6. HEALTH CARE CRIMES

Corporations in the health care industry, which now accounts for 20 percent of U.S, gross domestic product, have paid billions of dollars to the government over the last two decades in penalties and settlements as a result of huge enforcement efforts in that sector. This short chapter touches on what is a large stand-alone practice field.

The idea in this chapter is to get a feel for the nature and breadth of the main substantive legal prohibitions the government relies on, the dynamics driving settlements, and some of the difficult problems that can face corporations and individuals subject to this legal regime.

A. Selected Statutes

The statutory and regulatory regime is as complex and extensive in the area of health care as anywhere in the field of corporate crime. The three provisions the government uses most often in this area are:

(1) the **anti-kickback** statute, which is primarily used to police corrupt billing schemes in hospitals and medical practices;

(2) the prohibitions against **misbranding** food and drugs (the FDCA), which are primarily used to target pharmaceutical companies' marketing practices; and

(3) the **False Claims Act**, which is a general prohibition on bilking the government that includes a very significant private enforcement mechanism comprising the first of the "whistleblower" regimes we will encounter.

These statutes are lengthy. It is important to read the excerpts in full and identify the basic prohibitions in each, while thinking about their breadth of applications in terms of the size and diversity of health care products and services in the U.S. economy.

42 U.S.C. § 1320a-7b (Anti-kickback Statute) (excerpts)

(a) **Making or causing to be made false statements or representations**

Whoever—

> (1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program (as defined in subsection (f) of this section),
>
> (2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment,
>
> (3) having knowledge of the occurrence of any event affecting

(A) his initial or continued right to any such benefit or payment, or

(B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized,

(4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person,

(5) presents or causes to be presented a claim for a physician's service for which payment may be made under a Federal health care program and knows that the individual who furnished the service was not licensed as a physician, or

(6) for a fee knowingly and willfully counsels or assists an individual to dispose of assets (including by any transfer in trust) in order for the individual to become eligible for medical assistance under a State plan under subchapter XIX of this chapter, if disposing of the assets results in the imposition of a period of ineligibility for such assistance under section 1396p(c) of this title,

shall

(i) in the case of such a statement, representation, concealment, failure, or conversion by any person in connection with the furnishing (by that person) of items or services for which payment is or may be made under the program, be guilty of a felony and upon conviction thereof fined not more than $25,000 or imprisoned for not more than five years or both, or

(ii) in the case of such a statement, representation, concealment, failure, conversion, or provision of counsel or assistance by any other person, be guilty of a misdemeanor and upon conviction thereof fined not more than $10,000 or imprisoned for not more than one year, or both. In addition, in any case where an individual who is otherwise eligible for assistance under a Federal health care program is convicted of an offense under the preceding provisions of this subsection, the administrator of such program may at its option (notwithstanding any other provision of such program) limit, restrict, or suspend the eligibility of that individual for such period (not exceeding one year) as it deems appropriate; but the imposition of a limitation, restriction, or suspension with respect to the eligibility of any individual under this sentence shall not affect the eligibility of any other person for assistance under the plan, regardless of the relationship between that individual and such other person.

(b) **Illegal remunerations**

(1) 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—

(A) 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, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item 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 $25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer 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, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item 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 $25,000 or imprisoned for not more than five years, or both.

(3) Paragraphs (1) and (2) shall not apply to— [a long list of statutory exceptions]. . . .

(h) **Actual knowledge or specific intent not required**

With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.

42 U.S.C. § 1320a-7 (Exclusion Statute) (excerpts)

(a) **Mandatory exclusion**

The Secretary shall exclude the following individuals and entities from participation in any Federal health care program (as defined in section 1320a–7b(f) of this title):

(1) **Conviction of program-related crimes**

Any individual or entity that has been convicted of a criminal offense related to the delivery of an item or service under subchapter XVIII of this chapter or under any State health care program.

(2) **Conviction relating to patient abuse**

Any individual or entity that has been convicted, under Federal or State law, of a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service.

(3) **Felony conviction relating to health care fraud**

Any individual or entity that has been convicted for an offense which occurred after August 21, 1996, under Federal or State law, in connection with the delivery of a health care item or service or with respect to any act or omission in a health care program (other than those specifically described in paragraph (1)) operated by or financed in whole or in part by any Federal, State, or local government agency, of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.

(4) **Felony conviction relating to controlled substance**

Any individual or entity that has been convicted for an offense which occurred after August 21, 1996, under Federal or State law, of a criminal offense consisting of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

(b) **Permissive exclusion**

The Secretary may exclude the following individuals and entities from participation in any Federal health care program (as defined in section 1320a–7b(f) of this title):

(1) **Conviction relating to fraud**

Any individual or entity that has been convicted for an offense which occurred after August 21, 1996, under Federal or State law—

(A) of a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

(i) in connection with the delivery of a health care item or service, or

(ii) with respect to any act or omission in a health care program (other than those specifically described in subsection (a)(1) of this section) operated by or financed in whole or in part by any Federal, State, or local government agency; or

(B) of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct with respect to any act or omission in a program (other than a health care program) operated by or financed in whole or in part by any Federal, State, or local government agency.

(2) **Conviction relating to obstruction of an investigation or audit**

Any individual or entity that has been convicted, under Federal or State law, in connection with the interference with or obstruction of any investigation or audit related to—

(i) any offense described in paragraph (1) or in subsection (a); or

(ii) the use of funds received, directly or indirectly, from any Federal health care program (as defined in section 1320a–7b(f) of this title).

(3) **Misdemeanor conviction relating to controlled substance**

Any individual or entity that has been convicted, under Federal or State law, of a criminal offense consisting of a misdemeanor relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

(4) **License revocation or suspension**

Any individual or entity—

(A) whose license to provide health care has been revoked or suspended by any State licensing authority, or who otherwise lost such a license or the right to apply for or renew such a license, for reasons bearing on the individual's or entity's professional competence, professional performance, or financial integrity, or

(B) who surrendered such a license while a formal disciplinary proceeding was pending before such an authority and the proceeding concerned the individual's or entity's professional competence, professional performance, or financial integrity.

(5) **Exclusion or suspension under Federal or State health care program**

Any individual or entity which has been suspended or excluded from participation, or otherwise sanctioned, under—

(A) any Federal program, including programs of the Department of Defense or the Department of Veterans Affairs, involving the provision of health care, or

(B) a State health care program,

for reasons bearing on the individual's or entity's professional competence, professional performance, or financial integrity.

(6) **Claims for excessive charges or unnecessary services and failure of certain organizations to furnish medically necessary services**

Any individual or entity that the Secretary determines—

(A) has submitted or caused to be submitted bills or requests for payment (where such bills or requests are based on charges or cost) under subchapter XVIII of this chapter or a State health care program containing charges (or, in applicable cases, requests for payment of costs) for items or services furnished substantially in excess of such individual's or entity's usual charges (or, in applicable cases, substantially in excess of such individual's or entity's costs) for such items or services, unless the Secretary finds there is good cause for such bills or requests containing such charges or costs;

(B) has furnished or caused to be furnished items or services to patients (whether or not eligible for benefits under subchapter XVIII of this chapter or under a State health care program) substantially in excess of the needs of such patients or of a quality which fails to meet professionally recognized standards of health care;

(C) is—

(i) a health maintenance organization (as defined in section 1396b (m) of this title) providing items and services under a State plan approved under subchapter XIX of this chapter, or

(ii) an entity furnishing services under a waiver approved under section 1396n (b)(1) of this title,

and has failed substantially to provide medically necessary items and services that are required (under law or the contract with the State under subchapter XIX of this chapter) to be provided to individuals covered under that plan or waiver, if the failure has adversely affected (or has a substantial likelihood of adversely affecting) these individuals; or

(D) is an entity providing items and services as an eligible organization under a risk-sharing contract under section 1395mm of this title and has failed substantially to provide medically necessary items and services that are required (under law or such contract) to be provided to individuals covered under the risk-sharing contract, if the failure has adversely affected (or has a substantial likelihood of adversely affecting) these individuals. . . .

Federal Food, Drug, and Cosmetic Act (FDCA) (Excerpts)

21 U.S.C. § 331

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise. . . .

(jj)

(1) The failure to submit the certification required by section 282(j)(5)(B) of title 42, or knowingly submitting a false certification under such section.

(2) The failure to submit clinical trial information required under subsection (j) of section 282 of title 42.

(3) The submission of clinical trial information under subsection (j) of section 282 of title 42 that is false or misleading in any particular under paragraph (5)(D) of such subsection (j). . . .

21 U.S.C. § 352

A drug or device shall be deemed to be misbranded—

(a) **False or misleading label**

If its labeling is false or misleading in any particular. Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading under this paragraph if the health care economic information directly relates to an indication approved under section 355 of this title or under section 262(a) of title 42 for such drug and is based on competent and reliable scientific evidence. . . .

(f) **Directions for use and warnings on label**

Unless its labeling bears

(1) adequate directions for use; and

(2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. . . .

(j) **Health-endangering when used as prescribed**

If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof. . . .

21 U.S.C. § 333

(a) **Violation of section 331 of this title; second violation; intent to defraud or mislead**

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both. . . .

(c) **Exceptions in certain cases of good faith, etc.**

No person shall be subject to the penalties of subsection (a)(1) of this section,

(1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or

(2) for having violated section 331(a) or (d) of this title, if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 331(a) of this title, that such article is not adulterated or misbranded, within the meaning of this chapter designating this chapter or to the effect, in case of an alleged violation of section 331(d) of this title, that such article is not an article which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce. . . .

False Claims Act (Excerpts)

31 U.S.C. § 3729

(a) **Liability for Certain Acts.—**

(1) **In general.—** Subject to paragraph (2), any person who—

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

(2) **Reduced damages.—** If the court finds that—

(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;

(B) such person fully cooperated with any Government investigation of such violation; and

(C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation,

the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of that person.

(3) **Costs of civil actions.—** A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

(b) **Definitions.—** For purposes of this section—

(1) the terms "knowing" and "knowingly"—

(A) mean that a person, with respect to information—

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud; . . .

(4) the term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

31 U.S.C. § 3730

(a) **Responsibilities of the Attorney General.—** The Attorney General diligently shall investigate a violation under section 3729. If the Attorney General finds that a person has violated or is violating section 3729, the Attorney General may bring a civil action under this section against the person.

(b) **Actions by Private Persons.—**

(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government

pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall—

(A) proceed with the action, in which case the action shall be conducted by the Government; or

(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

(5) When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

(c) **Rights of the Parties to Qui Tam Actions.—**

(1) If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2).

(2)

(A) The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

(B) The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances. Upon a showing of good cause, such hearing may be held in camera.

(C) Upon a showing by the Government that unrestricted participation during the course of the litigation by the person initiating the action would interfere

with or unduly delay the Government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment, the court may, in its discretion, impose limitations on the person's participation, such as—

(i) limiting the number of witnesses the person may call;

(ii) limiting the length of the testimony of such witnesses;

(iii) limiting the person's cross-examination of witnesses; or

(iv) otherwise limiting the participation by the person in the litigation.

