use to make the best clinical decision for their patient.”

Bishop queried the database for all controlled substance prescriptions written by the appellants from January 2011 through May 2015 and for the top prescribers of Abstral and Subsys in the state. The PDMP data was also used to create the summary exhibits showing the number of the appellants' patients receiving certain other drugs, the percentage of prescriptions by drug schedule, the number of prescriptions written on dates the appellants were out of the office, and their prescribing of various drugs over time.

At trial, the appellants objected to the admission of the PDMP data on the grounds that it contained multiple levels of hearsay and violated their Confrontation Clause rights because it was based on testimonial evidence. The district court overruled those objections. The appellants reassert those arguments on appeal.

i. Hearsay

[43] We address the appellants' hearsay objections first. This Court reviews evidentiary rulings for abuse of discretion. *See United States v. Todd*, 108 F.3d 1329, 1331 (11th Cir. 1997). Hearsay is an out of court statement offered for its truth. [Fed. R. Evid. 801\(c\)](#). Hearsay is inadmissible unless it falls within an enumerated exception. [Fed. R. Evid. 802](#). When evidence contains multiple levels of hearsay, each statement must meet a hearsay exception to be admissible. [Fed. R. Evid. 805](#).

[44] The appellants argue that the PDMP reports contain three types of out of court “statements” that were offered for their truth: (1) the prescriptions written by doctors for controlled substances, which are transmitted to pharmacies; (2) the information about the prescriptions that the dispensing pharmacists put into the PDMP database; and (3) the reports that PDMP users can create from the data. However, the prescriptions that were written by Ruan and Couch—or in some cases Palmer, a co-conspirator—are not hearsay because they constitute an opposing party’s ***1151** statement. See *Fed. R. Evid. 801(d)(2)(D) & (E)*. Additionally, the PDMP reports themselves are not hearsay because they are a “data compilation” pursuant to *Federal Rule of Evidence 803(6)*. See *United States v. Glasser*, 773 F.2d 1553, 1558–59 (11th Cir. 1985) (computer printouts containing compilations of various mortgage account transactions which were the basis of the prosecution are admissible under the business records exception); *United States v. Fujii*, 301 F.3d 535, 539 (7th Cir. 2002) (“Computer data compiled and presented in computer printouts prepared specifically for trial is admissible under *Rule 803(6)*, even though the *printouts* themselves are not kept in the ordinary course of business.”); *United States v. Arias-Izquierdo*, 449 F.3d 1168, 1184 (11th Cir. 2006) (citing *Fujii* for the proposition that a mere printout of “electronically stored information” is not an additional statement for hearsay purposes).¹⁷

[45] That leaves the pharmacists’ statements that they filled the prescriptions written by the doctors. We agree with the district court that these statements are the business records of the reporting pharmacies and are thus admissible under the business records exception to the hearsay rule. See *Fed. R. Evid. 803(6)*. The business records exception provides, in pertinent part:

A record of an act, event, condition, opinion, or diagnosis [is admissible] if:

(A) the record was made at or near the time by—or from information transmitted by—someone with knowledge;

(B) the record was kept in the course of a regularly conducted activity of a business, organization, occupation, or calling, whether or not for profit;

(C) making the record was a regular practice of that activity;

(D) all these conditions are shown by the testimony of the custodian or another qualified witness, or by a certification that complies with Rule 902(11) or (12) or with a statute permitting certification; and

(E) the opponent does not show that the source of information or the method or circumstances of preparation indicate a lack of trustworthiness.

Fed. R. Evid. 803(6). This Court has recognized that “[t]he touchstone of admissibility under the business records exception to the hearsay rule is reliability, and a trial judge has broad discretion to determine the admissibility of such evidence.” *United States v. Bueno-Sierra*, 99 F.3d 375, 378 (11th Cir. 1996) (per curiam).

[46] [47] [48] The appellants argue that the requirement found in subsection (D) of the business records exception is not met because the custodian of the records—Bishop, an ADPH employee—did not actually enter any data into the PDMP and admitted that she could not vouch for the data’s reliability. They contend that the government should have offered witnesses from each of the pharmacies across Alabama, Florida, and Mississippi who actually entered prescription data into the database. But this Court has held that “the proponent of a document ordinarily need not be the entity whose first-hand knowledge was the basis of the facts sought to be proved.” *Bueno-Sierra*, 99 F.3d at 379. The proponent ***1152** must merely “establish that it was the business practice of the recording entity to obtain such information from persons with personal knowledge and the business practice of the proponent to maintain the records produced by the recording entity.” *Id.* We are satisfied that Bishop did that here. She testified that the pharmacists, who have knowledge of the prescriptions, enter the data in the database at the same time they dispense the controlled substances. Thus, subsection (A)’s requirement that “the record[s] were] made at or near the time by—or from information transmitted by—someone with knowledge,” is met. Bishop further explained that federal law and regulations require keeping prescription records, and state law requires submitting the data to the PDMP. This makes keeping the records part of the pharmacies’ “regularly conducted activity” as well as a “regular practice” of their business, as required by subsections (B) and (C) of the business records exception. See also *United States v. Towns*, 718 F.3d 404, 407–10 (5th Cir. 2013) (finding that logs and records a business keeps because it is required to do so by state or federal regulations meet this standard). Bishop further testified that the ADPH

considered the PDMP reports its “business records” and relies on the records through its “daily” assistance to doctors and pharmacists in accessing the database as “a tool for the prescribers and the dispensers ... to make the best clinical decision for their patient.” She thus established that it was the ADPH’s “business practice” to obtain and maintain the records. See *Bueno-Sierra*, 99 F.3d at 379.

[49] Finally, the PDMP report itself does not lack trustworthiness under subsection (E). The appellants point to the disclaimer the ADPH lists on each page of the report stating that it “does not warrant the above information to be accurate or complete” because the report is “based on the search criteria and the data provided by the dispensing entities.” While we understand that the prescription data is only as reliable as the individual putting it into the system, pharmacists have every incentive to ensure the data they enter is accurate. Inaccurate data could lead to dangerous drug interactions and overdoses as well as giving drugs to addicts or to those who might sell them on a secondary market. Doctors and pharmacists use the system every day to look up patients’ medication histories. The appellants themselves accessed it thousands of times in their practice. The appellants have failed to demonstrate the untrustworthiness of the pharmacists’ out of court statements that they filled the prescriptions reported in the PDMP.

Because the PDMP reports comprised records of regularly conducted activity made by persons with knowledge whose job duties entailed making those records, and Bishop, as custodian, certified that information and there was no evidence of untrustworthiness, we find that the district court properly admitted the PDMP data under the business records exception to the hearsay rule.¹⁸

ii. Confrontation Clause

[50] [51] [52] We now turn to the appellants’ claim that the admission of the PDMP data violated their Sixth Amendment rights under the Confrontation Clause.¹⁹ A defendant’s claim that an evidentiary ruling *1153 deprived him of a constitutional right is reviewed *de novo*. *Ignasiak*, 667 F.3d at 1227. “In *Crawford v. Washington*[], 541 U.S. 36, 53–54, 124 S.Ct. 1354, 158 L.Ed.2d 177 (2004)], the Supreme Court held that the Confrontation Clause bars the admission of the *testimonial* statements of a witness who did not appear at trial unless the witness was unavailable and the defendant had a prior opportunity to cross-examine him or

her.” *United States v. Caraballo*, 595 F.3d 1214, 1227 (11th Cir. 2010). “Testimonial statements are ones ‘that declarants would reasonably expect to be used prosecutorially.’” *United States v. Wilson*, 788 F.3d 1298, 1316 (11th Cir. 2015) (quoting *Crawford*, 541 U.S. at 51, 124 S.Ct. 1354). The appellants contend the reports are “testimonial” because the PDMP may assist law enforcement in prosecuting violators of controlled substance laws.

[53] [54] We disagree for several reasons. First, a statement is testimonial when its “primary purpose ... is to establish or prove past events potentially relevant to later criminal prosecution,” *Davis v. Washington*, 547 U.S. 813, 822, 126 S.Ct. 2266, 165 L.Ed.2d 224 (2006), and when the statement is “formal,” akin to “affidavits, depositions, prior testimony, or confessions,” *Caraballo*, 595 F.3d at 1228 (internal quotation marks omitted). On the other hand, “[c]ertain statements ‘by their nature [are] not testimonial—for example, business records or statements in furtherance of a conspiracy.’” *Wilson*, 788 F.3d at 1316 (quoting *Crawford*, 541 U.S. at 56, 124 S.Ct. 1354). Because the PDMP reports are business records as explained above, they are not testimonial and do not violate the Confrontation Clause. See *United States v. Naranjo*, 634 F.3d 1198, 1213–14 (11th Cir. 2011) (bank records and checks not testimonial).

[55] Second, even if the reports were not business records, they are nonetheless not testimonial. Pharmacists are required by law to enter the PDMP data for the primary purpose of aiding physicians in treating patients, such as combating addiction. See *Ala. Code* §§ 20-2-210, 213(d). In *United States v. Barker*, the Fifth Circuit found a nurse’s report about a sexual assault non-testimonial, even though she knew at the time she wrote it that it would be given to police and could be used in a prosecution, because her primary purpose in writing the report was to “medically evaluate and treat” the victim. 820 F.3d 167, 171–72 (5th Cir. 2016). Similarly, here, the fact that the pharmacists may be aware when they input the data that law enforcement also has access to the database if needed during an investigation does not transform the data entry into the type of formal statement required for testimonial evidence. The district court’s admission of the PDMP data did not violate the appellants’ Confrontation Clause rights.

2. Exclusion of Other Evidence

Next, the appellants argue that the district court erroneously excluded three additional categories of evidence: (1)

information about patients who received legitimate medical care by Ruan and Couch (hereinafter “good patient” evidence); (2) relatedly, videos of undercover agents posing as patients attempting to obtain opioids from Ruan and being denied; and (3) the testimony of Debi Phillips (“Phillips”), PPSA’s former operations manager, on various issues. Rather than contend that the district court abused its discretion in deeming this evidence irrelevant under [Federal Rule of Evidence 401](#),²⁰ the appellants argue that *1154 its exclusion violated their Fifth and Sixth Amendment rights to present a complete defense.²¹

[56] [57] [58] [59] “Whether the exclusion of evidence violated a constitutional guarantee is a legal question reviewed *de novo*.” [United States v. Sarra](#), 575 F.3d 1191, 1209 n.24 (11th Cir. 2009). “[T]he Constitution guarantees criminal defendants a meaningful opportunity to present a complete defense.” [United States v. Mitrovic](#), 890 F.3d 1217, 1221 (11th Cir. 2018) (quoting [Nevada v. Jackson](#), 569 U.S. 505, 509, 133 S.Ct. 1990, 186 L.Ed.2d 62 (2013)). However, this Court has recognized that this right “is not absolute, and is subject to reasonable restrictions.” *Id.* (citing [United States v. Scheffer](#), 523 U.S. 303, 308, 118 S.Ct. 1261, 140 L.Ed.2d 413 (1998)). “[S]tate and federal rulemakers have broad latitude under the Constitution to establish rules excluding evidence from criminal trials. Such rules do not abridge an accused’s right to present a defense so long as they are not ‘arbitrary’ or ‘disproportionate to the purposes they are designed to serve.’” *Id.* (quoting [Scheffer](#), 523 U.S. at 308, 118 S.Ct. 1261). Indeed, the “trial judge’s role as gatekeeper is to ensure that the factfinder bases its decision only on relevant and reliable information.” *Id.* at 1222 (citing [United States v. Frazier](#), 387 F.3d 1244, 1272 (11th Cir. 2004)). Thus, “[w]hile a criminal defendant must be given every meaningful opportunity to present a complete defense, in doing so he must comply with the procedural and evidentiary rules designed to facilitate a search for the truth.” *Id.* (quoting [Frazier](#), 387 F.3d at 1272).

The appellants rely largely on [United States v. Hurn](#), 368 F.3d 1359 (11th Cir. 2004), for their position that, even if a particular rule of evidence would normally bar the admission of certain evidence, there may sometimes be compelling reasons to grant an exception to evidentiary rules. *See id.* at 1363 n.2 (“[T]he fact that a particular rule of evidence requires the exclusion of certain evidence is not dispositive, as particular applications of a generally valid rule may unconstitutionally deny a defendant his rights under the Compulsory Process or Due Process Clauses.”). In [Hurn](#), this Court pointed to four circumstances in which a district court’s

exclusion of a criminal defendant’s evidence might violate the Constitution:

First, a defendant must generally be permitted to introduce evidence directly pertaining to any of the actual elements of the charged offense or an affirmative defense. Second, a defendant must generally be permitted to introduce evidence pertaining to collateral matters that, through a reasonable chain of inferences, could make the existence of one or more of the elements of the charged offense or an affirmative defense more or less certain. Third, a defendant generally has the right to introduce evidence that is not itself tied to any of the elements of the crime or affirmative defense, but that could have a substantial impact on the credibility of an important government witness. Finally, a defendant must generally be permitted to introduce evidence that, while not directly or indirectly relevant to any of the elements of the charged events, nevertheless tends to place the story presented by the prosecution in a significantly different light, such that a reasonable jury might receive it differently.

*1155 *Id.* at 1363 (footnotes omitted). The Court explained that two considerations are appropriate in analyzing a defendant’s claim that his constitutional right to present a defense was violated: (1) whether the right was actually violated, and (2) if so, whether that error was harmless beyond a reasonable doubt. *Id.* at 1362–63.

Keeping these principles in mind, we address each of the appellants’ categories of excluded evidence in turn.

i. “Good Patient” Evidence and Undercover Videos

[60] The government’s case against the appellants was built upon several dozen PPSA patients whose treatment was

alleged to be illegal out of the roughly 8,000 patients PPSA had in 2015. Specifically, the government presented live testimony of 14 patients—or family members of deceased patients—who criticized the appellants’ prescription of opioids and other medications to them. The government also created a list of the appellants’ “top 28” patients who received Subsys or Abstral and whose medical records did not indicate a [diagnosis of cancer](#). Experts reviewed these patients’ files and gave their opinions that Ruan and Couch’s care of these patients did not meet minimum standards.

The appellants wished to present evidence about patients not identified by the government and whose treatment was not alleged to be illegal. These “good patients” would have testified about how their quality of life improved through the care they received at PPSA. The district court concluded that this evidence was irrelevant and would waste time in an already lengthy trial because the government did not allege that PPSA was entirely a sham practice or that all of the appellants’ prescriptions were illegal.²² The appellants could, however, put on evidence favorable to them from any patients identified or called by the government in its case in chief. Indeed, Couch called five patients and Ruan called three.

The appellants argue that the district court impaired their right to present a complete defense by excluding this “good patient” evidence, particularly the testimony of Michael Tiller, one of Couch’s patients. Tiller intended to testify that he believed that Subsys was beneficial to him, despite the off-label use; he generally approved of Couch’s treatment of him and trusted him as his physician; and his experiences at PPSA were consistent with his experiences at other physicians’ facilities.²³ The appellants contend that Tiller’s proposed testimony satisfies the first, second, and fourth categories of evidence summarized in [Hurn](#).

The first [Hurn](#) circumstance is implicated when evidence is excluded that directly pertains to a formal element of a charged offense. *See* 368 F.3d at 1363. The appellants contend that Tiller’s testimony would have helped disprove Counts 2, 3, and 4—conspiracies to knowingly or intentionally prescribe controlled substances outside the usual course of professional practice or without a legitimate medical purpose. We disagree. The appellants were not charged with illegally prescribing medicine to all *1156 their patients, and the jury was aware that they had thousands of patients to whom they may have provided legitimate care. However, a finding that even one prescription was illegal—or for the RICO count,

at least two acts of racketeering activity—sufficed to convict for the Controlled Substances Act violations. Thus, whether Tiller approved of his treatment by Couch does not “directly pertain” to whether the appellants’ treatment of the many other patients identified by the government was outside the course of professional practice. *See Hurn*, 368 F.3d at 1363.

[61] The second category of [Hurn](#) evidence is that which, though not directly bearing on an element of the offense charged, tends to prove collateral matters relating to the defense. *See* 368 F.3d at 1364. The appellants argue that Tiller’s testimony would have tended to prove that Couch was operating a legitimate practice, a collateral matter. In discussing this category, the [Hurn](#) court addressed the introduction of evidence that tends to negate the *mens rea* of an offense. *Id.* at 1364–65. [Hurn](#) cited as an example *United States v. Sheffield*, 992 F.2d 1164 (11th Cir. 1993), in which the defendant, an Air Force employee, was convicted of embezzling Air Force property by ordering subordinates to make fishing lures with base property and on government time. *Id.* at 1165. This Court held that evidence should have been admitted of a legitimate custom on an Air Force base of making retirement presents for high-ranking officials using base materials because it would have rebutted the *mens rea* element of the offense of embezzlement. *Id.* If the defendant was acting pursuant to a legitimate custom when he ordered the production of the lures, he did not possess the state of mind necessary for the offense of embezzlement. *Id.* at 1170.

Here, however, Tiller’s testimony does not tend to negate the *mens rea* element of the Controlled Substances Act offenses—knowingly or intentionally prescribing controlled substances outside the usual course of professional practice or without a legitimate medical purpose. Nowhere did the government allege that Couch’s treatment of Tiller was outside the usual course of professional practice, and nothing Tiller would have testified about would have been probative of Couch’s actions towards the patients that the government asserted were provided with illegal prescriptions, like Officer Kelley, who received powerful opioids from Couch after only a cursory visit with him and without a showing of medical need.

[62] [63] Nor have the appellants established that the fourth type of evidence in [Hurn](#) is implicated in this case—that which “complete[s] the picture” of the charged crimes and presents the government’s evidence in a more favorable or different light that might influence a reasonable juror. *See* 368 F.3d at 1367. This circumstance recognizes that

defendants have a right to combat “the government's selective presentation of entirely truthful evidence [that] cast[s] a defendant in an inaccurate, unfavorable light” or that makes “entirely legitimate, normal, or accepted acts appear unusual or suspicious.” *Id.* at 1366–67. The *Hurn* court held that a defendant should be allowed “to introduce additional evidence to dispel this unjustified taint, even if that evidence does not directly or indirectly bear on a particular element of an offense.” *Id.* at 1367. For instance, in *Todd*, 108 F.3d at 1333, the defendant was convicted of embezzling from his company's employee retirement fund plan. The government used evidence that the defendant and his family members who worked at the company all received extremely high salaries to prove the defendant's greed and motive to steal. *Id.* This Court reversed the defendant's conviction because he was not permitted to introduce *1157 evidence that all employees who worked at his company, not just his family members, received large salaries and benefits. *Id.* at 1334. Such evidence would have “complete[d] the picture,” *See Hurn*, 368 F.3d at 1367, by putting “a different spin” on the defendant's intent, *See Todd*, 108 F.3d at 1334. Similarly in *Sheffield*, this Court noted that the retirement gift evidence, aside from being probative of the defendant's intent or lack thereof to embezzle, also should have been admitted to “put the charges against Mr. Sheffield in context, ‘to complete the story of the crime on trial.’ ” 992 F.2d at 1170 (quoting *United States v. Mills*, 704 F.2d 1553, 1559 (11th Cir. 1983)).

But here, the “good patient” evidence was not necessary to “complete the picture,” because it was undisputed that the appellants treated thousands of patients and there was no allegation that they mistreated them all. Indeed, the government told the jury in its opening:

[T]here were definitely some [patients] that were treated very appropriately in this office. There is no question about that, that there were certainly instances where Dr. Ruan and Dr. Couch did a really good job for their patients. We're not here because of that. We're here for the times that they were prescribing these drugs outside the usual course of professional practice.

The admonition was repeated in closing: “By and large their patients were legitimate patients. And I told you right from the very start and it has always been our contention that a majority of the patients that went there had legitimate pain needs and were in need of legitimate pain treatment.” Thus, there was no need to dispel the “taint” that PPSA was a sham practice. PPSA only accepted patients with insurance and refused patients paying cash. Diagnostic tools such as nerve conduction tests, fluoroscopes, [electromyographs](#), and MRIs were frequently used to discover the source of patient pain. Ken Cross, PPSA's former manager and a government witness, described PPSA in 2014 as “one of the best, well-rounded pain centers in this area.” In sum, Tiller's testimony “was not necessary to correct any misleading impressions that may have been created by the government's evidence.” *See Hurn*, 368 F.3d at 1367.

[64] For the same reasons, Ruan was not prejudiced by the district court's exclusion of undercover videos of DEA agents acting as “patients” seeking opioids from him but being denied. As noted, the government introduced videos at trial from Officer Kelley's appointments with Couch at PPSA, which comprised Counts 5–7 against him for illegal drug distribution. The DEA had also sent two undercover patients to see Ruan, but neither received opioid prescriptions. A nurse practitioner examined each patient, and each was then seen by Ruan, who told them that it was not appropriate to prescribe controlled substances because of better alternatives. One was referred for surgery, and the other given an anti-inflammatory ointment. At a pretrial conference, the government successfully moved to prevent Ruan from introducing these videos at trial. Akin to Tiller's testimony, these videos do not refute the inculpatory evidence against Ruan demonstrating that at other times, Ruan did prescribe opioids to patients outside the usual course of professional practice or without a legitimate medical purpose, such as in the four patient files reviewed by Dr. Greenberg comprising Counts 8, 9, 11, and 12.

[65] Before concluding that there was no theory under which the appellants' constitutional rights were violated by the district court's evidentiary rulings, we emphasize that we have carefully considered the appellants' contention that the government's *1158 closing arguments compounded the prejudice they suffered from the inability to present “good patient” evidence. Specifically, the appellants point to three statements made by the prosecutor in rebuttal closing: “The defendants had the same subpoena power as the United States of America. That means they can subpoena anybody they

want to come in this courtroom, just like the United States can.”; “The[appellants] could call anybody they wanted to in connection with this case.”; and later, “We called for you 14 patients in comparison to the few patients the defense called”. The appellants contend that these statements implied that Ruan and Couch could not find witnesses who benefitted from their treatment to rebut the many witnesses that testified for the government, even though the government had obtained a motion *in limine* prohibiting evidence of “good patients.” They raised this issue in their motion for a new trial, which the district court denied.