(D) Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.

(3) If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government's expense). When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

(4) Whether or not the Government proceeds with the action, upon a showing by the Government that certain actions of discovery by the person initiating the action would interfere with the Government's investigation or prosecution of a criminal or civil matter arising out of the same facts, the court may stay such discovery for a period of not more than 60 days. Such a showing shall be conducted in camera. The court may extend the 60-day period upon a further showing in camera that the Government has pursued the criminal or civil investigation or proceedings with reasonable diligence and any proposed discovery in the civil action will interfere with the ongoing criminal or civil investigation or proceedings.

(5) Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties to an action under this section. For purposes of the preceding sentence, a finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.

(d) **Award to Qui Tam Plaintiff.—**

(1) If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action. Where the action is one which the court finds to be based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, the court may award such sums as it considers appropriate, but in no case more than 10 percent of the proceeds, taking into account the significance of the information and the role of the person bringing the action in advancing the case to litigation. Any payment to a person under the first or second sentence of this paragraph shall be made from the proceeds. Any such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(2) If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(3) Whether or not the Government proceeds with the action, if the court finds that the action was brought by a person who planned and initiated the violation of section 3729 upon which the action was brought, then the court may, to the extent the court considers appropriate, reduce the share of the proceeds of the action which the person would otherwise receive under paragraph (1) or (2) of this subsection, taking into account the role of that person in advancing the case to litigation and any relevant circumstances pertaining to the violation. If the person bringing the action is convicted of criminal conduct arising from his or her role in the violation of section 3729, that person shall be dismissed from the civil action and shall not receive any share of the proceeds of the action. Such dismissal shall not prejudice the right of the United States to continue the action, represented by the Department of Justice.

(4) If the Government does not proceed with the action and the person bringing the action conducts the action, the court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the court

finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment. . . .

[This statutory scheme has a series of additional sections that govern many details of procedure and discovery in suits brought under the False Claims Act.]

B. "Qui Tam" Suits and the False Claims Act

Here is a nice example of a False Claims Act lawsuit (one in which the government declined to intervene), helpfully laid out for us by the Supreme Court. Notice how the Court's discussion of the requirements of proof under the FCA serves as review for concepts we have already covered. Once again, the legal concept of fraud proves pivotal to understanding a matter of corporate wrongdoing.

UNIVERSAL HEALTH SERVICES, INC. v. UNITED STATES, 136 S. Ct. 1989 (2016)

THOMAS, J., delivered the opinion for a unanimous Court.

The False Claims Act, 31 U.S.C. § 3729 *et seq.*, imposes significant penalties on those who defraud the Government. This case concerns a theory of False Claims Act liability commonly referred to as "implied false certification." According to this theory, when a defendant submits a claim, it impliedly certifies compliance with all conditions of payment. But if that claim fails to disclose the defendant's violation of a material statutory, regulatory, or contractual requirement, so the theory goes, the defendant has made a misrepresentation that renders the claim "false or fraudulent" under § 3729(a)(1)(A). This case requires us to consider this theory of liability and to clarify some of the circumstances in which the False Claims Act imposes liability. . . .

Enacted in 1863, the False Claims Act "was originally aimed principally at stopping the massive frauds perpetrated by large contractors during the Civil War." *United States v. Bornstein*, 423 U.S. 303, 309, 96 S. Ct. 523, 46 L. Ed. 2d 514 (1976). "[A] series of sensational congressional investigations" prompted hearings where witnesses "painted a sordid picture of how the United States had been billed for nonexistent or worthless goods, charged exorbitant prices for goods delivered, and generally robbed in purchasing the necessities of war." *United States v. McNinch*, 356 U.S. 595, 599, 78 S. Ct. 950, 2 L. Ed. 2d 1001 (1958). Congress responded by imposing civil and criminal liability for 10 types of fraud on the Government, subjecting violators to double damages, forfeiture, and up to five years' imprisonment. Act of Mar. 2, 1863, ch. 67, 12 Stat. 696.

Since then, Congress has repeatedly amended the Act, but its focus remains on those who present or directly induce the submission of false or fraudulent claims. See 31 U.S.C. § 3729(a) (imposing civil liability on "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"). A "claim" now includes direct requests to the Government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits

programs. See § 3729(b)(2)(A). The Act's scienter requirement defines "knowing" and "knowingly" to mean that a person has "actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." § 3729(b)(1)(A). And the Act defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." § 3729(b)(4).

Congress also has increased the Act's civil penalties so that liability is "essentially punitive in nature." *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765, 784, 120 S. Ct. 1858, 146 L. Ed. 2d 836 (2000). Defendants are subjected to treble damages plus civil penalties of up to $10,000 per false claim. § 3729(a); 28 CFR § 85.3(a)(9) (2015) (adjusting penalties for inflation).

The alleged False Claims Act violations here arose within the Medicaid program, a joint state-federal program in which healthcare providers serve poor or disabled patients and submit claims for government reimbursement. *See generally* 42 U.S.C. § 1396 *et seq.* The facts recited in the complaint, which we take as true at this stage, are as follows. For five years, Yarushka Rivera, a teenage beneficiary of Massachusetts' Medicaid program, received counseling services at Arbour Counseling Services, a satellite mental health facility in Lawrence, Massachusetts, owned and operated by a subsidiary of petitioner Universal Health Services. Beginning in 2004, when Yarushka started having behavioral problems, five medical professionals at Arbour intermittently treated her. In May 2009, Yarushka had an adverse reaction to a medication that a purported doctor at Arbour prescribed after diagnosing her with bipolar disorder. Her condition worsened; she suffered a seizure that required hospitalization. In October 2009, she suffered another seizure and died. She was 17 years old.

Thereafter, an Arbour counselor revealed to respondents Carmen Correa and Julio Escobar—Yarushka's mother and stepfather—that few Arbour employees were actually licensed to provide mental health counseling and that supervision of them was minimal. Respondents discovered that, of the five professionals who had treated Yarushka, only one was properly licensed. The practitioner who diagnosed Yarushka as bipolar identified herself as a psychologist with a Ph. D., but failed to mention that her degree came from an unaccredited Internet college and that Massachusetts had rejected her application to be licensed as a psychologist. Likewise, the practitioner who prescribed medicine to Yarushka, and who was held out as a psychiatrist, was in fact a nurse who lacked authority to prescribe medications absent supervision. Rather than ensuring supervision of unlicensed staff, the clinic's director helped to misrepresent the staff's qualifications. And the problem went beyond those who treated Yarushka. Some 23 Arbour employees lacked licenses to provide mental health services, yet—despite regulatory requirements to the contrary—they counseled patients and prescribed drugs without supervision.

When submitting reimbursement claims, Arbour used payment codes corresponding to different services that its staff provided to Yarushka, such as "Individual Therapy" and

"family therapy." Staff members also misrepresented their qualifications and licensing status to the Federal Government to obtain individual National Provider Identification numbers, which are submitted in connection with Medicaid reimbursement claims and correspond to specific job titles. For instance, one Arbour staff member who treated Yarushka registered for a number associated with "'Social Worker, Clinical,'" despite lacking the credentials and licensing required for social workers engaged in mental health counseling.

After researching Arbour's operations, respondents filed complaints with various Massachusetts agencies. Massachusetts investigated and ultimately issued a report detailing Arbour's violation of over a dozen Massachusetts Medicaid regulations governing the qualifications and supervision required for staff at mental health facilities. Arbour agreed to a remedial plan, and two Arbour employees also entered into consent agreements with Massachusetts.

In 2011, respondents filed a *qui tam* suit in federal court, see 31 U.S.C. § 3730, alleging that Universal Health had violated the False Claims Act under an implied false certification theory of liability. The operative complaint asserts that Universal Health (acting through Arbour) submitted reimbursement claims that made representations about the specific services provided by specific types of professionals, but that failed to disclose serious violations of regulations pertaining to staff qualifications and licensing requirements for these services. Specifically, the Massachusetts Medicaid program requires satellite facilities to have specific types of clinicians on staff, delineates licensing requirements for particular positions (like psychiatrists, social workers, and nurses), and details supervision requirements for other staff. *See* 130 Code Mass. Regs. §§ 429.422–424, 429.439 (2014). Universal Health allegedly flouted these regulations because Arbour employed unqualified, unlicensed, and unsupervised staff. The Massachusetts Medicaid program, unaware of these deficiencies, paid the claims. Universal Health thus allegedly defrauded the program, which would not have reimbursed the claims had it known that it was billed for mental health services that were performed by unlicensed and unsupervised staff. The United States declined to intervene. . . .

We first hold that the implied false certification theory can, at least in some circumstances, provide a basis for liability. By punishing defendants who submit "false or fraudulent claims," the False Claims Act encompasses claims that make fraudulent misrepresentations, which include certain misleading omissions. When, as here, a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided. . . .

The False Claims Act imposes civil liability on "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." § 3729(a)(1)(A). Congress did not define what makes a claim "false" or "fraudulent." But

"[i]t is a settled principle of interpretation that, absent other indication, Congress intends to incorporate the well-settled meaning of the common-law terms it uses." *Sekhar v. United States,* 570 U.S. ——, ——, 133 S. Ct. 2720, 2724, 186 L. Ed. 2d 794 (2013) (internal quotation marks omitted). And the term "fraudulent" is a paradigmatic example of a statutory term that incorporates the common-law meaning of fraud. *See Neder v. United States,* 527 U.S. 1, 22, 119 S. Ct. 1827, 144 L. Ed. 2d 35 (1999) (the term "actionable 'fraud' " is one with "a well-settled meaning at common law").[1]

Because common-law fraud has long encompassed certain misrepresentations by omission, "false or fraudulent claims" include more than just claims containing express falsehoods. The parties and the Government agree that misrepresentations by omission can give rise to liability.

The parties instead dispute whether submitting a claim without disclosing violations of statutory, regulatory, or contractual requirements constitutes such an actionable misrepresentation. Respondents and the Government invoke the common-law rule that, while nondisclosure alone ordinarily is not actionable, "[a] representation stating the truth so far as it goes but which the maker knows or believes to be materially misleading because of his failure to state additional or qualifying matter" is actionable. Restatement (Second) of Torts § 529, p. 62 (1976). They contend that every submission of a claim for payment implicitly represents that the claimant is legally entitled to payment, and that failing to disclose violations of material legal requirements renders the claim misleading. Universal Health, on the other hand, argues that submitting a claim involves no representations, and that a different common-law rule thus governs: nondisclosure of legal violations is not actionable absent a special "'duty . . . to exercise reasonable care to disclose the matter in question,'" which it says is lacking in Government contracting. Brief for Petitioner 31 (quoting Restatement (Second) of Torts § 551(1), at 119).

We need not resolve whether all claims for payment implicitly represent that the billing party is legally entitled to payment. The claims in this case do more than merely demand payment. They fall squarely within the rule that half-truths—representations that state the truth only so far as it goes, while omitting critical qualifying information—can be actionable misrepresentations. A classic example of an actionable half-truth in contract law is the seller who reveals that there may be two new roads near a property he is selling, but fails to disclose that a third potential road might bisect the property. See *Junius Constr. Co. v. Cohen,* 257 N.Y. 393, 400, 178 N.E. 672, 674 (1931) (Cardozo, J.). . . . Likewise, an applicant for an adjunct position at a local college makes an actionable misrepresentation when his resume lists prior jobs and then retirement, but fails to disclose that his "retirement" was a prison stint for perpetrating a $12 million bank fraud. See 3 D. Dobbs, P. Hayden, & H. Bublick, Law of Torts § 682, pp. 702–

[30] The False Claims Act abrogates the common law in certain respects. For instance, the Act's scienter requirement "require[s] no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(B). But we presume that Congress retained all other elements of common-law fraud that are consistent with the statutory text because there are no textual indicia to the contrary. *See Neder,* 527 U.S., at 24–25, 119 S. Ct. 1827.

703, and n.14 (2d ed. 2011) (citing *Sarvis v. Vermont State Colleges*, 172 Vt. 76, 78, 80–82, 772 A.2d 494, 496, 497–499 (2001)).

So too here, by submitting claims for payment using payment codes that corresponded to specific counseling services, Universal Health represented that it had provided individual therapy, family therapy, preventive medication counseling, and other types of treatment. Moreover, Arbour staff members allegedly made further representations in submitting Medicaid reimbursement claims by using National Provider Identification numbers corresponding to specific job titles. And these representations were clearly misleading in context. Anyone informed that a social worker at a Massachusetts mental health clinic provided a teenage patient with individual counseling services would probably—but wrongly—conclude that the clinic had complied with core Massachusetts Medicaid requirements (1) that a counselor "treating children [is] required to have specialized training and experience in children's services," 130 Code Mass. Regs. § 429.422, and also (2) that, at a minimum, the social worker possesses the prescribed qualifications for the job, § 429.424(C). By using payment and other codes that conveyed this information without disclosing Arbour's many violations of basic staff and licensing requirements for mental health facilities, Universal Health's claims constituted misrepresentations.

Accordingly, we hold that the implied certification theory can be a basis for liability, at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.

The second question presented is whether, as Universal Health urges, a defendant should face False Claims Act liability only if it fails to disclose the violation of a contractual, statutory, or regulatory provision that the Government expressly designated a condition of payment. We conclude that the Act does not impose this limit on liability. But we also conclude that not every undisclosed violation of an express condition of payment automatically triggers liability. Whether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry.

Nothing in the text of the False Claims Act supports Universal Health's proposed restriction. Section 3729(a)(1)(A) imposes liability on those who present "false or fraudulent claims" but does not limit such claims to misrepresentations about express conditions of payment. *See SAIC*, 626 F.3d, at 1268 (rejecting any textual basis for an express-designation rule). Nor does the common-law meaning of fraud tether liability to violating an express condition of payment. A statement that misleadingly omits critical facts is a misrepresentation irrespective of whether the other party has expressly signaled the importance of the qualifying information.

The False Claims Act's materiality requirement also does not support Universal Health.

Under the Act, the misrepresentation must be material to the other party's course of action. But, as discussed below, statutory, regulatory, and contractual requirements are not automatically material, even if they are labeled conditions of payment. *Cf. Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 39, 131 S. Ct. 1309, 179 L. Ed. 2d 398 (2011) (materiality cannot rest on "a single fact or occurrence as always determinative" (internal quotation marks omitted)).

Nor does the Act's scienter requirement, § 3729(b)(1)(A), support Universal Health's position. A defendant can have "actual knowledge" that a condition is material without the Government expressly calling it a condition of payment. If the Government failed to specify that guns it orders must actually shoot, but the defendant knows that the Government routinely rescinds contracts if the guns do not shoot, the defendant has "actual knowledge." Likewise, because a reasonable person would realize the imperative of a functioning firearm, a defendant's failure to appreciate the materiality of that condition would amount to "deliberate ignorance" or "reckless disregard" of the "truth or falsity of the information" even if the Government did not spell this out.

Universal Health nonetheless contends that False Claims Act liability should be limited to undisclosed violations of expressly designated conditions of payment to provide defendants with fair notice and to cabin liability. But policy arguments cannot supersede the clear statutory text. In any event, Universal Health's approach risks undercutting these policy goals. The Government might respond by designating every legal requirement an express condition of payment. But billing parties are often subject to thousands of complex statutory and regulatory provisions. Facing False Claims Act liability for violating any of them would hardly help would-be defendants anticipate and prioritize compliance obligations. And forcing the Government to expressly designate a provision as a condition of *payment* would create further arbitrariness. Under Universal Health's view, misrepresenting compliance with a requirement that the Government expressly identified as a condition of payment could expose a defendant to liability. Yet, under this theory, misrepresenting compliance with a condition of eligibility to even participate in a federal program when submitting a claim would not. . . .

We need not decide whether § 3729(a)(1)(A)'s materiality requirement is governed by § 3729(b)(4) or derived directly from the common law. Under any understanding of the concept, materiality "look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." 26 R. Lord, Williston on Contracts § 69:12, p. 549 (4th ed. 2003) (Williston). In tort law, for instance, a "matter is material" in only two circumstances: (1) "[if] a reasonable man would attach importance to [it] in determining his choice of action in the transaction"; or (2) if the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter "in determining his choice of action," even though a reasonable person would not. Restatement (Second) of Torts § 538, at 80. Materiality in contract law is substantially similar. *See* Restatement (Second) of Contracts § 162(2), and Comment *c*, pp. 439, 441 (1979) ("[A] misrepresentation is material" only if it would "likely . . . induce a reasonable person to manifest his assent," or the defendant "knows that for some special

reason [the representation] is likely to induce the particular recipient to manifest his assent" to the transaction).

The materiality standard is demanding. The False Claims Act is not "an all-purpose antifraud statute," *Allison Engine*, 553 U.S., at 672, 128 S. Ct. 2123 or a vehicle for punishing garden-variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial. . . .

In sum, when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

These rules lead us to disagree with the Government's and First Circuit's view of materiality: that any statutory, regulatory, or contractual violation is material so long as the defendant knows that the Government would be entitled to refuse payment were it aware of the violation. At oral argument, the United States explained the implications of its position: If the Government contracts for health services and adds a requirement that contractors buy American-made staplers, anyone who submits a claim for those services but fails to disclose its use of foreign staplers violates the False Claims Act. To the Government, liability would attach if the defendant's use of foreign staplers would entitle the Government not to pay the claim in whole or part—irrespective of whether the Government routinely pays claims despite knowing that foreign staplers were used. Likewise, if the Government required contractors to aver their compliance with the entire U.S. Code and Code of Federal Regulations, then under this view, failing to mention noncompliance with any of those requirements would always be material. The False Claims Act does not adopt such an extraordinarily expansive view of liability. . . .

Because both opinions below assessed respondents' complaint based on interpretations of § 3729(a)(1)(A) that differ from ours, we vacate the First Circuit's judgment and remand the case for reconsideration of whether respondents have sufficiently pleaded a False Claims Act violation. We emphasize, however, that the False Claims Act is not a means of imposing treble damages and other penalties for insignificant regulatory or

contractual violations. This case centers on allegations of fraud, not medical malpractice. Respondents have alleged that Universal Health misrepresented its compliance with mental health facility requirements that are so central to the provision of mental health counseling that the Medicaid program would not have paid these claims had it known of these violations. Respondents may well have adequately pleaded a violation of § 3729(a)(1)(A). But we leave it to the courts below to resolve this in the first instance.[2]

Problem 6-1

What are the pluses and minuses of a "qui tam," also known as a "private attorney general," model for enforcing the law, as reflected in the False Claims Act? Should this model be used more widely? If so, how would one optimally structure such regimes in other areas of corporate wrongdoing?

C. Drug Misbranding

Moving from the False Claims Act to the Federal Food Drug and Cosmetic Act (FDCA), this case deals with the interaction of misbranding violations, the First Amendment, and corporate speech—a growing area for challenge to the regulatory and enforcement regime in this field.

UNITED STATES v. CARONIA, 703 F.3d 149 (2d Cir. 2008)

CHIN, Circuit Judge:

Defendant-appellant Alfred Caronia appeals from a judgment of conviction entered in the United States District Court for the Eastern District of New York (Eric N. Vitaliano, *J.*) on November 30, 2009, following a jury trial at which Caronia was found guilty of conspiracy to introduce a misbranded drug into interstate commerce, a misdemeanor violation of 21 U.S.C. §§ 331(a) and 333(a)(1). Specifically, Caronia, a pharmaceutical sales representative, promoted the drug Xyrem for "off-label use," that is, for a purpose not approved by the U.S. Food and Drug Administration (the "FDA"). Caronia argues that he was convicted for his speech—for promoting an FDA-approved drug for off-label use—in violation of his right of free speech under the First Amendment. We agree. Accordingly, we vacate the judgment of conviction and remand the case to the district court.

Under the Federal Food, Drug and Cosmetic Act (the "FDCA"), before drugs are distributed into interstate commerce, they must be approved by the FDA for specific uses. 21 U.S.C. § 355(a). To obtain FDA approval, drug manufacturers are required to demonstrate, through clinical trials, the safety and efficacy of a new drug for each intended use or indication.

[2] For the outcome of this case on remand, *see* 842 F.3d 103 (1st Cir. 2016).

Once FDA-approved, prescription drugs can be prescribed by doctors for both FDA-approved and -unapproved uses; the FDA generally does not regulate how physicians use approved drugs. . . .

Indeed, courts and the FDA have recognized the propriety and potential public value of unapproved or off-label drug use. . . . The FDA itself has observed:

> Once a drug has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such "unapproved" or, more precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.

U.S. Food and Drug Administration, *FDA Drug Bulletin,* 12 FDA Drug Bull. 1, 5 (1982).

The FDCA prohibits "misbranding," or "[t]he introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is . . . misbranded." 21 U.S.C. § 331(a). A drug is misbranded if, *inter alia,* its labeling fails to bear "adequate directions for use," 21 U.S.C. § 352(f), which FDA regulations define as "directions under which the lay[person] can use a drug safely and for the purposes for which it is intended," 21 C.F.R. § 201.5. FDA regulations define intended use by reference to "the objective intent of the persons legally responsible for the labeling of drugs," which may be demonstrated by, among other evidence, "oral or written statements by such persons or their representatives" and "the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised." 21 C.F.R. § 201.128.