[66] However, when viewed in context, at least the first two statements are not as egregious as they first appear. The prosecutor was not discussing the ability of the appellants to call patient-witnesses in their favor but was instead addressing the adequacy of the government's own charts, specifically the appellants' ability to call statisticians or other experts to critique those charts:

Now, both attorneys told you that all this is is [sic] numbers, that the government just put up all these charts, pie charts, picture charts. *The defendants had the same subpoena power as the United States of America. That means they can subpoena anybody they want to come in this courtroom, just like the United States can.* If those charts aren't accurate, if those charts weren't what was happening, don't you think they would have brought you somebody to tell you that this chart is not right?

This isn't what the facts showed. This isn't what the numbers are. And they want to tell you that numbers don't mean anything. But numbers control. You can't wait to be 16. You can't wait to be 21, you can't wait to make a 100 on a test. Most everything we do has to do with numbers. And if these numbers weren't correct, these charts weren't correct, they'd be the first one to show you and tell you with evidence and with witnesses.

In connection with that, they could also have called doctors who would have said that they referred people to these doctors. That didn't happen.

They could call anybody they wanted to call in connection with this case.

The third remark, however, gives us pause. The prosecutor argued that “[i]t doesn't have to be 50, it doesn't have to be 1000” inappropriate prescriptions; one prescription outside the usual course of professional practice “is breaking the law.” She then recounted several of the patients the government

had called and, in transitioning to discuss one called by the defense, commented that “[w]e called for you 14 patients in comparison to the few patients the defense called.” This statement is troubling because the government knew that the appellants were prevented from having patients testify that their quality of life had improved through care received by Ruan and Couch.

[67] [68] [69] [70] [71] “[A] prosecutor must refrain from improper methods calculated to produce a wrongful conviction.” *United States v. Rodriguez*, 765 F.2d 1546, 1559 (11th Cir. 1985). For example, a prosecutor may not make “improper suggestions, insinuations and assertions calculated to mislead the jury.” *Id.* (quoting *United States v. Phillips*, 664 F.2d 971, 1030 (5th Cir. 1981)). To establish prosecutorial misconduct, a defendant must establish that the *1159 remarks were improper and that they prejudicially affected his substantial rights. *United States v. Lopez*, 590 F.3d 1238, 1256 (11th Cir. 2009). “A defendant's substantial rights are prejudicially affected when a reasonable probability arises that, but for the remarks, the outcome of the trial would have been different. When the record contains sufficient independent evidence of guilt, any error is harmless.” *Id.* (quoting *United States v. Eckhardt*, 466 F.3d 938, 947 (11th Cir. 2006)). In determining whether a prosecutor's remarks had a reasonable probability of changing the trial's outcome, this Court may look to:

- (1) the degree to which the challenged remarks have a tendency to mislead the jury and to prejudice the accused;
- (2) whether they are isolated or extensive;
- (3) whether they were deliberately or accidentally placed before the jury; and
- (4) the strength of the competent proof to establish the guilt of the accused.

Id. (quoting *Davis v. Zant*, 36 F.3d 1538, 1546 (11th Cir. 1994)).

The prosecutor's remarks were improper, but when examined in the context of the entire trial, the appellants cannot show that the remarks prejudiced them. As mentioned, the jury knew that the appellants treated thousands of patients and were not alleged to have mistreated them all. The three remarks were a minor portion of lengthy closing arguments in a lengthy trial, and the evidence of the appellants' guilt for violating the Controlled Substances Act was substantial. Additionally, the district court repeatedly instructed the

jury that the attorneys' arguments were not evidence. See [Rodriguez, 765 F.2d at 1560](#) (curative instructions considered in determining prejudice from prosecutorial misconduct). For all of these reasons, we conclude that the district court's exclusion of "good patient" evidence did not violate the appellants' constitutional right to present a complete defense.

ii. Phillips's Testimony

[72] The appellants also argue that three separate limitations placed on the testimony of PPSA's former operations manager, Phillips, violated their rights to present a complete defense. First, the government put on evidence that PPSA's electronic medical records frequently contained descriptions of physical examinations conducted by the doctors that never actually happened. The government often asked the PPSA patients that it called to testify about having a light shown in their eyes or having their thyroid checked, with the patients saying it did not happen, despite the medical record purportedly showing otherwise. To rebut this evidence, the appellants called Phillips to explain PPSA's billing practice and operations. She testified that the electronic records system PPSA used relied on templates to pre-populate office visit notes with exams performed, even if the exams were not actually performed. Using a sample patient file that Phillips did not actually work on, Couch asked her to explain how a biller at the office would have reviewed the doctor's notes for an office visit to determine that the bill had been coded correctly for submission to insurance companies. Because Phillips did not prepare the bill for the patient, she was permitted to explain only "what was generally looked at." Phillips nonetheless testified at length, explaining that a biller typically reviewed the recorded "chief complaint, history of present illness, review of systems," and diagnostic code. But when Couch sought to ask her about a specific physical exam listed in the sample bill, the court concluded that she lacked personal knowledge. The appellants say that if allowed, Phillips would have explained that these pre-populated fields were not used *1160 to select the billing level that PPSA submitted to insurers, and they submitted a proffer to that extent.

The appellants contend that this evidence triggers the second [Hurn](#) factor, collateral evidence relative to proving a defense, see [368 F.3d at 1367](#), because it rebuts the government's evidence suggesting that the appellants committed fraud by listing unnecessary or unperformed examinations in order to increase billing revenue. We find no prejudice because

the government successfully proved health care and mail or wire fraud through other illegal acts unrelated to Phillips's testimony about billing codes, such as that PPSA falsely certified to insurers that some patients had [cancer](#) so that the insurers would pay for their TIRF prescriptions, and that PPSA improperly billed BCBS for office visits conducted by nurse practitioners using Couch's physician identification number. We thus find that the excluded evidence could not have affected the trial's outcome.

[73] The second limitation on Phillips's testimony that the appellants challenge occurred after the government cross-examined her about PPSA's practice of billing insurers for visits conducted by physicians when only Palmer saw patients. Phillips testified that Palmer was in collaboration with Couch. On redirect examination, Couch sought to ask Phillips whether "there [is] guidance out there on billing for a practice when a nurse practitioner and a doctor bill in collaboration?" The government objected that the question was too general to elicit a relevant answer and reminded the court that BCBS had different requirements than other insurers. The court sustained the objection, and Couch did not rephrase the question in a more specific way.

The appellants contend that Phillips would have testified that she consulted the Alabama Board of Medical Examiners' guidance and was satisfied that PPSA's collaborative practice followed the relevant guidelines, and they submitted a proffer to that effect. According to the appellants, evidence that Phillips made efforts to ensure that the doctors' collaborative practice was compliant with the law would negate any intent to defraud health care companies by billing for services performed by nurse practitioners. Thus, they contend the exclusion of this testimony was error under the first [Hurn](#) category because it would disprove one of the elements of health care and mail or wire fraud charged in Counts 15 and 19: the intent to defraud.

We again disagree. The specific charge was that the appellants violated a policy specific to BCBS requiring doctors to actually see patients before using the higher billing number. Neither the Alabama Board of Medical Examiners' guidance on collaborative practice nor the fact that other insurers may not have had that same policy was relevant to the charge.

[74] The third limitation on Phillips's testimony challenged by the appellants occurred as she was recalling Officer Kelley's first undercover visit to PPSA, when he was turned away because he did not have insurance until his

“referring chiropractor,” Dr. Wetzel, who was working with the DEA, made a call to PPSA requesting that they make an exception for a cash-only patient. Phillips testified that she overheard PPSA’s new patient coordinator, Shannon Hackworth, speaking with Dr. Wetzel and that Hackworth was “upset” and “crying.” Phillips then spoke to Dr. Wetzel for a few minutes, after which Officer Kelley was permitted to keep his appointment and pay cash “only for that visit.” The district court sustained the government’s hearsay objection regarding what Dr. Wetzel told Phillips, explaining that it was “already in that [PPSA] accepted *1161 him ... because of Dr. Wetzel’s insistence ... [T]here’s nothing else that’s relevant.” Couch then attempted to elicit from Phillips that Dr. Wetzel was angry, made comments that Phillips perceived as threats, and vouched for his “patient” Officer Kelley by saying that he was a business owner and had sufficient funds to pay for his visit. However, the district court sustained the government’s objection to relevance, finding that Couch was not charged with giving Officer Kelley an appointment but with illegally prescribing him controlled substances.

The appellants argue that Phillips’s testimony would have placed Officer Kelley’s first visit in a different light and completed the picture for the jury, *See Hurn*, 368 F.3d at 1363, by explaining why Phillips decided to allow a cash-only patient into PPSA—she felt pressured by Dr. Wetzel’s allegedly threatening call.

However, we don’t see an error of constitutional magnitude here. The fact that Dr. Wetzel’s call precipitated Officer Kelley’s admittance to the practice had been established during Officer Kelley’s own testimony and was not in dispute. There was no evidence that either Palmer or Couch knew about the call, and thus it could not have affected their decisions to prescribe Officer Kelley drugs that he did not need. In other words, information that Phillips felt threatened by Dr. Wetzel’s insistence that PPSA take Officer Kelley in would have not given the jury a reason to acquit Couch of the charges related to his conduct during Officer Kelley’s visits.

3. Expert Testimony

[75] [76] The appellants also argue that government expert Dr. Aultman was not qualified to give her opinions, and that the district court improperly limited their cross-examination of her. The district court overruled these objections at trial. A district court’s decisions regarding the admissibility of expert testimony will not be set aside unless we determine that the

court abused its discretion. *Frazier*, 387 F.3d at 1259. “By definition ... under the abuse of discretion standard of review there will be occasions in which we affirm the district court even though we would have gone the other way had it been our call.” *Id.* (quoting *In re Rasbury*, 24 F.3d 159, 168 (11th Cir. 1994)). In order to reverse, we must find that the district court “has made a clear error of judgment, or has applied the wrong legal standard.” *Id.* (citing *Maiz v. Virani*, 253 F.3d 641, 662 (11th Cir. 2001)).

[77] We first address Dr. Aultman’s qualifications. The proponent of the expert’s testimony must show that the expert is qualified based on her “knowledge, skill, experience, training, or education.” *Frazier*, 387 F.3d at 1261 (emphasis omitted) (quoting *Fed. R. Evid.* 702).²⁴ Based on her training and experience, we find that Dr. Aultman was qualified as an expert to testify as to whether Ruan and Couch’s treatment of some patients was outside the usual course of professional practice. Dr. Aultman has a medical degree and completed a residency in internal medicine. She has practiced for over twenty years in *1162 Mississippi: at the time of trial she was a hospitalist, but she has also practiced general medicine in a private clinic and palliative care in a hospice setting. She regularly prescribes opioids, benzodiazepines, and muscle relaxers to patients with acute and chronic pain, and she has prescribed *fentanyl* to hospice patients. She has previously testified as an expert witness in federal court cases involving illegitimate pain-medication prescriptions and has reviewed patient files for the DEA since 2002. Dr. Aultman testified generally about the doctor-patient relationship, examination and prescribing practices, pain assessments, and documenting patient information. She also testified specifically regarding her review of the medical files of four PPSA patients and Officer Kelley, opining that the appellants’ treatment of these patients was outside the usual course of professional practice, as shown by a lack of accurate patient histories and the infrequent use of non-opioid treatment options. Her testimony pertained to Counts 1–7 and 15, as each depended on allegations of prescribing outside the usual course of professional practice.

We are not concerned, although the appellants say we should be, that Dr. Aultman is not a board-certified pain management physician and does not have her own specialty clinic like PPSA. This Court has held that a “proffered physician need not be a specialist in the particular medical discipline to render expert testimony relating to that discipline.” *McDowell v. Brown*, 392 F.3d 1283, 1297 (11th Cir. 2004) (quoting *Gaydar v. Sociedad Instituto Gineco-Quirurgico y Planificacion*,

345 F.3d 15, 24 (1st Cir. 2003));²⁵ See also *Gayton v. McCoy*, 593 F.3d 610, 617 (7th Cir. 2010) (“[C]ourts often find that a physician in general practice is competent to testify about problems that a medical specialist typically treats.”);²⁶ *Dickenson v. Cardiac & Thoracic Surgery of E. Tenn.*, 388 F.3d 976, 979–80, 982 (6th Cir. 2004) (reversing a district court’s exclusion of a cardiac thoracic surgeon’s testimony on the standard of care applicable to pulmonologists); *Doe v. Biological, Inc.*, 971 F.2d 375, 385 (9th Cir. 1992) (“The fact that the experts were not licensed hematologists does not mean that they were testifying beyond their area of expertise. Ordinarily, courts impose no requirement that an expert be a specialist in a given field, although there may be a requirement that he or she be of a certain profession, such as a doctor.”); *United States v. Viglia*, 549 F.2d 335, 336–37 (5th Cir. 1977) (pediatrician may testify about drug’s effect on obese persons despite no experience treating obese patients). Despite not being a pain management specialist, Dr. Aultman’s familiarity with prescribing opioids and treating chronic pain qualified her to opine on the appellants’ conduct.

[78] Additionally, the appellants questioned Dr. Aultman on cross-examination about her experience treating pain. They even established that as a hospitalist, she did not have her own clinical practice and that when a patient “presented with a significant amount of pain that was beyond [her] specialization, [she] referred that patient” to someone else. “A district court’s gatekeeper role ... ‘is not intended to *1163 supplant the adversary system or the role of the jury.’ ” *Maiz*, 253 F.3d at 666 (quoting *Allison v. McGhan*, 184 F.3d 1300, 1311 (11th Cir. 1999)). “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking [debatable] but admissible evidence.” *Id.* (quoting *Allison*, 184 F.3d at 1311). We find no abuse of discretion in the admission of Dr. Aultman as an expert, and the weight of her testimony was for the jury to evaluate.

[79] [80] We turn now to the appellants’ claim that the district court improperly limited their cross-examination of Dr. Aultman. First, Couch sought to elicit a statement from Dr. Aultman that she could not practice pain management in Mississippi under a 2016 requirement by that state’s medical licensing board that pain management doctors have either completed a residency in that sub-specialty or be board certified in it, or otherwise have completed 100 hours of specialized continuing medical education. The district court did not abuse its discretion in sustaining the government’s

relevance objection to this line of questioning. “[T]he district court enjoys ‘wide latitude’ to impose ‘reasonable limits’ on cross-examination based on, among other things, ‘confusion of the issues’ and ‘interrogation that is repetitive or only marginally relevant.’ ” *United States v. Maxwell*, 579 F.3d 1282, 1296 (11th Cir. 2009) (quoting *Delaware v. Van Arsdall*, 475 U.S. 673, 679, 106 S.Ct. 1431, 89 L.Ed.2d 674 (1986)). Dr. Aultman’s cross-examination had already established that she had never been board certified in pain management, had a residency or fellowship in pain management, or been peer reviewed in a pain management journal. That she was not licensed in Mississippi as a pain management specialist was repetitive and would have risked confusing the jury, considering that Mississippi’s standards did not govern the appellants’ Alabama practice and did not go into effect until after the indictment period in this case.

[81] The appellants also contend that the district court erred in limiting the scope of Ruan’s cross-examination of Dr. Aultman regarding her previous work for the government. Dr. Aultman testified that she had been paid about \$7,600 for her work on the appellants’ case and that she had worked for the DEA or the Department of Justice on “five or six cases last year [2016].” Ruan asked her to confirm that between 2000 and 2014, she “had signed government contracts totaling more than \$325,000.” The government objected that payments for other contracts were irrelevant, and the district court sustained the objection.

[82] [83] [84] The government contends that there was no error here since the jury had already heard of Dr. Aultman’s \$7,600 fee for this case; the evidence of the additional contract amounts would have been cumulative; and the district court had discretion to curtail the cross-examination. We disagree. “While the district court has ‘discretionary authority to rule on the admissibility of evidence, including the power to limit cross-examination,’ this discretion is limited by the guarantee of the Sixth Amendment’s Confrontation Clause that a criminal defendant has the right to cross-examine prosecutorial witnesses.” *Maxwell*, 579 F.3d at 1295 (quoting *United States v. Garcia*, 13 F.3d 1464, 1468 (11th Cir. 1994)). “In particular, ... ‘a presumption favors free cross-examination on possible bias, motive, ability to perceive and remember, and general character for truthfulness.’ ” *Id.* at 1295–96 (quoting *United States v. Phelps*, 733 F.2d 1464, 1472 (11th Cir. 1984)). “[T]he test for the Confrontation Clause is whether a reasonable jury would have received a significantly different impression of the witness” *1164 credibility had counsel pursued the proposed line of cross-

examination.” *Id.* at 1296 (quoting *Garcia*, 13 F.3d at 1469). Aside from Confrontation Clause concerns, proof of bias or motive to lie is also almost always relevant under *Federal Rule of Evidence* 402, as “[a] successful showing of bias on the part of a witness would have a tendency to make the facts to which he testified less probable in the eyes of the jury than it would be without such testimony.” *United States v. Abel*, 469 U.S. 45, 51–52, 105 S.Ct. 465, 83 L.Ed.2d 450 (1984).

Applying these principles leads us to the conclusion that the district court abused its discretion by allowing the jury to believe that Dr. Aultman's financial involvement with the government was substantially less than was accurate. All the jury knew is that Dr. Aultman had been paid roughly \$7,600 in expert fees for this case, and the appellants sought to show that she had signed contracts *over 40 times* that much from the government over the years. This evidence was certainly not cumulative and instead would have been probative of Dr. Aultman's credibility in light of her extensive relationship with the government.

This Court held similarly in *United States v. Williams*, 954 F.2d 668 (11th Cir. 1992). There, the district court allowed a government informant to testify regarding the percentage (25%) he received from successful undercover operations and the amount of money he had already been paid in that case. *Id.* at 671–72. However, the district court excluded testimony detailing the total amount of money the informant had received for his work as an informant because the sum was “outrageous” and therefore prejudicial. *Id.* at 671, 672 n.3. That evidence included the fact that the informant had received \$450,000 in reward money, including 25% of a \$1,258,000 seizure (i.e., \$314,500). *Id.* This Court reversed, reasoning that “[t]he jury has the right to know what may be motivating a witness, especially a government paid, regularly employed, informant-witness.” *Id.* at 672; *See also Collins v. Wayne Corp.*, 621 F.2d 777, 784 (5th Cir. 1980) (“A showing of a pattern of compensation in past cases raises an inference of the possibility that the witness has slanted his testimony in those cases so he would be hired to testify in future cases.”).

[85] [86] Ultimately, however, although we find that the district court abused its discretion in limiting this testimony, we find the error harmless. “[E]videntiary and other nonconstitutional errors do not constitute grounds for reversal unless there is a reasonable likelihood that they affected the defendant's substantial rights; where an error had no substantial influence on the outcome, and sufficient evidence uninfected by error supports the verdict, reversal

is not warranted.” *United States v. Arbolaez*, 450 F.3d 1283, 1290 (11th Cir. 2006) (quoting *United States v. Hawkins*, 905 F.2d 1489, 1493 (11th Cir.1990)). As previously detailed, there was ample other evidence aside from Dr. Aultman's testimony to convict the appellants of RICO conspiracy (Count 1), drug distribution conspiracies (Counts 2–4), and health care fraud conspiracy (Count 15). Thus, it is unlikely that Dr. Aultman's testimony affected the outcome on those charges. Couch specifically argues that the error was not harmless because Dr. Aultman was the only expert to review the medical file of undercover DEA agent Officer Kelley, whose treatment by Couch formed the basis of Counts 5–7. Recall that her opinion was that Couch prescribed controlled substances to Officer Kelley outside the usual course of professional practice. However, this Court has held that expert testimony, while helpful, is not required to prove violations of the Controlled Substances Act, and “a jury can find that a *1165 doctor prescribed controlled substances not in the usual course of his medical practice and was acting other than for a legitimate medical purpose from evidence received from lay witnesses surrounding the facts and circumstances of the prescriptions.” *Joseph*, 709 F.3d at 1103 (quoting *United States v. Rogers*, 609 F.2d 834, 839 (5th Cir. 1980)). In additional support of these counts, Officer Kelley himself testified that he did not need the opioids that Couch prescribed him, and the jury viewed the undercover videos of his visits to PPSA. The jury saw that Officer Kelley touched the floor without pain and heard him request “Roxy” pills. They heard that a drug test and a PDMP check would have shown that he was neither filling the prescriptions nor taking the drugs. This evidence, which suggests that Couch prescribed controlled substances to Officer Kelley only after a cursory visit with him and without a showing of medical need, was sufficient to convict Couch on Counts 5–7, without Dr. Aultman's additional opinion.

C. Jury Instructions

[87] The appellants next contend that the district court erred in refusing to give their proposed jury instruction regarding Counts 1–7, 13–15, and 17, which addressed specifically the applicable standard by which to judge a physician's conduct for violations of the Controlled Substances Act. The appellants' proposed “Instruction 18” stated in pertinent part:

In making a medical judgment concerning the right treatment for an individual patient, physicians have wide discretion to choose among a wide range of options. No single national standard exists. Therefore, in determining whether a Defendant acted without a legitimate medical

purpose or outside the usual course of professional practice, you should examine all of a Defendant's actions and the surrounding circumstances.