The consequences for misbranding are criminal. 21 U.S.C. § 333(a)(2) ("[I]f any person commits such a violation ... such persons shall be imprisoned for not more than three years or fined not more than $10,000, or both."). Pharmaceutical manufacturers and their representatives can face misdemeanor charges for misbranding or felony charges for fraudulent misbranding. The government has repeatedly prosecuted—and obtained convictions against—pharmaceutical companies and their representatives for misbranding based on their off-label promotion. . . .

The FDCA and its accompanying regulations do not expressly prohibit the "promotion" or "marketing" of drugs for off-label use. The regulations do recognize that promotional statements by a pharmaceutical company or its representatives can serve as proof of a drug's intended use. Off-label promotional statements could thus presumably constitute evidence of an intended use of a drug that the FDA has not approved. The FDA, however, has concluded that "[a]n approved drug that is marketed for an unapproved use (whether in labeling or not) is misbranded because the labeling of such drug does not include 'adequate directions for use.'" *See* FDA, Draft Guidance, *supra,* at 2–3 (quoting 21 U.S.C. § 352(f)); *accord United States v. Caronia,* 576 F.Supp.2d 385, 392 n. 5 (E.D.N.Y. 2008); *see also* Gov't Br. 48 n.18 (contending no set of directions can

constitute adequate labeling for drug's off-label use). Thus, the government has treated promotional speech as more than merely evidence of a drug's intended use—it has construed the FDCA to prohibit promotional speech as misbranding itself.

Orphan Medical, Inc. ("Orphan"), now known as Jazz Pharmaceutical, was a Delaware-incorporated pharmaceutical company that primarily developed drugs to treat pain, sleep disorders, and central nervous system disorders. Orphan manufactured the drug Xyrem, a powerful central nervous system depressant. In 2005, after Jazz Pharmaceuticals acquired Orphan, Jazz continued to manufacture and sell Xyrem, grossing $20 million in combined Xyrem sales in 2005.

Xyrem can cause serious side effects, including difficulty breathing while asleep, confusion, abnormal thinking, depression, nausea, vomiting, dizziness, headache, bedwetting, and sleepwalking. If abused, Xyrem can cause additional medical problems, including seizures, dependence, severe withdrawal, coma, and death.

Xyrem's active ingredient is gamma-hydroxybutryate ("GHB"). GHB has been federally classified as the "date rape drug" for its use in the commission of sexual assaults.

Despite the risks associated with Xyrem and GHB, the FDA approved Xyrem for two medical indications. In July 2002, the FDA approved Xyrem to treat narcolepsy patients who experience cataplexy, a condition associated with weak or paralyzed muscles. In November 2005, the FDA approved Xyrem to treat narcolepsy patients with excessive daytime sleepiness ("EDS"), a neurological disorder caused by the brain's inability to regulate sleep-wake cycles.

To protect against its serious safety concerns, in 2002, the FDA required a "black box" warning to accompany Xyrem. The black box warning is the most serious warning placed on prescription medication labels. Xyrem's black box labeling stated, among other things, that the drug's safety and efficacy were not established in patients under 16 years of age, and the drug had "very limited" experience among elderly patients.

To identify patients suffering side effects from the drug, the FDA also regulated Xyrem distribution, allowing only one centralized Missouri pharmacy to distribute Xyrem nationally.

In March 2005, Orphan hired Caronia as a Specialty Sales Consultant to promote Xyrem. Caronia primarily worked in Queens, Nassau, and Suffolk counties. Caronia's salary was based on his individual sales.

In July 2005, Caronia started Orphan's "speaker programs" for Xyrem. Speaker programs enlist physicians, for pay, to speak to other physicians about FDA-approved drug use. Orphan's speaker programs for Xyrem presented the benefits of the drug among patients with cataplexy and narcolepsy. Orphan hired Dr. Peter Gleason to promote Xyrem through its speaker programs.

Under Orphan's procedures, if Caronia, as a sales consultant for Xyrem, was asked about the off-label use of Xyrem, he was not permitted to answer; instead, when such questions were posed, Orphan sales consultants would fill out "medical information request forms" and send them to Orphan, and Orphan would send information to the inquiring physician. In contrast, physicians employed by Orphan as promotional speakers for Xyrem were permitted to answer off-label use questions; their responses were often informed by their own experiences with Xyrem.

In the spring of 2005, the federal government launched an investigation of Orphan and Gleason. The investigation focused on the off-label promotion of Xyrem. Caronia and Gleason were audio-recorded on two occasions as they promoted Xyrem for unapproved uses, including unapproved indications and unapproved subpopulations. The first conversation was recorded on October 26, 2005 between Caronia and Dr. Stephen Charno, a physician who, as a government cooperator, posed as a prospective Xyrem customer. The second conversation was recorded on November 2, 2005; it taped a meeting arranged by Caronia to introduce Charno to Gleason.

On October 26, 2005, Caronia plainly promoted the use of Xyrem in unapproved indications with Charno:

> [Caronia]: And right now the indication is for narcolepsy with cataplexy . . . excessive daytime . . . and fragmented sleep, but because of the properties that . . . it has it's going to insomnia, Fibromyalgia[,] periodic leg movement, restless leg, ahh also looking at ahh Parkinson's and . . . other sleep disorders are underway such as MS.
>
> [Charno]: Okay, so then so then it could be used for muscle disorders and chronic pain and . . .
>
> [Caronia]: Right.
>
> [Charno]: . . . and daytime fatigue and excessive sleepiness and stuff like that?
>
> [Caronia]: Absolutely. Absolutely. Ahh with the Fibromyalgia.

Caronia further directed Charno to list different "diagnosis codes" when prescribing Xyrem, for insurance purposes, including Fibromyalgia, chronic fatigue, or chronic pain.

On separate occasions, Caronia and Gleason each explained to prospective physician-customers that Xyrem could be used with patients under age sixteen, an unapproved Xyrem subpopulation:

> [Caronia]: Um, the youngest patients we have are sixteen in the studies as old as sixty-five. Ahh there have been reports of patients as

> young as fourteen using it and obviously greater than sixty-five. It's a very safe drug.

(October 26, 2005 Recording Tr. (I) at 7).

> [Gleason]: Well, it's actually approved for sixteen and above um, I've had people under thirteen and I've certainly talked to neurologists that have narcoleptics . . . between eight and ten . . . [but] I start at two-thirds the dose, but [if] they're real frail I only start with one-third the dose.

(November 2, 2005 Recording Tr. (II) at 51). . . .

On November 30, 2009, the district court sentenced Caronia to one year of probation, 100 hours of community service, and a $25 special assessment.

On appeal, Caronia principally argues that the misbranding provisions of the FDCA prohibit off-label promotion, and therefore, unconstitutionally restrict speech. Caronia argues that the First Amendment does not permit the government to prohibit and criminalize a pharmaceutical manufacturer's truthful and non-misleading promotion of an FDA-approved drug to physicians for off-label use where such use is not itself illegal and others are permitted to engage in such speech. . . .

While the FDCA makes it a crime to misbrand or conspire to misbrand a drug, the statute and its accompanying regulations do not expressly prohibit or criminalize off-label promotion. Rather, the FDCA and FDA regulations reference "promotion" only as evidence of a drug's intended use. *See* 21 C.F.R. § 201.128 (discussing how drug's intended use can be demonstrated). Thus, under the principle of constitutional avoidance, explained *infra*, we construe the FDCA as not criminalizing the simple promotion of a drug's off-label use because such a construction would raise First Amendment concerns. Because we conclude from the record in this case that the government prosecuted Caronia for mere off-label promotion and the district court instructed the jury that it could convict on that theory, we vacate the judgment of conviction. . . .

The government contends—and the dissent agrees—that the First Amendment is not implicated in this case. Specifically, the government argues that "[p]romoting an approved drug for off-label uses is not itself a prohibited act under the FDCA" and "the promotion of off-label uses plays an *evidentiary* role in determining whether a drug is misbranded under 21 U.S.C. § 352(f)(1)." (Gov't Br. 51 (citing 21 U.S.C. § 331)). The government contends that Caronia was not prosecuted for his speech, but that Caronia's promotion of Xyrem for off-label use served merely as "evidence of intent," or evidence that the "off-label uses were intended ones[ ] for which Xyrem's labeling failed to provide any directions." (Gov't Br. 52).

Even assuming the government can offer evidence of a defendant's off-label promotion to prove a drug's intended use and, thus, mislabeling for that intended use, that is not what happened in this case.

First, the government's contention that it did not prosecute Caronia for promoting the off-label use of an FDA-approved drug is belied by its conduct and arguments at trial. The excerpts quoted above demonstrate that the government repeatedly argued that Caronia engaged in criminal conduct by promoting and marketing the off-label use of Xyrem, an FDA-approved drug. The district court record thus confirms overwhelmingly that Caronia was, in fact, prosecuted and convicted for promoting Xyrem off-label. Indeed, in the government's summation and rebuttal at trial, Caronia's off-label promotion of Xyrem is highlighted over forty times.

Second, the government's assertion now that it used Caronia's efforts to promote Xyrem for off-label use only as evidence of intent is simply not true. Even if the government could have used Caronia's speech as evidence of intent, the district court record clearly shows that the government did not so limit its use of that evidence. *See Mitchell*, 508 U.S. at 489–90, 113 S. Ct. 2194 (instructing that, when speech is introduced as evidence of intent, "'[s]uch testimony is to be scrutinized with care to be certain the statements are not expressions of mere lawful and permissible difference of opinion with our own government'" (quoting *Haupt v. United States*, 330 U.S. 631, 642, 67 S. Ct. 874, 91 L. Ed. 1145 (1947))). The government never argued in summation or rebuttal that the promotion was evidence of intent. The government never suggested that Caronia engaged in any form of misbranding other than the promotion of the off-label use of an FDA-approved drug. The government never suggested, for example, that Caronia conspired to place false or deficient labeling on a drug. Rather, the record makes clear that the government prosecuted Caronia *for* his promotion and marketing efforts.

Third, the government's summation and the district court's instruction left the jury to understand that Caronia's speech was itself the proscribed conduct. Indeed, the district court flatly stated to the jury that pharmaceutical representatives are prohibited from engaging in off-label promotion. Although the district court explained the remaining elements of misbranding and conspiring to misbrand to the jury, this specific instruction—together with the government's summation—would have led the jury to believe that Caronia's promotional speech was, by itself, determinative of his guilt. . . .

Fourth, the government clearly prosecuted Caronia for his words—for his speech. A pharmaceutical representative's promotion of an FDA-approved drug's off-label use is speech. As the Supreme Court has held: "Speech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment." *Sorrell v. IMS Health, Inc.*, —— U.S. ——, 131 S. Ct. 2653, 2659, 180 L. Ed. 2d 544 (2011). Here, the proscribed conduct for which Caronia was prosecuted was precisely his speech in aid of pharmaceutical marketing.

Accordingly, we conclude that the government did prosecute Caronia for his speech, and we turn to whether the prosecution was permissible.

While the government and the FDA have construed the FDCA's misbranding provisions to prohibit off-label promotion by pharmaceutical manufacturers, as we have observed, the FDCA itself does not expressly prohibit or criminalize off-label promotion. The FDCA defines misbranding in terms of whether a drug's labeling is adequate for its intended use, and permits the government to prove intended use by reference to promotional statements made by drug manufacturers or their representatives. Assuming that this approach to the use of evidence of speech is permissible, it affords little support to the government on this appeal because Caronia was not prosecuted on this basis. Rather, the government's theory of prosecution identified Caronia's speech alone as the proscribed conduct. The district court accepted this theory. . . .

As we now explain, we decline the government's invitation to construe the FDCA's misbranding provisions to criminalize the simple promotion of a drug's off-label use by pharmaceutical manufacturers and their representatives because such a construction—and a conviction obtained under the government's application of the FDCA—would run afoul of the First Amendment.

The First Amendment protects against government regulation and suppression of speech on account of its content. Content-based speech restrictions are subject to "strict scrutiny"—that is, the government must show that the regulation at issue is narrowly tailored to serve or promote a compelling government interest. Content-based government regulations are "presumptively invalid." *R.A.V.*, 505 U.S. at 382, 112 S. Ct. 2538. Meanwhile, non-content-based regulation and regulation of commercial speech—expression solely related to the economic interests of the speaker and its audience—are subject to intermediate scrutiny. Criminal regulatory schemes, moreover, warrant even more careful scrutiny. . . .

In applying these principles, we have a benefit not available to the district court: the Supreme Court's decision in *Sorrell v. IMS Health, Inc.*, —– U.S. ——–, 131 S. Ct. 2653, 180 L. Ed. 2d 544 (2011), a case involving speech restrictions on pharmaceutical marketing. In *Sorrell*, the Vermont Prescription Confidentiality Law (the "VPCL") prohibited pharmaceutical companies and similar entities from using prescriber-identifying information for marketing purposes; it was challenged on First Amendment grounds.

The *Sorrell* Court held that "[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the . . . First Amendment. . . . [The] creation and dissemination of information are speech within the meaning of the [Constitution]." *Id.* at 2659, 2667. The Court held that the Vermont statute set forth content- and speaker-based restrictions, and that the statute was therefore subject to heightened scrutiny. Because the VPCL disfavored speech with a particular content (marketing) when expressed by certain disfavored speakers (pharmaceutical manufacturers), the Court held that it unconstitutionally restricted speech.

In reaching this conclusion, *Sorrell* engaged in a two-step inquiry. First, the Court considered whether the government regulation restricting speech was content- and

speaker-based. The Court held that it was; the regulation was therefore subject to heightened scrutiny and was "presumptively invalid." Second, the Court considered whether the government had shown that the restriction on speech was consistent with the First Amendment under the applicable level of heightened scrutiny. The Court did not decide the level of heightened scrutiny to be applied, that is, strict, intermediate, or some other form of heightened scrutiny. Rather, after observing that "[i]n the ordinary case, it is all but dispositive to conclude that a law is content-based," the Court concluded that the Vermont statute was unconstitutional even under the lesser intermediate standard set forth in *Central Hudson.* The Court further observed that the "outcome is the same whether a special commercial speech inquiry or a stricter form of judicial scrutiny is applied."

In considering whether the government had shown that the restriction on speech was consistent with the First Amendment, the *Sorrell* Court turned to *Central Hudson. See id.* at 2667–68. *Central Hudson* sets forth a four-part test to determine whether commercial speech is protected by the First Amendment. First, as a threshold matter, to warrant First Amendment protection, the speech in question must not be misleading and must concern lawful activity. Second, to justify regulations restricting speech, the asserted government interest must be substantial. Third, the regulation must directly advance the governmental interest asserted, "to a material degree," "[A] commercial speech regulation 'may not be sustained if it provides only ineffective or remote support for the government's purpose.'" *Liquormart,* 517 U.S. at 505, 116 S. Ct. 1495 (quoting *Cent.,* 447 U.S. at 564, 100 S. Ct. 2343). Fourth, the regulation must be "narrowly drawn," and may not be more extensive than necessary to serve the interest. The government cannot "completely suppress information when narrower restrictions on expression would serve its interests as well." *Cent. Hudson,* 447 U.S. at 565, 100 S. Ct. 2343. "Under the commercial speech inquiry, it is the [government's] burden to justify its content-based law as consistent with the First Amendment." *Sorrell,* 131 S. Ct. at 2667 (citing *Thompson,* 535 U.S. at 373, 122 S. Ct. 1497). . . .

The government's construction of the FDCA's misbranding provisions to prohibit and criminalize the promotion of off-label drug use by pharmaceutical manufacturers is content- and speaker-based, and, therefore, subject to heightened scrutiny.

First, the government's interpretation of the FDCA's misbranding provisions to prohibit off-label promotion is content-based because it distinguishes between "favored speech" and "disfavored speech on the basis of the ideas or views expressed." *See Turner Broad.,* 512 U.S. at 643, 114 S. Ct. 2445; *accord Sorrell,* 131 S. Ct. at 2663. Under this construction, speech about the government-approved use of drugs is permitted, while certain speech about the off-label use of drugs—that is, uses not approved by the government—is prohibited, even though the off-label use itself is not. Indeed, the content of the regulated speech drives this construction of the FDCA; as in *Sorrell,* the "express purpose and practical effect" of the government's ban on promotion is to "diminish the effectiveness of [off-label drug] marketing by manufacturers." *See Sorrell,* 131 S. Ct. at 2663.

Second, this construction is speaker-based because it targets one kind of speaker—pharmaceutical manufacturers—while allowing others to speak without restriction. In *Sorrell,* pharmaceutical companies were barred from obtaining and using prescriber-identifying information for marketing purposes, but a wide range of other speakers, including private and academic researchers, could acquire and use the information. Similarly, here, because off-label prescriptions and drug use are legal, the government's application of the FDCA permits physicians and academics, for example, to speak about off-label use without consequence, while the same speech is prohibited when delivered by pharmaceutical manufacturers. This construction "thus has the effect of preventing [pharmaceutical manufacturers]—and only [pharmaceutical manufacturers]—from communicating with physicians in an effective and informative manner." *Sorrell,* 131 S. Ct. at 2663.

Additionally, a claim to First Amendment protection here is more compelling than in *Sorrell* because this case involves a criminal regulatory scheme subject to more careful scrutiny.

Accordingly, the government's construction of the FDCA's misbranding provisions to prohibit and criminalize off-label promotion is content- and speaker-based, and subject to heightened scrutiny under *Sorrell.*

The first two prongs of *Central Hudson* are easily satisfied here. First, promoting off-label drug use concerns lawful activity (off-label drug use), and the promotion of off-label drug use is not in and of itself false or misleading. Second, the government's asserted interests in drug safety and public health are substantial. . . .

The government's construction of the FDCA as prohibiting off-label promotion does not, by itself, withstand scrutiny under *Central Hudson's* third prong. First, off-label drug usage is not unlawful, and the FDA's drug approval process generally contemplates that approved drugs will be used in off-label ways. In effect, even if pharmaceutical manufacturers are barred from off-label promotion, physicians can prescribe, and patients can use, drugs for off-label purposes. As off-label drug use itself is not prohibited, it does not follow that prohibiting the truthful promotion of off-label drug usage by a particular class of speakers would directly further the government's goals of preserving the efficacy and integrity of the FDA's drug approval process and reducing patient exposure to unsafe and ineffective drugs. *See Sorrell,* 131 S. Ct. at 2668–69 (holding government interest in protecting physician privacy not directly served when law made prescriber-identifying information available to "all but a narrow class of disfavored speakers").

Second, prohibiting off-label promotion by a pharmaceutical manufacturer while simultaneously allowing off-label use "paternalistically" interferes with the ability of physicians and patients to receive potentially relevant treatment information; such barriers to information about off-label use could inhibit, to the public's detriment, informed and intelligent treatment decisions. . . . In fact, in granting safe harbor to manufacturers by permitting the dissemination of off-label information through

scientific journals, the FDA itself "recognizes that public health can be served when health care professionals receive truthful and non-misleading scientific and medical information on unapproved uses" of approved drugs. Dep't of Health and Human Serv., Good Reprint Practices, *supra,* at III, V; *see Wash. Legal Found. v. Henney,* 202 F.3d 331, 335 (D.C. Cir. 2000) (discussing FDA "safe harbor," where certain forums for off-label discussion, such as continuing medical education programs and scientific publications, would not be used against manufacturers in misbranding enforcement actions).

Here, as the FDA recognizes, it is the physician's role to consider multiple factors, including a drug's FDA-approval status, to determine the best course of action for her patient. . . . While some off-label information could certainly be misleading or unhelpful, this case does not involve false or misleading promotion. Moreover, in the fields of medicine and public health, "where information can save lives," it only furthers the public interest to ensure that decisions about the use of prescription drugs, including off-label usage, are intelligent and well-informed.

The government's construction of the FDCA essentially legalizes the outcome—off-label use—but prohibits the free flow of information that would inform that outcome. If the government's objective is to shepherd physicians to prescribe drugs only on-label, criminalizing manufacturer promotion of off-label use while permitting others to promote such use to physicians is an indirect and questionably effective means to achieve that goal. . . .

The last prong of *Central Hudson* requires the government's regulation to be narrowly drawn to further the interests served. Here, the government's construction of the FDCA to impose a complete and criminal ban on off-label promotion by pharmaceutical manufacturers is more extensive than necessary to achieve the government's substantial interests. Numerous, less speech-restrictive alternatives are available, as are non-criminal penalties.

To advance the integrity of the FDA's drug approval process and increase the safety of off-label drug use, the government could pursue several alternatives without excessive First Amendment restrictions. For example, if the government is concerned about the use of drugs off-label, it could more directly address the issue. If the government is concerned that off-label promotion may mislead physicians, it could guide physicians and patients in differentiating between misleading and false promotion, exaggerations and embellishments, and truthful or non-misleading information. The government could develop its warning or disclaimer systems, or develop safety tiers within the off-label market, to distinguish between drugs. The government could require pharmaceutical manufacturers to list all applicable or intended indications when they first apply for FDA approval, enabling physicians, the government, and patients to track a drug's development. To minimize off-label use, or manufacturer evasion of the approval process for such use, the government could create other limits, including ceilings or caps on off-label prescriptions. The FDA could further remind physicians and manufacturers

of, and even perhaps further regulate, the legal liability surrounding off-label promotion and treatment decisions. Finally, where off-label drug use is exceptionally concerning, the government could prohibit the off-label use altogether. . . .

The government contends that these alternative means of reducing patient exposure to unsafe, untested drugs and maintaining the integrity of the FDA-approval process are "indefensible" because they are not administrable, feasible, or otherwise effective. In the absence of any support, such conclusory assertions are insufficient to sustain the government's burden of demonstrating that the proposed alternatives are less effective than its proposed construction of the FDCA in furthering the government interests identified. . . .