If a physician dispenses or distributes a Controlled Substance in good faith while medically treating a patient, then the physician has dispensed or distributed that Controlled Substance for a legitimate medical purpose and within the usual course of professional practice, and you must return a not guilty verdict for the applicable count. Good faith in this context means good intentions and the honest exercise of professional judgment as to the patient's needs. It means that the Defendant acted in accordance with what he reasonably believed to be proper medical practice. If you find that a Defendant acted in good faith in dispensing or distributing a Controlled Substance, as charged in the indictment, then you must return a not guilty verdict.

The Government must prove, beyond a reasonable doubt, that the decision to dispense or distribute a Controlled Substance fell below a standard of medical practice generally recognized and accepted in the United States before you can return a guilty verdict as to that alleged violation of the Controlled Substances Act. But a Defendant's negligence, failure to meet a standard of care, or medical malpractice, on its own is not enough to convict him. An unintentional failure to act how a reasonable doctor would have under similar circumstances is, by itself, insufficient to prove that a Defendant dispensed or distributed a Controlled Substance outside the usual course of professional practice and for no legitimate medical purpose.

To prove a violation of the Controlled Substances Act in this case, the Government must prove, beyond a reasonable doubt, that the physician's decisions to distribute or dispense a Controlled Substance were inconsistent with any accepted method of treating *1166 a pain patient – that the physician, in fact, operated as a drug pusher.

The district court refused to give the appellants' proposed instruction for several reasons. The court found too subjective the appellants' request that the court equate subjective "good faith"—acting with "good intentions and the honest exercise of professional judgment as to the patients' needs"—with prescribing "for a legitimate medical purpose and within the usual course of professional practice." The court also found that the language distinguishing the civil standard of care from the criminal standard would unnecessarily confuse the

jury, and that the language requiring proof that the physician operated as a "drug pusher" was legally incorrect.

The district court instead instructed the jury as follows:

For a controlled substance to be lawfully dispensed by a prescription, the prescription must have been issued by a practitioner both within the usual course of professional practice and for a legitimate medical purpose. If the prescription was issued either, one, not for a legitimate medical purpose or, two, outside the usual course of professional practice, then the prescription was not lawfully issued.

A controlled substance is prescribed by a physician in the usual course of professional practice and, therefore, lawfully if the substance is prescribed by him in good faith as part of his medical treatment of a patient in accordance with the standard of medical practice generally recognized and accepted in the United States. The appellants in this case maintain at all times they acted in good faith and in accordance with standard of medical practice generally recognized and accepted in the United States in treating patients.

Thus a medical doctor has violated [section 841](#) when the government has proved beyond a reasonable doubt that the doctor's actions were either not for a legitimate medical purpose or were outside the usual course of professional medical practice.

[88] [89] This Court reviews a district court's rejection of a proposed jury instruction for an abuse of discretion. [United States v. Jockisch](#), 857 F.3d 1122, 1126 (11th Cir. 2017). A district court commits reversible error if: "(1) the requested instruction was a correct statement of the law, (2) its subject matter was not substantially covered by other instructions, and (3) its subject matter dealt with an issue in the trial court that was so important that failure to give it seriously impaired the defendant's ability to defend himself." [United States v. Carrasco](#), 381 F.3d 1237, 1242 (11th Cir. 2004) (quoting [United States v. Paradies](#), 98 F.3d 1266, 1286 (11th Cir. 1996)). A district court may properly refuse to give an instruction that fails any one of these prongs. See [Jockisch](#), 857 F.3d at 1126.

1. Good Faith Instruction

We first address the appellants' proposed "good faith" instruction, which we find is an incorrect statement of the law. This Court has held that "[w]hether a defendant acts in the usual course of his professional practice must be evaluated based on an objective standard, not a subjective standard." *Joseph*, 709 F.3d at 1097; *See also Tobin*, 676 F.3d at 1282–83; *Merrill*, 513 F.3d at 1306; *United States v. Williams*, 445 F.3d 1302, 1309 (11th Cir. 2006), *abrogated on other grounds by United States v. Lewis*, 492 F.3d 1219, 1220 (11th Cir. 2007) (en banc). This rule reflects the Supreme Court's decision in *United States v. Moore*, 423 U.S. 122, 96 S.Ct. 335, 46 L.Ed.2d 333 (1975), the first case by the Supreme Court establishing that physicians can be prosecuted for violating *1167 the Controlled Substances Act "when their activities fall outside the usual course of professional practice." *Id.* at 124, 96 S.Ct. 335. Yet under the appellants' proposed instruction, as long as a physician subjectively believes that he is meeting a patient's medical needs by prescribing a controlled substance, then he cannot be convicted of violating the Act no matter how far outside the bounds of professional medical practice his conduct falls. In other words, good faith is a complete defense. This Court has repeatedly rejected good faith instructions nearly identical to that proposed by the appellants here because they failed to include the objective standard by which to judge the physician's conduct. *See Joseph*, 709 F.3d at 1097; *Merrill*, 513 F.3d at 1305; *Williams*, 445 F.3d at 1309. And in these cases, this Court has approved the same instruction that the district court ultimately gave here:

A controlled substance is prescribed by a physician in the usual course of a professional practice and, therefore, lawfully, if the substance is prescribed by him in good faith as part of his medical treatment of a patient in accordance with the standard of medical practice generally recognized and accepted in the United States.

Joseph, 709 F.3d at 1092; *Tobin*, 676 F.3d at 1281; *Merrill*, 513 F.3d at 1306; *Williams*, 445 F.3d at 1309.

The appellants recognize that this Court has rejected nearly identical proposed jury instructions but argue that this Court should reconsider its prior holdings. However, under the Eleventh Circuit's prior panel precedent rule, this Court is

bound by its holdings in *Williams* and *Joseph*. *See United States v. Steele*, 147 F.3d 1316, 1317–18 (11th Cir. 1998) (en banc) ("Under our prior precedent rule, a panel cannot overrule a prior one's holding even though convinced it is wrong."); *See also Smith v. GTE Corp.*, 236 F.3d 1292, 1303 (11th Cir. 2001) ("[W]e categorically reject any exception to the prior panel precedent rule based upon a perceived defect in the prior panel's reasoning or analysis as it relates to the law in existence at that time.>").

[90] Nor did the district court's refusal to give the appellants' proposed "good faith" instruction seriously impair the appellants' ability to present an effective defense. The district court's instruction told the jury that good faith was a defense to a Controlled Substances Act violation as long as the appellants' conduct also was in accordance with the standards of medical practice generally recognized and accepted in the United States, and it highlighted that the appellants "maintain[ed] at all times they acted in good faith and in accordance with [that] standard." The jury could have accepted this defense and acquitted based on the good faith instruction that the district court provided. *Cf. United States v. Yeager*, 331 F.3d 1216, 1224 (11th Cir. 2003) ("The jury could have accepted this defense and acquitted Yeager by reference to the instructions, particularly the materiality instruction. Therefore, we can find no error in the refusal of the reasonable reliance instruction.").

2. Drug Pusher Instruction

[91] Next, we find that the proposed "drug pusher" instruction is also an incorrect statement of the law. The appellants argue that the Supreme Court's decisions in *Moore*, 423 U.S. 122, 96 S.Ct. 335, and *Gonzales v. Oregon*, 546 U.S. 243, 126 S.Ct. 904, 163 L.Ed.2d 748 (2006), taken together, support giving a jury instruction that equates bad physicians to drug pushers. We disagree. Like it or not, the term "drug pusher" connotes imagery of back-alley illicit drug deals, not an established medical practice like PPSA. And while the Supreme Court in *Moore* described the physician-defendant in that case as a *1168 "large-scale [drug] 'pusher,'" 423 U.S. at 143, 96 S.Ct. 335, the Supreme Court nowhere suggested that acting as a drug dealer or pusher as conventionally understood is necessary for a Controlled Substances Act conviction, *id.* at 139–42, 96 S.Ct. 335. Rather, as previously noted, the Supreme Court held that a physician violates the Controlled Substances Act if his conduct "fall[s] outside the usual course of professional

practice,” *id.* at 124, 96 S.Ct. 335, which could occur in a manner of different ways. Additionally, this Court’s precedents applying *Moore* do not suggest that acting as a drug pusher is necessary to convict a physician for violations of 21 U.S.C. § 841. See *Joseph*, 709 F.3d at 1096; *Tobin*, 676 F.3d at 1282–83; *Merrill*, 513 F.3d at 1306; *Williams*, 445 F.3d at 1309.

As for the appellants’ reliance on *Gonzales*, that case has no application here. *Gonzales* was not a criminal prosecution. Rather, the Supreme Court applied administrative law to analyze an interpretive rule issued by the Attorney General indicating that physicians who dispense controlled substances for use in physician-assisted suicides of terminally ill patients would be violating the Controlled Substances Act because assisted suicide was not a “legitimate medical purpose” under the Act. See 546 U.S. at 248–49, 126 S.Ct. 904. The Attorney General’s judgment conflicted with Oregon law, which permitted the practice. The Supreme Court struck down the interpretive rule because it exceeded the Attorney General’s delegated authority under the Controlled Substances Act. *Id.* at 267, 126 S.Ct. 904. In addressing the Act’s purpose and design, the Supreme Court stated that “[t]he [Act] and our case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood.” *Id.* at 269–70, 126 S.Ct. 904. In describing the Act in such a way, the Supreme Court was referring to its previous decision in *Moore*. But the Supreme Court nowhere displayed the intention to upset or limit its holding in *Moore*; in fact, it cited *Moore* with approval. See *id.* at 269, 126 S.Ct. 904.

Numerous courts have since rejected the argument that those statements in *Gonzales* have any bearing on *Moore*’s holding or that they limit the scope of liability for physicians under § 841 to “drug or street dealer” activity. For example, in *United States v. Volkman*, 797 F.3d 377 (6th Cir.), *cert. denied*, — U.S. —, 136 S. Ct. 348, 193 L.Ed.2d 250 (2015), the Sixth Circuit held that “*Gonzales* did nothing to alter the reality that ‘knowingly distributing prescriptions outside the course of professional practice is a sufficient condition to convict a defendant under the criminal statutes relating to controlled substances.’” *Id.* at 386 (quoting *United States v. Kanner*, 603 F.3d 530, 535 (8th Cir. 2010)). In *Volkman*, the defendant proposed the following jury instruction, derived from the Supreme Court’s statements in *Gonzales*: “In other words, in order to find the defendant guilty, you must find that

he used his prescription-writing power as a means to engage in the illicit drug-dealing and trafficking as conventionally understood.” *Id.* at 385. The Sixth Circuit held that such an instruction was an incorrect statement of the law because it improperly “cabined the scope of what the jury could consider.” *Id.* at 386. The court stated, “If Volkman’s goal was to conjure up the unsavory specter of ‘street’ drug dealing—complete with imagery of shady characters conducting quick, suspicious handoffs—then his instruction was not an accurate statement of the law, for ‘street’ drug dealing is not necessary to prove a violation of the [Controlled Substances Act].” *Id.*

*1169 Similarly, in *Kanner*, 603 F.3d at 533–35, the Eighth Circuit rejected the defendant’s argument that the indictment should have included the above-quoted language from *Gonzales*, holding that “*Gonzales* did not supplant the standard for violations of the [Controlled Substances Act].” See *id.* at 535 (“Rather, post *Gonzales*, ‘knowingly distributing prescriptions outside the course of professional practice is a sufficient condition to convict a defendant under the criminal statutes relating to controlled substances.’” (quoting *United States v. Armstrong*, 550 F.3d 382, 397 (5th Cir. 2008))); See also *United States v. Lovern*, 590 F.3d 1095, 1100 (10th Cir. 2009) (“Unlike *Gonzales*, we have before us no interpretive rule seeking to define a practice as lacking any legitimate medical purpose Instead, in this case the government sought to establish that the conduct of the ... physicians was inconsistent with the usual course of professional practice the old-fashioned way: through witnesses and documentary proof at trial focused on the contemporary norms of the medical profession.”). We agree with these courts that *Gonzales* did nothing to disturb the holding of *Moore*, which sets out a standard for violations of the Controlled Substances Act that is based solely on the statutory provisions themselves. To require the jury to find that the appellants acted as drug pushers would violate these principles.

3. Civil Standard of Care Instruction

[92] Finally, we address the appellants’ argument that the district court permitted jurors to conflate civil and criminal standards by refusing to give their proposed instruction because it would be too confusing for the jury. While the instruction proposed by the appellants, which stated that “a Defendant’s negligence, failure to meet a standard of care, or medical malpractice, on its own is not enough to convict him”, is an accurate statement of the law, we do not agree that

its exclusion from the instructions impaired the appellants' ability to adequately present their defense.

First, there is no dispute that the district court instructed the jury on the correct criminal standard for Controlled Substances Act violations. This instruction is in keeping with this Court's guidance in *Williams* that an instruction explaining that the government must prove that a doctor dispensed controlled substances "outside the usual course of professional practice ... properly state[d] the standard by which a [doctor's] conduct must be judged." 445 F.3d at 1307–08.

Nonetheless, the appellants argue that an instruction distinguishing the civil standard was necessary because the government and several of its medical experts confused the two during trial. The appellants point out that the government conflated the terms "standard of care" and "usual course of professional practice" when examining Dr. Greenberg. They also emphasize that Dr. Vohra actually equated those terms in his testimony, and that while Dr. Aultman was never asked to provide a definition of "the usual course of professional practice," the government regularly asked her opinion on whether certain conduct would be within that standard. However, we find that the district court's instruction at the end of trial defining the criminal standard adequately cured any incorrect references to the civil standard of care by experts or the prosecution.

Additionally, the district court instructed the jury that if the appellants acted in good faith, they acted lawfully. Other courts have found that such an instruction sufficiently covered that the jury was not to convict based on a civil standard of care. See *United States v. McIver*, 470 F.3d 550, 560 (4th Cir. 2006) ("The inclusion of a good faith instruction is a plainspoken method of explaining to the jury a critical *1170 difference between the two standards."); *United States v. Feingold*, 454 F.3d 1001, 1012 (9th Cir. 2006) (jury instructions that informed the jury that "[a] practitioner may not be convicted of unlawful distribution of controlled substances when he distributes controlled substances in good faith to patients in the regular course of professional practice" and that "the government must prove beyond a reasonable doubt that the defendant prescribed or distributed the controlled substance other than for a legitimate medical purpose and not in the usual course of professional practice" correctly articulated the standard of liability under § 841(a) (1)).

Finally, the appellants presented an expert to provide an explanation of the "usual course of professional practice." Dr. Warfield's definition was that medical malpractice is not outside the usual course of professional practice. At closing, the appellants argued that malpractice is not enough to convict. Thus, the jury was able to consider these standards in determining whether the appellants' conduct was criminal. See *Joseph*, 709 F.3d at 1097 (highlighting the fact that "[e]xperts for both the prosecution and the defense testified about the accepted standard of medical practice").

D. Ruan's Sentence

Ruan also challenges the sentence imposed by the district court. First, he argues that the district court clearly erred in finding that at least 10.6% of the prescriptions written were illegal. Next, he argues that the district court clearly erred when it applied an obstruction-of-justice enhancement based on his testimony that he was unaware that one of his employees was forging prescriptions. Then, he argues that the district court plainly erred by applying an enhancement under U.S.S.G. § 2S1.1(b)(2)(B) because he was convicted under § 1956(h). He also argues that the district court clearly erred in calculating the restitution amount based on the number of off-label prescriptions for TIRFs and overmedicated patients. Finally, he argues that the district court erred in ordering forfeiture for the RICO Act violation because the evidence was insufficient to support his conviction. The government argues that any error in calculating the guideline range was harmless because the district court said that it would have imposed the same sentence, regardless of any errors in calculating the guidelines range.

1. Harmless Error

[93] We first address the government's harmless-error argument. Where a defendant preserves a challenge to the guidelines calculations, we have held that any error is harmless if (1) the district court stated it would impose the same sentence even if it decided the guidelines issue in the defendant's favor, and (2) assuming an error occurred and the lower guideline range argued for by the defendant applied, "the final sentence resulting from consideration of the § 3553(a) factors would still be reasonable." *United States v. Keene*, 470 F.3d 1347, 1349 (11th Cir. 2006). This is because "[t]he Supreme Court and this Court have long recognized that it is not necessary to decide guidelines issues or remand cases for new sentence proceedings where the guidelines

error, if any, did not affect the sentence.” *Id.* (alteration in original). We need not reach the substantive reasonableness issue where a district court’s decision is based on a clearly erroneous fact. *United States v. Slaton*, 801 F.3d 1308, 1320 (11th Cir. 2015).

[94] We examine “whether the sentence is substantively reasonable under the totality of the circumstances.” *United States v. Tome*, 611 F.3d 1371, 1378 (11th Cir. 2010). The party who is challenging the sentence bears the burden of showing *1171 that it is “unreasonable in light of the record and the § 3553(a) factors.” *Id.*

The district court must impose a sentence that is “sufficient, but not greater than necessary, to comply with the purposes” set forth in 18 U.S.C. § 3553(a)(2), including the need to reflect the seriousness of the offense, promote respect for the law, provide just punishment for the offense, deter criminal conduct, and protect the public from the defendant’s future criminal conduct. 18 U.S.C. § 3553(a)(2). Additionally, the court must consider: (1) the nature and circumstances of the offense; (2) the history and characteristics of the defendant; (3) the kinds of sentences available; (4) the guideline sentencing range; (5) any pertinent policy statements; (6) the need to avoid unwarranted sentencing disparities among defendants with similar records who have been convicted of similar conduct; and (7) the need to provide restitution to any victims. 18 U.S.C. § 3553(a)(1), (3)–(7).

[95] [96] In determining whether to sentence a defendant outside the guidelines, a district court must “consider the extent of the deviation and ensure that the justification is sufficiently compelling to support the degree of the variance.” *Gall v. United States*, 552 U.S. 38, 50, 128 S.Ct. 586, 169 L.Ed.2d 445 (2007). “[A] major departure should be supported by a more significant justification than a minor one,” and the district court “must adequately explain the chosen sentence to allow for meaningful appellate review and to promote the perception of fair sentencing.” *Id.*

Here, the district court’s statement that it would have imposed the same sentence did not render the alleged Guidelines errors harmless. If Ruan succeeded on his Guideline challenges, the offense level would be 25, which, with a criminal history score of I, results in a lower guideline range of 57 to 71 months. The district court did not provide sufficient fact-finding or explanation to support an upward variance from 71 to 252 months. See *Gall*, 552 U.S. at 50, 128 S.Ct. 586. Thus, the sentence would have been substantively unreasonable, so

the alleged Guidelines errors were not harmless. See *Keene*, 470 F.3d at 1349.

2. Drug Quantity Calculation

[97] [98] [99] [100] Next, we address each of Ruan’s arguments in turn. First, Ruan argues that the district court clearly erred in finding that at least 10.6% of the prescriptions written were illegal. When reviewing for procedural reasonableness, we consider legal issues *de novo*, review factual findings for clear error, and apply the guidelines to the facts with due deference, which is akin to clear error review. *United States v. Rothenberg*, 610 F.3d 621, 624 (11th Cir. 2010). The district court’s determination of the quantity of drugs used to establish a base offense level for sentencing purposes is reviewed for clear error. *United States v. Reeves*, 742 F.3d 487, 506 (11th Cir. 2014). We may affirm for any reason supported by the record, even if not relied upon by the district court. *United States v. Chitwood*, 676 F.3d 971, 975 (11th Cir. 2012).

[101] [102] [103] To be clearly erroneous, a finding must leave us with a “definite and firm conviction that a mistake has been committed.” *Rothenberg*, 610 F.3d at 624 (quoting *United States v. Rodriguez-Lopez*, 363 F.3d 1134, 1137 (11th Cir. 2004)). A factual finding cannot be clearly erroneous when the factfinder is choosing between two permissible views of the evidence. *United States v. Saingerard*, 621 F.3d 1341, 1343 (11th Cir. 2010) (per curiam). “‘We accord great deference to the district court’s credibility determinations’ of drug-quantity witnesses.” *1172 *United States v. Barsoum*, 763 F.3d 1321, 1333 (11th Cir. 2014) (quoting *United States v. Gregg*, 179 F.3d 1312, 1316 (11th Cir. 1999)).

[104] [105] The government bears the burden of establishing drug quantity by a preponderance of the evidence. *United States v. Rodriguez*, 398 F.3d 1291, 1296 (11th Cir. 2005). The district court must ensure that the government “carries this burden by presenting reliable and specific evidence.” *United States v. Lawrence*, 47 F.3d 1559, 1566 (11th Cir. 1995). In the medical context, drug distribution requires proof that either: (a) the prescription was not for a legitimate medical purpose; or (b) the prescription was not made in the “usual course of professional practice.” *Joseph*, 709 F.3d at 1102.

[106] [107] When the drug amount that is seized does not reflect the scale of the offense, the district court must

approximate the drug quantity. *United States v. Frazier*, 89 F.3d 1501, 1506 (11th Cir. 1996). In estimating the drug quantity attributable to the defendant, the court may rely on evidence demonstrating the average frequency and amount of a defendant's drug sales over a given period. *Id.* This determination “may be based on fair, accurate, and conservative estimates of the quantity of drugs attributable to a defendant ... [but] cannot be based on calculations of drug quantities that are merely speculative.” *United States v. Zapata*, 139 F.3d 1355, 1359 (11th Cir. 1998) (per curiam).