Problem 6-2

Does the Second Circuit's *Caronia* opinion hold promise for the corporate crime defense bar in areas of enforcement beyond off-label drug promotion? Can you think of a context *outside* of the health care fraud area in which the defense could mount an argument based on the *Caronia* decision?

D. Alternative Theories for Pharmaceutical Misconduct (and the opioid crisis)

The argument adopted by the court in *Caronia* has the potential to seriously impede the government's efforts to apply a "misbranding" theory under the FDCA to deal with misconduct in pharmaceutical marketing. As the following examples demonstrate, the creative federal prosecutor can often find alternative statutes and theories to use with corporate wrongdoing.

The following prosecution was predicated on 18 U.S.C. § 371, which is the broad, catch-all federal conspiracy statute.[3] A compounding center in Massachusetts—which is a small pharmacy-like business that does not simply sell medications but also manufactures some types in small volume—produced an antifungal treatment that caused a meningitis outbreak in 2012, sickening hundreds of people and causing over 100 deaths. Prosecutors sought a legal theory that would fit this terrible conduct and its unusual regulatory context.

UNITED STATES v. CARTER, 15 F.4th 26 (1st Cir. 2021)

BARRON, Circuit Judge:

These consolidated appeals are the latest to reach us in connection with the federal

[3] "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.

criminal investigation that ensued after patients across the country became seriously ill or died in the fall of 2012 after having been injected with a contaminated medication traced to the New England Compounding Center ("NECC"). NECC was a licensed pharmacy based in Framingham, Massachusetts. It combined drugs with other substances to create specialized medications -- a practice known as compounding. . . . [T]he appellant here is the government. It challenges the post-verdict judgments of acquittal that the District Court entered in favor of Sharon Carter and Gregory Conigliaro, who were, respectively, NECC's former Director of Operations and NECC's former Vice President, Secretary, Treasurer, and General Manager. . . .

Neither Carter nor Conigliaro was charged with playing any direct role in the physical compounding of the contaminated medication that was linked to patient illnesses and deaths. Instead, each was charged only with counts that pertained to their roles in connection with other aspects of NECC's operations. Among those charges was one that alleged that each had, while working at NECC, conspired to defraud the United States in violation of 18 U.S.C. § 371 "by interfering with and obstructing" the ability of the United States Food and Drug Administration ("FDA") to oversee the practices of NECC. . . .

In detailing the alleged § 371 conspiracy, the indictment charged the defendants with "interfering with and obstructing the lawful governmental functions of the FDA." In support of this contention, the indictment alleged that Carter, Conigliaro, and their co-conspirators had agreed to enter into a conspiracy defraud the FDA by "purport[ing] to be operating NECC as a state-regulated pharmacy, dispensing drugs pursuant to valid, patient-specific prescriptions as required by Massachusetts law, rather than as a drug manufacturer distributing drugs in bulk to customers without prescriptions and thereby subject to heightened regulatory oversight by the FDA" pursuant to its authority under the Food, Drug, and Cosmetic Act ("FDCA").

Passed in 1938, the FDCA gave the FDA authority to regulate "any new drug." Act of June 25, 1938, Pub. L. 75-717, 52 Stat. 1040 (codified at 21 U.S.C. § 301 et seq.); FDCA § 505(a) (codified at 21 U.S.C. § 355(a)). During the time of the alleged conspiracy, the FDCA defined "new drug" as "[a]ny drug ... not generally recognized ... as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p). It further provided that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed [with the FDA] is effective with respect to such drug." Id. § 355(a). In addition, it provided that any "new drug" must be made in accordance with "current good manufacturing practice" ("GMP") -- a set of regulations that the FDA subsequently promulgated to impose strict safety controls on manufacturers of new drugs. Id. § 351(a)(2)(B); see also 21 U.S.C. § 371(a) ("The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the [Commissioner of the FDA].").

Compounded drugs would appear to fit within the FDCA's definition of a "new drug."

After all, "[d]rug compounding is a process [that] combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient ... that [is typically] not commercially available." Thompson v. Western States Med. Cntr., 535 U.S. 357, 360-61, 122 S.Ct. 1497, 152 L.Ed.2d 563 (2002). Nevertheless, for the first fifty years after the FDCA's enactment, "the FDA generally left regulation of compounding to the States." Id. at 362, 122 S.Ct. 1497.

"[E]ventually," however, the FDA "became concerned ... that some pharmacists were manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA's new drug requirements." Id. It then began to take a more proactive role in the oversight of compounders -- at least those compounders that the FDA concluded behaved as manufacturers. Id. at 362-63, 122 S.Ct. 1497.

The indictment here centered on the role that the alleged conspirators supposedly played in defrauding the FDA. In particular, the indictment claimed that the defendants conspired to prevent the FDA from being able to determine whether NECC was a manufacturer or a pharmacy by intentionally misrepresenting the nature of the company's operations. The indictment explained in that respect that, as a "manufacturer," NECC would have been subject to heightened regulatory oversight by the FDA pursuant to its authority under the FDCA, while, as a "pharmacy," NECC would have been primarily regulated by state pharmacy boards. By conspiring to misrepresent to the FDA that NECC was operating only as a pharmacy and not as a manufacturer, the indictment alleged, the defendants conspired to interfere with the FDA's oversight function with respect to NECC and thereby conspired to defraud the United States in violation of § 371, given that such regulatory oversight by FDA is a "government function."

The indictment also alleged how the defendants carried out the alleged conspiracy to misrepresent the company's operations. Specifically, it alleged that the defendants agreed to participate in a conspiracy by which NECC would regularly misrepresent to the FDA that it was shipping its compounded medications to customers (which were hospitals and medical facilities rather than patients in their own right) pursuant to valid, patient-specific prescriptions. Yet, in fact, the indictment alleged, the company was processing the customers' orders for those medications without there being any such prescriptions. It then described three methods by which NECC allegedly disguised the fact that it was shipping compounded drugs in this manner before turning to the roles that that conspirators allegedly each played in carrying out the deception.

One such alleged method involved "backfilling." Here, NECC allegedly allowed customers to place their first order for medications without supplying any prescriptions or patient names. NECC then collected from customers the roster of patient names to whom these customers ended up prescribing and administering the medications on site. Thereafter, NECC allegedly attached such a roster either retrospectively to that first order or used it to process a subsequent order by the same customer -- thereby making it look as if NECC had filled the orders only after it had received valid, patient-specific

prescriptions from a customer.

A second alleged method involved NECC's processing of orders using prescriptions for fictitious patients. Sometimes, according to the indictment, NECC processed orders using the names of celebrities or fantasy characters that customers had supplied, such as "Michael Jackson" and "Wonder Woman." At other times, the indictment alleged, NECC used the names of customers' staff members or those of previous patients that customers had supplied. At still other times, NECC allegedly fabricated the prescriptions rather than relying on its customers to do so. And, finally, according to the indictment, NECC sometimes used a given patient name for multiple medications and for multiple units of the same medication in a single order, applying a ratio that would look plausible to regulators rather than filling a valid multidose prescription.

Pursuant to yet a third alleged method of shipping the drugs without a valid patient-specific prescription, according to the indictment, NECC processed some customers' orders using just the names of those institutional customers. NECC allegedly did so even though the customer was a hospital or medical facility that would then itself later dispense the drug to a patient and thus was not itself a patient for whom a prescription had been issued. Under this method, then, the drug was shipped by NECC to its customers without there being any patient identified who had been issued a prescription for it.

The indictment alleged that the defendants helped NECC deploy these methods despite knowing that the company was representing to the FDA that it was a compounding pharmacy that dispensed drugs only pursuant to valid prescriptions for individual patients and therefore was not subject to the FDA's GMP regulations that govern drug manufacturers. In setting forth this allegation, the indictment highlighted several statements allegedly made by the defendants that purportedly showed their awareness of both the alleged scheme and the regulatory background in which NECC's scheme was taking place.

The indictment included, for example, Conigliaro's alleged statements to the FDA that NECC was a "compounding-only pharmacy, not a manufacturer" and thus "not subject to GMP." Also cited in the indictment was an email Carter shared with NECC's order-processing staff, instructing them that "the MAX total number of units ... per patient must make sense," that "all names must resemble 'real' names," and not to use "obviously fake names [ ] (Mikey Mouse)" because she "must be able to logically explain to a regulator why [NECC] processed x# of units per patient" (emphasis added).
. . .

Many of the documents that the government introduced at trial were the product of two search warrants executed against NECC and its sales-affiliate, Medical Sales Management. The evidence introduced included order forms that NECC had filled for its customers under various "patient" names, such as "Ted Bundy" and "Barney Fife." The evidence also included an employee manual that Carter signed that detailed the "FDA Modernization Act of 1997-Pharmacy Compounding Provisions" and "[h]ow to

handle an FDA inspection" (as well as many of the emails described in the indictment).

In addition, the government introduced testimony from several former employees who testified to Carter's and Conigliaro's understanding of the importance to NECC of the company being considered a pharmacy and not a manufacturer in the eyes of regulators. Ken Boneau, for example, one such former sales representative, testified that during his training as a new employee, it was explained to him that "if the FDA regulated [NECC], there would be a lot of limitations" and that it was "important that the FDA not regulate NECC." Beth Reynolds, an NECC licensing coordinator, further testified to conversations that she had with Conigliaro and others about NECC needing to comply with state laws requiring the compounder to meet state manufacturing guidance. As to Carter, the government introduced testimony from former employees, including Boneau and Mario Giamei, Jr., about emails that they had received from Carter about what to do in the event that NECC's customers did not provide patient names with orders. And, finally, FDA Agent Michael Mangiacotti testified that during the search of NECC's offices, he found signs posted in the sales staff's cubicles with instructions from Carter warning NECC employees about the need to give "regulators" the impression that NECC was compounding drugs after receipt of real patient names. . . .

The FDA responded to the concerns about compounding by issuing a Compliance Policy Guide in 1992. FDA Compliance Policy Guide (CPG) Sec. 7132.16 (1992) (the "1992 CPG"). It explained "that while retail pharmacies ... are exempted from certain requirements of the [FDCA], they are not the subject of any general exemption from the [FDCA's] new drug, adulteration, or misbranding provisions." Western States, 535 U.S. at 360-61, 122 S.Ct. 1497 (quoting the 1992 CPG).

The Guide announced that the FDA "may, in the exercise of its enforcement discretion, initiate federal enforcement actions ... when the scope and nature of a pharmacy's activities raise[ ] the kinds of concerns normally associated with a manufacturer and ... result[ ] in significant violations of the new drug, adulteration, or misbranding provisions of the Act." Id. (quoting the 1992 CPG). But, the Guide also announced that the FDA otherwise would continue to exercise discretionary abstention from the policing of prescription-based compounding pharmacies as well as pharmacies that compounded drugs without prescriptions in "very limited quantities" for buyers with whom they could demonstrate an "established professional practitioner-patient-pharmacy relationship." Id. at 363, 122 S.Ct. 1497 (quoting the 1992 CPG).

Congress codified parts of the FDA's 1992 Guide concerning compounding a number of years later in the Food and Drug Administration Modernization Act of 1997 ("FDAMA"). See Pub. L. 105-115, 111 Stat. 2296, § 127 (codified at 21 U.S.C. § 503A (1997)). In particular, as the District Court noted:

> [The FDAMA] created a safe harbor for compounded drugs, exempting them from the FDCA's "new drug" requirements provided that certain criteria were met, most pertinently, that they

> be compounded in response to a valid prescription or only in limited non-prescription quantities where an established relationship existed between the specific pharmacist, patient, and prescribing physician.

The next major development of note occurred in 2002. That was when the Supreme Court of the United States struck down adjacent provisions of the FDAMA in Thompson v. Western States on the ground that they violated the First Amendment. See Western States, 535 U.S. at 377, 122 S.Ct. 1497. The Court did not reach the question of severability in that decision. See id. at 360, 122 S.Ct. 1497. But, thereafter, a circuit split ensued as to what, if anything, remained of the FDAMA and its provisions regulating compounders.

The Ninth Circuit held that the FDAMA as a whole was invalid. See Western States Med. Ctr. v. Shalala, 238 F.3d 1090 (9th Cir. 2001). The Fifth Circuit held, in contrast, that the FDAMA stripped of those unconstitutional provisions remained viable after Western States. See Med. Ctr. Pharmacy v. Mukasey, 536 F.3d 383 (5th Cir. 2008). Our circuit did not weigh in on the issue.

The FDA reacted to Western States in 2002 by issuing a new CPG. See FDA Compliance Policy Guide Sec. 460.200 Pharmacy Compounding (2002) (the "2002 CPG"). The 2002 CPG sought to head off any uncertainty that might result from the Supreme Court's decision in Western States with respect to the FDA's continued enforcement approach by, as the District Court explained, "essentially reembrac[ing] the FDA's 1992 guidance." Conigliaro, 384 F. Supp. 3d at 160.

The 2002 CPG reiterated that, for enforcement purposes, the FDA would continue to draw a line between, on the one hand, compounders that operated like traditional retail pharmacies in that they produced and sold drugs "upon receipt of a valid prescription for an individually identified patient from a licensed practitioner," and, on the other hand, compounders that operated like manufacturers in that they, for instance, "receive[d] and use[d] large quantities of bulk drug substances to manufacture large quantities of unapproved drug products in advance of receiving a valid prescription for them." The FDA assured compounders of the first kind, which operated as retail pharmacies, that it would abstain from enforcement actions, but warned compounders of the second kind, which operated as manufacturers, that it would "seriously consider enforcement action" against them. The FDA, moreover, specified that one of the factors it would consider in determining whether a compounder fell into this latter category of manufacturers was whether it "compound[ed] ... drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions." This 2002 CPG, while not legally binding, remained in effect through the end of the alleged conspiracy in 2012.

Carter and Conigliaro drew on this regulatory history in making their legal impossibility and due process arguments to the District Court. They claimed that, during the relevant

period, there was "no discernible federal law" or regulation that "defin[ed] any clear distinction between a compounding pharmacy and a drug manufacturer." As a result, the defendants argued, it was legally impossible to conspire to interfere with the FDA's "government functions" overseeing compounders. Moreover, the defendants argued that, in light of this history, it would violate notions of fair warning embedded in the Due Process Clause of the Fifth Amendment to find them criminally liable under § 371. . . .

Questions implicating the FDA's authority to regulate compounders as "manufacturers" under the FDCA in the relevant period are of central import to the defenses at issue. We thus emphasize up front that the analysis of those defenses that follows adopts -- as we have explained above we understand the District Court itself to have also adopted -- the premise (for which no preserved challenge has been made) that, during the life of the conspiracy, the FDA possessed the statutory authority under the FDCA to regulate NECC as a "manufacturer" because a compounded drug was a "new drug" within the meaning of the FDCA, see 21 U.S.C. § 321(p), whatever the FDA's own view (even if "mistaken") may have been as to whether it possessed that authority.

It is important to be clear about this premise for the following reason. We do not dispute that, if the FDCA itself were properly construed to be limited in a way that precluded the FDA from exercising such regulatory power over NECC during the period of the alleged conspiracy, even if the FDA sought to exercise such authority after making known in advance its intention to do so, a legal impossibility defense would be available to the defendants on that basis. Thus, in rejecting the defense of legal impossibility here, we do not mean to suggest otherwise. . . .

As a threshold matter, we are dubious that, even if the FDA had disavowed its legal authority during the life of the conspiracy, it would follow that the offense charged here was legally impossible to commit. And that is so because the offense charged here was conspiracy to defraud the FDA by means of deceptive practices that were designed to prevent the agency from determining that the company was operating as a manufacturer.

An agency's "mistaken" disavowal of authority is not written in stone. See FCC v. Fox Television Stations, Inc., 556 U.S. 502, 513, 129 S.Ct. 1800, 173 L.Ed.2d 738 (2009); Massachusetts v. EPA, 549 U.S. 497, 532, 127 S.Ct. 1438, 167 L.Ed.2d 248 (2007). Thus, the FDA would appear to have been entitled at any time to reverse course and assert the authority that (for purposes of evaluating the existence of this variant of the legal impossibility defense) we understand the FDCA itself would have entitled it to assert vis-a-vis compounders like NECC, at least so long as the FDA in reversing course did so on a going-forward basis and after providing due notice. Indeed, it is hard for a disavowal of authority to be "mistaken" -- as the District Court plainly indicated it was assuming any disavowal here might have been -- if the authority in fact does not exist. See Conigliaro, 384 F. Supp. 3d at 158.

Thus, even if there had been a mistaken disavowal of authority by the FDCA vis-a-vis its power to treat compounders like NECC as manufacturers, we do not see why such a mistaken disavowal would provide the basis for a legal impossibility defense that would

bar a finding that Carter and Conigliaro violated § 371. Regulated parties who conspire to trick an agency into thinking they are conducting themselves other than they are -- and in a manner that would be material to an agency's decision about whether it may wish to assert regulatory authority that it had previously disavowed but legally might be capable of asserting upon rethinking the disavowal -- may easily be understood to have defrauded the United States, notwithstanding that during the period that the conspiracy was ongoing the agency had wrongly construed its power too narrowly. The deception by the alleged conspirators could be found to have prevented the agency from rethinking its authority in light of how regulated parties were in fact operating and thereby lulled the agency into not determining that it needed to reverse course and, on a prospective basis after providing due notice, assert the regulatory authority that it had previously disclaimed.

There is, however, also a more record-specific reason in this case for rejecting this disavowal-based ground for crediting a defense of legal impossibility to the charges at issue. The record fails to support a finding that the claimed disavowal occurred. . . .

[T]he District Court did not identify any statement in which the FDA during the time period in question publicly or internally disavowed that it possessed regulatory power to treat a compounding pharmacy as a manufacturer, including even one engaged in practices not unlike those in which the government asserts the record suffices to show that NECC was then engaged. . . .

This conclusion is not undermined by the support in the record for the District Court's finding that "the evidence plainly show[ed] that during the life of the charged conspiracy, the FDA was not, and did not believe that it should be, in the business of regulating companies like NECC that were engaged in anticipatory pharmacy compounding." That finding does not establish that the FDA understood itself to lack the power under the FDCA to treat a compounding pharmacy like NECC as a manufacturer. It establishes only that, at that time, the FDA was of the view that a certain type of dispensing by compounding pharmacies -- because of the bounded way in which it was undertaken -- was not something that the FDA "should" be in the "business" of policing. That is not itself evidence of a disavowal of authority, let alone a disavowal of authority to regulate the practices in which NECC was engaged.

The defendants nevertheless insist that the District Court was correct in finding that the FDA had disavowed its authority over compounders like NECC by the time the alleged conspiracy took place. In support, they point to the testimony of Samia Nasr, who led FDA's Center for Drug Evaluation and Research Compounding Team from 2011 to 2016. Nasr testified at trial that the FDA put all inspections of compounding pharmacies on hold from 2009 to 2012.

With respect to NECC, the defendants contend, this hold became manifest in the FDA's 2011 and 2012 correspondence with the Colorado Board of Pharmacy that the defendants introduced into evidence. There, the Colorado regulators notified the FDA that NECC was shipping drugs in bulk quantities across state lines and the FDA, in response,

referred the Colorado regulators to the Massachusetts Board of Pharmacy rather than investigating the allegation. According to the defendants, the "national moratorium" on inspections compels the conclusion that the FDA "affirmatively disclaimed its authority" to regulate compounders.

The evidence to which the defendants point, however, shows at most that the FDA made an internal policy decision not to exercise its authority over compounders -- a decision that lacked legally binding force that would preclude the FDA from reversing course (after giving proper notice) on even a prospective basis. Cf. Fox Television Stations, 556 U.S. at 515, 129 S.Ct. 1800. The defendants thus fail to show that the evidence compelled a reasonable jury to conclude that the FDA disavowed its legal right to regulate compounders, such that it understood itself to be as powerless legally during the period of the alleged conspiracy as if the FDCA had been amended during that period of time to strip the FDA of exercising the power it was not exercising. And, for that reason, the first ground on which the District Court based its conclusion of legal impossibility -- or, at least, the first ground the parties treat the District Court as having based that conclusion on -- does not hold up. . . .

As an initial matter, we do not find persuasive the notion that it was legally impossible for the defendants to have conspired to interfere with a government function just because it was unclear during the life of the conspiracy whether the government had that function or understood itself to have it. That it is unclear to alleged conspirators whether the government will assert a regulatory function because it is convinced that the government is uncertain of its authority to assert it provides no basis for concluding that such a function does not exist. Thus, if the government function was one that the government had the legal authority to exercise -- and we have no reason not to assume that was the case, at least with respect to prospective exercise after the provision of due notice -- then we do not see how it would be legally impossible for the defendants to conspire to trick the government into wrongly concluding through misrepresentations about NECC's means of operating that it could not be regulated pursuant to that function. . . .

Thus, such lack of clarity cannot in and of itself make it legally impossible for the defendants to have conspired to interfere with a government function, insofar as the function's existence is not disputed as a matter of law and there is no basis for concluding that the function could not be asserted after the provision of due notice prospectively. For, if that is the case, then so long as the evidence is otherwise sufficient the fact that the FDA's authority was less than clear during the alleged conspiracy -- and that the FDA itself understood it to be unclear during that time frame -- is of no moment for purposes of assessing the availability of the defense of legal impossibility to the § 371 charges at issue. After all, those charges concern an alleged conspiracy to trick the FDA into thinking that a company subject to its regulatory authority was operating differently than it was in order to conceal the fact that its actual manner of operating would make it subject to more intensive regulatory oversight.