The drug guideline, § 2D1.1(a)(1), calculates a base offense level based on the total “marihuana equivalent” of all drugs involved in all the defendants’ offenses. U.S.S.G. § 2D1.1 cmt. nn.7, 8(B). The highest base offense level (38) applies for quantities over 90,000 kilograms; that is what the PSR applied here. PSR ¶ 65; U.S.S.G. § 2D1.1(c)(1). The marijuana equivalent of all the morphine, oxycodone, methadone, hydromorphone, oxymorphone, and fentanyl defendants prescribed over the course of the conspiracy was almost 855,000 kilograms. Here, the district court did not clearly err in concluding that at least 10.6% of the prescriptions were illegal. Testimony from two nurse practitioners, Palmer and Parker, suggested that half of the clinic's patients were overmedicated, and given those nurses’ qualifications and length of employment at the clinic, the district court was entitled to credit that testimony. *Barsoum*, 763 F.3d at 1333. Moreover, the evidence at trial indicated that significant amounts of Ruan and Couch's practice occurred outside the usual course of professional practice, including: altering prescription habits to further their financial interests; allowing a nurse practitioner to forge prescriptions for his and other nurses’ patients; leaving presigned prescription pads for nurses to use when the doctors were out of the office; insufficiently safeguarding high-risk patients; ignoring signs of potential drug diversion; failing to adequately get informed consent for prescriptions, especially for off-label prescriptions; not conducting adequate examinations to diagnose patients; and not first attempting more conservative care. The sheer breadth of improper conduct at the clinic means that the district court did not clearly err in concluding that at least 10.6% of the prescriptions were illegal.

3. Obstruction-of-Justice Enhancement

[108] [109] [110] Ruan next argues that the district court clearly erred in finding that he obstructed justice. In reviewing the district court's imposition of the obstruction-of-justice

enhancement under U.S.S.G. § 3C1.1, we review the district court's factual findings for clear error and its application of those findings to the Guidelines *de novo*. *United States v. Doe*, 661 F.3d 550, 565 (11th Cir. 2011). We accord great deference to a district court's credibility *1173 determinations when applying the obstruction-of-justice enhancement based on perjury. *United States v. Banks*, 347 F.3d 1266, 1269 (11th Cir. 2003).

[111] Pursuant to § 3C1.1, a defendant's offense level is increased by two levels if the defendant “willfully obstructed or impeded ... the administration of justice with respect to the investigation, prosecution, or sentencing of the instant offense of conviction,” such as by committing perjury. U.S.S.G. § 3C1.1 & cmt. n.4(B). Perjury occurs where a witness gives deliberately false testimony regarding a material matter, which is not caused by confusion, mistake, or faulty memory. *United States v. Dunnigan*, 507 U.S. 87, 94, 113 S.Ct. 1111, 122 L.Ed.2d 445 (1993).

[112] [113] “[I]f a defendant objects to a sentence enhancement resulting from [his] trial testimony, a district court must review the evidence and make independent findings necessary to establish a willful impediment to or obstruction of justice” *Id.* at 95, 113 S.Ct. 1111. To apply the enhancement, the district court must make a factual finding that the defendant gave perjured testimony on a material matter. *United States v. Vallejo*, 297 F.3d 1154, 1168 (11th Cir. 2002).

Here, the district court's finding that Ruan testified falsely about knowing about Palmer's forgery is not clearly erroneous. In his email to Couch, Ruan directed him to “talk to [Palmer] on cutting down” on the use of red flag drugs. This email can reasonably be read to demonstrate that Ruan knew Palmer was illicitly prescribing medication, especially when considered with the testimony that others, who worked both in and outside the office, were aware that Palmer was writing prescriptions. Because the district court was entitled to choose between two reasonable constructions of the evidence, it did not clearly err in finding that Ruan testified falsely. *See Saingerard*, 621 F.3d at 1343. Accordingly, we affirm as to this issue.

4. Money Laundering Conviction Enhancement

[114] [115] [116] Next, Ruan argues for the first time on appeal that the district court erred in applying a § 2S1.1(b)(2)

(B) enhancement because he was convicted under § 1956(h). A failure to preserve a procedural objection at sentencing means that we only review for plain error. *United States v. Vandergrift*, 754 F.3d 1303, 1307 (11th Cir. 2014). Under plain error review, we consider whether (1) an error occurred, (2) the error was plain, and (3) the error affects substantial rights. *United States v. Olano*, 507 U.S. 725, 732–36, 113 S.Ct. 1770, 123 L.Ed.2d 508 (1993). When these factors are met, we may exercise discretion and correct the error if it “seriously affects the fairness, integrity or public reputation of judicial proceedings.” *Id.* at 736, 113 S.Ct. 1770.

Under U.S.S.G. § 2S1.1(b)(2)(B), a two-level sentencing enhancement applies if a defendant was convicted under 18 U.S.C. § 1956. U.S.S.G. § 2S1.1(b)(2)(B). However, that enhancement does not apply “if the defendant was convicted of a conspiracy under 18 U.S.C. § 1956(h) and the sole object of that conspiracy was to commit an offense set forth in 18 U.S.C. § 1957.” U.S.S.G. § 2S1.1 cmt. n.3(C). If a defendant is convicted under § 1957, a one-level enhancement applies. U.S.S.G. § 2S1.1(b)(2)(A).

Here, the district court erred in applying the two-level sentencing enhancement under § 2S1.1(b)(2)(B), and it should have applied the one-level enhancement under § 2S1.1(b)(2)(A). However, this error did not affect Ruan's substantial rights. Ruan's original offense level was 44, which was treated as 43 because that is the maximum offense level used by the Guidelines. Because *1174 applying the correct enhancement would only reduce his offense level to 43, it would not have changed the calculation of the guideline range. Accordingly, the district court's error did not affect Ruan's substantial rights, so we affirm as to this issue.

5. Restitution Calculation

[117] [118] Next, Ruan argues that the district court's restitution calculation was clearly erroneous. “The district court's factual finding as to the specific amount of restitution is reviewed for clear error.” *United States v. Futrell*, 209 F.3d 1286, 1289 (11th Cir. 2000) (per curiam). “The district court's decision to allow an estimate of the victim's loss in a particular case” is reviewed for “abuse of discretion.” *Id.*

The Mandatory Victims Restitution Act (“MVRA”) provides that, in the case of certain offenses, a defendant must make restitution to the victim of the offense. 18 U.S.C. § 3663A(a) (1). In particular, the MVRA applies where a defendant

has been adjudicated guilty of: (1) a crime of violence; (2) an offense against property or under 21 U.S.C. § 856(a), including offenses committed by fraud or deceit; (3) an offense under 18 U.S.C. § 1365; or (4) an offense under 18 U.S.C. § 670. *Id.* § 3663A(c)(1)(A)(i)–(iv).

[119] [120] [121] [122] [123] The amount of restitution ordered by a district court “must be based on the amount of loss actually caused by the defendant's conduct.” *United States v. Liss*, 265 F.3d 1220, 1231 (11th Cir. 2001). The government must establish the loss amount by a preponderance of the evidence. 18 U.S.C. § 3664(e); *United States v. Valladares*, 544 F.3d 1257, 1269 (11th Cir. 2008) (per curiam). This burden “simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence.” *United States v. Trainor*, 376 F.3d 1325, 1331 (11th Cir. 2004) (quoting *Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Tr. for So. Cal.*, 508 U.S. 602, 622, 113 S.Ct. 2264, 124 L.Ed.2d 539 (1993)). Additionally, because “criminals rarely keep detailed records of their lawless dealings, totaling up every column and accounting for every misbegotten dollar ... the preponderance standard must be applied in a practical, common-sense way.” *Futrell*, 209 F.3d at 1292 (quoting *United States v. Savoie*, 985 F.2d 612, 617 (1st Cir. 1993)). As the determination of the restitution amount is an “inexact science,” the government “need not calculate the victim's actual loss with laser-like precision, but may instead provide a ‘reasonable estimate’ of that amount.” *United States v. Martin*, 803 F.3d 581, 595 (11th Cir. 2015) (first quoting *United States v. Huff*, 609 F.3d 1240, 1248 (11th Cir. 2010); then quoting *Futrell*, 209 F.3d at 1290). Notwithstanding the government's burden to prove the restitution amount, “[t]he defendant bears the burden to prove the value of any goods or services he provided that he claims should not be included in the restitution amount.” *United States v. Foster*, 878 F.3d 1297, 1308 (11th Cir. 2018) (ellipsis omitted) (quoting *United States v. Bane*, 720 F.3d 818, 829 n.10 (11th Cir. 2013)).

[124] When a district court orders restitution, it “must explain its findings with sufficient clarity to enable this [C]ourt to adequately perform its function on appellate review.” *Huff*, 609 F.3d at 1248. To that end, the district court must specifically find “whether the victim suffered a loss and the amount of those actual losses.” *Id.* at 1249 (emphasis omitted).

[125] Here, the district court ordered restitution to insurers BCBS, United Healthcare, Medicare, and TriCare for 85% of

the payments each insurer made for TIRF medications that Ruan and Couch prescribed during the indictment *1175 period. This percentage was based on evidence that no more than 15% of PPSA patients had active cancer and that TIRF medications were indicated only for cancer-related pain. Ruan argues that the 85% figure is overstated.

At sentencing, Ruan and Couch objected to the 85% figure, pointing out that Dr. Aultman had opined that it was not inherently illegal to prescribe medications off-label and that there was testimony from a BCBS representative that BCBS sometimes approved TIRFs for a non-cancer diagnosis. The government responded that even if non-cancer patients needed some kind of medication to control their pain, there was ample evidence that Ruan and Couch prescribed Abstral and Subsys to enrich themselves because they had a financial interest, not for appropriate patient care, and that such conduct was also outside the usual course of professional practice. Ruan now adds to his argument for the first time that deducting only 15% for cancer patients is not enough because the government's charts showed that out of the 25 patients to whom each doctor was prescribing the most TIRF medications, 44% of those patients, or 11 for each doctor, did have cancer.

The evidence at trial does not point to any precise number of TIRF prescriptions that were illegal. There is a possibility that PPSA's few cancer patients were prescribed TIRF medications at higher rates than its patients who did not have cancer. There may also have been some patients without a cancer diagnosis who were legitimately prescribed TIRFs off-label to control extreme pain. However, in light of the impracticality of determining which of the thousands of TIRF prescriptions were illegal,²⁷ and when one also considers the abundant evidence that the appellants prescribed millions of doses of TIRFs for their own financial gain (i.e., their investments in Galena stock and their payments as Insys speakers) rather than for the legitimate needs of their patients—a practice that made them some of the top TIRF prescribers nationwide—we find that 85% of all TIRF medications paid for by each insurer is a “reasonable estimate” of the actual loss to those insurers. See *Martin*, 803 F.3d at 595.

Moreover, it was Ruan's burden “to prove the value of any goods or services he provided that he claims should not be included in the restitution amount.” *Foster*, 878 F.3d at 1308 (quoting *Bane*, 720 F.3d at 829 n.10). But when asked by the district court at Couch's sentencing, which was held first and in which Ruan participated and adopted

Couch's counsel's arguments, “What do you think is a more appropriate figure?”, Couch's counsel stated: “Your honor, I don't have an alternative figure.” It was not enough for Ruan to assert that the government's estimate of the insurers' loss amount was improper, when that estimate was reasonable based on the facts presented at trial. Ruan had to show the value of the TIRF prescriptions he wrote that he claims were medically necessary, in order to enable the district court to offset them against the restitution amount. See *Foster*, 878 F.3d at 1308; *United States v. Bryant*, 655 F.3d 232, 254 (3d Cir. 2011) (emphasizing that the defendant has the burden of establishing offsets to restitution because he is in the best *1176 position to know the value of the legitimate goods or services provided to his victims). Ruan failed to carry that burden.

[126] Ruan also separately argues that it was error for the district court to have ordered restitution to be paid to insurers BCBS, United Healthcare, Medicare, and TriCare for 50% of each insurer's payments for the remaining Schedule II prescriptions dispensed by PPSA during the relevant period. This percentage was based on trial testimony from Palmer and Parker that at least half of PPSA's patients were overmedicated or had received prescriptions for larger doses of drugs than they needed.

At sentencing, the government stated that some of the victim insurers felt they were entitled to more than 50%—for instance, United Healthcare felt it was entitled to 80%—but all four insurers ultimately agreed with the government that 50% was a fair and accurate calculation based on the trial testimony. The government argued that it would be impossible to calculate which particular Schedule II prescriptions were illegal and that 50% was a reasonable estimate based on the evidence. Ruan and Couch disagreed, arguing that restitution should only be ordered for the value of specific prescriptions experts had testified were written outside the usual course of professional practice or not for a legitimate medical purpose, describing those amounts as “miniscule.”

[127] As with the TIRF prescriptions, the evidence at trial did not point to any precise number of the remaining Schedule II prescriptions as being illegal. Calculating the exact amount of loss to each of the four insurers would be impractical, if not impossible. The MVRA justifies the use of approximation in cases like this, provided the estimate is reasonable and based on a preponderance of the evidence. Here, two different nurse practitioners, who had firsthand knowledge of PPSA's

patients for years, each testified that at least half of the patients were overmedicated or had received prescriptions for larger quantities of drugs than they needed. This testimony was bolstered by the abundant evidence that Ruan and Couch's prescribing habits were consistently outside the usual course of professional practice during the indictment period, as evidenced by their allowing Palmer to forge prescriptions; leaving pre-signed prescriptions for nurses to use; failing to obtain informed consent from patients before writing multiple prescriptions for high doses of Schedule II drugs; and ignoring signs of drug diversion. Additionally, the 50% estimate was conservative because all of the illegal prescriptions were not included in calculating the restitution amount—only those for Schedule II drugs, which does not include drugs like benzodiazepines and Soma, the other two components of the dangerous “Holy Trinity” cocktail that the appellants prescribed so often. *See Futrell*, 209 F.3d at 1292 (“So long as the basis for reasonable approximation is at hand, difficulties in achieving exact measurements will not preclude a trial court from ordering restitution.”). We thus cannot say that the district court's estimate that the insurers were each owed 50% of payments they made for Schedule II drugs was speculative to the point of being clearly erroneous.

[128] Additionally, we find that the district court explained its findings with sufficient clarity to enable us to perform our duty on appellate review. Ruan's judgment of conviction

breaks down the amount of restitution that is owed individually by Ruan to each insurer and the amount that Ruan owes jointly and severally with Couch to each insurer. Ruan never objected to the actual losses sustained by any insurer, instead objecting only generally to the method of calculating the losses.

*1177 [129] For these reasons, the district court did not abuse its discretion in determining that the government had proven the restitution amount by a preponderance of the evidence.²⁸

III. CONCLUSION

For the foregoing reasons, we vacate Ruan and Couch's convictions on Count 16 of the Superseding Indictment, and we remand the cases to the district court for resentencing. We affirm Ruan and Couch's remaining convictions and sentences.

AFFIRMED IN PART, VACATED AND REMANDED IN PART.

All Citations

966 F.3d 1101, 112 Fed. R. Evid. Serv. 1759, 28 Fla. L. Weekly Fed. C 1387

Footnotes

- * Honorable L. Scott Coogler, United States District Judge for the Northern District of Alabama, sitting by designation.
- 1 As necessary, additional procedural details are set forth with each issue below.
- 2 Because the appellants challenge the sufficiency of the evidence against them at trial, the following facts have been established by viewing the evidence presented at trial in the light most favorable to the government. *See United States v. Schlei*, 122 F.3d 944, 952 (11th Cir. 1997).
- 3 For each doctor, the government used prescription records to identify the 25 patients receiving the most Abstral and Subsys prescriptions. Comparing those lists to PPSA's medical records showed that more than half of those patients—14 on each list—did not have cancer and were thus receiving TIRFs off-label. For those 28 patients, insurers paid more than \$5.5 million for Abstral and Subsys during the time covered by the Superseding Indictment.
- 4 Fentanyl is so powerful that, unlike other opioids, it is measured in micrograms (one millionth of a gram) (“mcg”), not milligrams (“mg”).

5 The full email reads as follows:

I noticed you have quite a few [patients] on [Roxicodone](#) 30mg ... and [Oxycontin](#) 80mg.

Based on the diversion study done in FL pill mills, these two are the most[] thought of in South FL, therefore [they are] considered [the] biggest reg [sic] flag[s]. I think you should talk to Justin [Palmer] on cutting down [Roxicodone](#) 30mg usage, especially [because] we are trying to convince [the] AL board of medical examiners that we have a great system to keep [patients] satisfied[] and addicts out. We [do not] want [Roxicodone](#) 30mg [to] mess things up, or at least contradict[] .. what we promote. I believe I have two [patients] on oxycodone 30mg, one of them is a W/C, cannot handle all others. Also, try to use Oxycontin 60mg instead of 80mg may also help.

Now, everyone in the nation knows that AL state prescribes the most pain killers in the nation, [so] we will need to adjust our routine regimen a bit. One of the things I have done is to wean off on [benzodiazepines], or ask their [primary care physician] to write their [benzodiazepine], as [benzodiazepine] prescription is also one of the things they look at and[] [w]e would rather be careful than sorry. Please remind [Palmer] about this stuff.

6 Indeed, despite the Superseding Indictment calling PPSA a “pill mill,” by the time of trial the government began referring to it as a “money mill” instead.

7 Where necessary below, additional trial evidence is discussed regarding some issues.

8 The district court ruled on the appellants’ common objections at Couch’s sentencing, which was the day before Ruan’s. Ruan’s attorney participated in these portions of Couch’s sentencing.

9 Couch does not challenge on appeal the sufficiency of the evidence on Counts 5–7, substantive drug distribution charges based on the prescriptions he wrote for Officer Kelley, or on Counts 13 and 14, substantive drug distribution charges based on prescriptions he wrote for his patients Kenneth Daves and Patrick Chausse.

10 We discuss the various counts of conviction slightly out of order for ease of analysis.

11 By the time of trial, Walker had died. Prior to Walker’s husband’s testimony, the jury was informed of her death and told that there were no allegations that Ruan or Couch was responsible.

12 The Schedule III conspiracy involved hydrocodone, which was reclassified to Schedule II in 2014.

13 Dwight Burns, Kathleen Burns’s husband, confirmed Burt’s testimony. By the time of trial, Kathleen Burns had died. Prior to her husband’s testimony, the jury was informed of her death and told that there were no allegations that Ruan or Couch was responsible.

14 Insys had a unit in its home office, called the “Internal Reimbursement Center,” to assist physicians in obtaining insurance approval for Insys.

15 Medicare, TriCare, and others allowed “incident to billing,” allowing submission of bills under a doctor’s provider number if the doctor was involved in the treatment, through participation or oversight.

16 That statute provides:

If “two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons

do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both.”

18 U.S.C. § 371.

- 17 Rule 803(6), as amended effective December 1, 2011, no longer lists a “data compilation” as an example of a business record. See [Fed. R. Evid. 803\(6\)](#). The December 1, 2011, amendments to the Federal Rules of Evidence were stylistic changes to simplify the rule language, with “no intent to change any result in any ruling on evidence admissibility.” [Fed. R. Evid. 803](#) advisory committee’s notes 2011 Amendments. Thus, case law construing former [Rule 803\(6\)](#) remains viable and is applicable here. And, Rule 101(b)(4) defines “record” as including a “data compilation.” [Fed. R. Evid. 101\(b\)\(4\)](#).
- 18 We need not address the government’s arguments that the PDMP data was also admissible under the public records and residual exceptions to the hearsay rule. See [Fed. R. Evid. 803\(8\)](#) & [807](#).
- 19 A criminal defendant has the right “to be confronted with the witnesses against him.” [U.S. Const. amend. VI](#).
- 20 See [Todd](#), 108 F.3d at 1331 (a district court’s evidentiary rulings are reviewed for an abuse of discretion).
- 21 The Sixth Amendment to the United States Constitution guarantees defendants the right to have “compulsory process for obtaining witnesses in his favor.” [U.S. Const. amend. VI](#); See also [United States v. Ramos](#), 933 F.2d 968, 974 (11th Cir. 1991) (“A criminal defendant’s right to present witnesses in his own defense during a criminal trial lies at the core of the fifth and fourteenth amendment guarantees of due process.”).
- 22 [Federal Rule of Evidence 401](#) defines relevant evidence as that which “has any tendency to make a fact [of consequence] more or less probable than it would be without the evidence.” Even if evidence is relevant, Rule 403 nonetheless vests district courts with wide discretion to exclude evidence if “its probative value is substantially outweighed by a danger of ... unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.”
- 23 Couch submitted a written proffer to the district court regarding only Tiller’s proposed testimony but contends that he would have called additional “good patients” if the court had permitted him to do so.
- 24 [Rule 702](#) provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

[Fed. R. Evid. 702](#).

- 25 In [McDowell](#), the court allowed a neurologist to testify regarding the standard of care of jail nurses. *Id.* Granted, the court looked to Georgia state law to determine the qualifications of an expert, rather than the Federal Rules of Evidence, but we don’t find any serious differences between the two regarding this issue. *Id.* at 1295–97.

- 26 In [Gayton](#), the Seventh Circuit held that a physician was not unqualified to testify about a heart-related death merely because he was not a cardiologist, but it ultimately upheld the exclusion of the physician's testimony because he lacked the necessary qualifications. [Id.](#) at 617–18.
- 27 We imagine that the only way to compute the exact losses that each insurer incurred by paying for TIRF prescriptions written at PPSA would be to present testimony from all of the patients who were prescribed TIRFs (over 1,000 during the indictment period) or opinions from medical experts who have reviewed their files. A consideration of each patient's medical needs would be necessary to determine whether the prescriptions written were illegal or legitimate. The MVRA does not require such “laser-like precision.” [Martin](#), 803 F.3d at 595.
- 28 Ruan also argues that the district court erred in ordering forfeiture because insufficient evidence established a RICO Act violation. The government responds that Ruan's forfeiture argument is waived because it was raised in a perfunctory manner without supporting arguments or citations, and that, in any event, the RICO conviction was valid. A party seeking to raise a claim or issue on appeal must raise it “plainly and prominently” or otherwise the issue is deemed abandoned. [United States v. Jernigan](#), 341 F.3d 1273, 1283 n.8 (11th Cir. 2003). Ruan's argument regarding forfeiture does not appear to be an independent claim that his forfeiture was illegal. Rather, his claim appears to be derivative of his claim that insufficient evidence supports his RICO conviction. Because we affirm the RICO conviction, we uphold the forfeiture order regarding the RICO violation.