Nor is there force to the contention that the defendants' legal impossibility defense to

their § 371 charges has merit because -- due to concerns about fair warning -- the high degree of uncertainty about which compounders were subject to FDA's regulations pertaining to drug manufacturers during the period of time at issue itself precluded the FDA from lawfully exercising regulatory authority over NECC as if it were a manufacturer even if the FDA otherwise would have had such authority under the FDCA. The defendants were not charged with violating the FDCA based on evidence showing that NECC was operating as a manufacturer. They were charged with violating § 371 for conspiring to interfere with the FDA's ability to determine whether to regulate NECC as such by misleading the FDA about practices of the company that could bear on just that determination.

Thus, absent the FDA lacking the legal power to do so even on a going forward basis -- and after having given the requisite degree of fair warning of its intention to do so -- we see no basis for concluding that the ambiguity about the FDA's authority that the District Court identified precluded it from being "reasonably clear at the relevant time that the defendant's conduct was criminal." Lanier, 520 U.S. at 267, 117 S.Ct. 1219. We appreciate the District Court's concern with the "worrisome position that, in this context, what is not affirmatively permitted by the law is criminally prohibited." Conigliaro, 384 F. Supp. 3d at 166. But, because the defendants were charged with conspiring to defraud the FDA by impeding its ability to determine NECC's status through misrepresentations about the company's operations, we do not find that "worrisome position" implicated here. . . .

[F]or purposes of a defense of legal impossibility, the FDA's actual exercise of its legal authority over compounders in general and over NECC specifically is irrelevant. That is so because the FDA's exercise of its legal authority can at most show the factual impossibility of actually interfering with the FDA's oversight function during the time of the alleged conspiracy. The defendants, however, were convicted of conspiring to defraud the United States by interfering with the FDA's oversight function, not of actually interfering with its oversight function. And, because, as the District Court correctly stated, "factual impossibility is not a defense to ... liability ... for inchoate offenses such as conspiracy or attempt," the literal inability of the defendants to actually interfere with the FDA's enforcement actions cannot be a defense. Conigliaro, 384 F. Supp. 3d at 153 (quoting Dixon, 449 F.3d at 202). Or, to put it differently, if a juror could find the defendants guilty of conspiring to interfere with the FDA's oversight function regardless of whether they succeeded in interfering with it, then that juror could also find them guilty of doing so even if the FDA did not actually engage in oversight over compounders during that time. See United States v. Jimenez Recio, 537 U.S. 270, 274, 123 S.Ct. 819, 154 L.Ed.2d 744 (2003). . . .

We come, then, to the government's challenge to the District Court's due process ground for acquittal. In determining whether the defendants' convictions comported with the due process requirement of fair notice, "the touchstone is whether the [relevant] statute, either standing alone or as construed, made it reasonably clear at the relevant time that the defendant's conduct was criminal." Lanier, 520 U.S. at 267, 117 S.Ct. 1219. The

defendants contend, and the District Court agreed, that such clarity was absent in this case. . . .

If the defendants had been charged and convicted of interfering with the FDA's oversight function over compounders that operated as manufacturers, we may assume that it would matter for due process purposes whether it was reasonably clear that the FDA possessed the function to regulate NECC's activities as a legal matter. But, here, as we noted in our discussion of legal versus factual impossibility, the defendants were not so charged. They were charged with the distinct offense of conspiring to interfere with the FDA's oversight function over compounders that operated as manufacturers. And, with respect to that offense, the uncertainty that the District Court described regarding FDA authority does not preclude it from being reasonably clear that a conspiracy to pass off NECC as a kind of compounding pharmacy that it was not -- through the stratagems detailed in the indictment - -- was one prohibited by § 371. Or, at least, that uncertainty does not do so if we find -- as we must, given the arguments made to us -- that the FDA remained free throughout the life of the conspiracy to choose to regulate compounders as manufacturers under the FDCA in accord with the 2002 CPG insofar as it gave notice of its intention to do so. . . .

What is the line between selling pharmaceuticals and dealing drugs? Nothing has raised this question more pointedly than the massive opioids crisis of the last decade or so. The Supreme Court recently attempted to clarify that line. Before the Court had issued its opinion, the First Circuit had taken a detailed stab at the problem in the most prominent criminal case charged to date involving a pharmaceutical company selling opioid products. The Supreme Court's opinion comes first.

XIULU RUAN V. UNITED STATES, 142 S. Ct. 2370 (2022)

JUSTICE BREYER delivered the opinion of the Court.

A provision of the Controlled Substances Act, codified at 21 U. S. C. §841, makes it a federal crime, "*[e]xcept as authorized*[,] . . . for any person knowingly or intentionally . . . to manufacture, distribute, or dispense . . . a controlled substance," such as opioids. 84 Stat. 1260, 21 U. S. C. §841(a) (emphasis added). Registered doctors may prescribe these substances to their patients. But, as provided by regulation, a prescription is only authorized when a doctor issues it "for a legitimate medical purpose . . . acting in the usual course of his professional practice." 21 CFR §1306.04(a) (2021).

In each of these two consolidated cases, a doctor was convicted under §841 for dispensing controlled substances not "as authorized." The question before us concerns the state of mind that the Government must prove to convict these doctors of violating the statute. We hold that the statute's "knowingly or intentionally" *mens rea* applies to authorization. After a defendant produces evidence that he or she was authorized to dispense controlled substances, the Government must prove beyond a reasonable doubt

that the defendant knew that he or she was acting in an unauthorized manner, or intended to do so.

The question we face concerns §841's exception from the general prohibition on dispensing controlled substances contained in the phrase "[e]xcept as authorized." In particular, the question concerns the defendant's state of mind. To prove that a doctor's dispensation of drugs via prescription falls within the statute's prohibition and outside the authorization exception, is it sufficient for the Government to prove that a prescription was *in fact* not authorized, or must the Government prove that the doctor *knew* or *intended* that the prescription was unauthorized?

Petitioners Xiulu Ruan and Shakeel Kahn are both doctors who actively practiced medicine. They both possessed licenses permitting them to prescribe controlled substances. The Government separately charged them with unlawfully dispensing and distributing drugs in violation of §841. Each proceeded to a jury trial, and each was convicted of the charges.

At their separate trials, Ruan and Kahn argued that their dispensation of drugs was lawful because the drugs were dispensed pursuant to valid prescriptions. As noted above, a regulation provides that, "to be effective," a prescription "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR §1306.04(a). We assume, as did the courts below and the parties here, that a prescription is "authorized" and therefore lawful if it satisfies this standard. At Ruan's and Kahn's trials, the Government argued that the doctors' prescriptions failed to comply with this standard. The doctors argued that their prescriptions did comply, and that, even if not, the doctors did not knowingly deviate or intentionally deviate from the standard. . . .

Applying the presumption of scienter, we have read into criminal statutes that are "*silent* on the required mental state"—meaning statutes that contain no *mens rea* provision whatsoever—"'that *mens rea* which is necessary to separate wrongful conduct from "otherwise innocent conduct."'" *Elonis*, 575 U. S., at 736 , 135 S. Ct. 2001 , 192 L. Ed. 2d 1 (quoting *Carter* v. *United States*, 530 U. S. 255 , 269 , 120 S. Ct. 2159 , 147 L. Ed. 2d 203 (2000); emphasis added). Unsurprisingly, given the meaning of scienter, the *mens rea* we have read into such statutes is often that of knowledge or intent. See, *e.g.*, *Staples* v. *United States*, 511 U.S. 600 , 619 , 114 S. Ct. 1793 , 128 L. Ed. 2d 608 (1994); *United States* v. *United States Gypsum Co.*, 438 U.S. 422 , 444-446 , 98 S. Ct. 2864 , 57 L. Ed. 2d 854 (1978).

And when a statute is not silent as to *mens rea* but instead "*includes* a general scienter provision," "the presumption applies with equal or greater force" to the scope of that provision. *Rehaif*, 588 U.S., at ___, 139 S. Ct. 2191 , 2195 , 204 L. Ed. 2d 594 (emphasis added). We have accordingly held that a word such as "knowingly" modifies not only the words directly following it, but also those other statutory terms

that "separate wrongful from innocent acts." *Id.*, at ___ , 139 S.Ct. 2191 , 2197 , 204 L. Ed. 2d 594 ; see, *e.g.*, *ibid.* ; *United States* v. *X-Citement Video, Inc.*, 513 U.S. 64 , 72 , 115 S. Ct. 464 , 130 L. Ed. 2d 372 (1994); *Liparota* v. *United States*, 471 U.S. 419 , 426 , 105 S. Ct. 2084 , 85 L. Ed. 2d 434 (1985).

Section 841 contains a general scienter provision—"knowingly or intentionally." And in §841 prosecutions, a lack of authorization is often what separates wrongfulness from innocence. Defendants who produce evidence that they are "authorized" to dispense controlled substances are often doctors dispensing drugs via prescription. We normally would not view such dispensations as inherently illegitimate; we expect, and indeed usually want, doctors to prescribe the medications that their patients need. In §841 prosecutions, then, it is the fact that the doctor issued an *unauthorized* prescription that renders his or her conduct wrongful, not the fact of the dispensation itself. In other words, authorization plays a "crucial" role in separating innocent conduct—and, in the case of doctors, socially beneficial conduct—from wrongful conduct. *X-Citement Video*, 513 U. S., at 73 , 115 S. Ct. 464 , 130 L. Ed. 2d 372 . Applying §841 's "knowingly or intentionally" *mens rea* to the authorization clause thus "helps advance the purpose of scienter, for it helps to separate wrongful from innocent acts." *Rehaif*, 588 U. S., at ___, 139 S. Ct. 2191 , 2197 , 204 L. Ed. 2d 594 ; see also *X-Citement Video*, 513 U. S., at 72-73 , 115 S. Ct. 464 , 130 L. Ed. 2d 372.

In addition, the regulatory language defining an authorized prescription is, we have said, "ambiguous," written in "generalit[ies], susceptible to more precise definition and open to varying constructions." *Gonzales* v. *Oregon*, 546 U. S. 243 , 258 , 126 S. Ct. 904 , 163 L. Ed. 2d 748 (2006); see *id.*, at 257 , 126 S. Ct. 904 , 163 L. Ed. 2d 748 (regulation "gives little or no instruction on" major questions); see also 21 CFR §1306.04(a) (regulation defining "effective" prescription as one "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice"). The conduct prohibited by such language (issuing invalid prescriptions) is thus "often difficult to distinguish from the gray zone of socially acceptable . . . conduct" (issuing valid prescriptions). *United States Gypsum*, 438 U. S., at 441 , 98 S. Ct. 2864 , 57 L. Ed. 2d 854 . A strong scienter requirement helps to diminish the risk of "overdeterrence," *i.e.*, punishing acceptable and beneficial conduct that lies close to, but on the permissible side of, the criminal line. . . .

The Government, of course, can prove knowledge of a lack of authorization through circumstantial evidence. See *ibid.* And the regulation defining the scope of a doctor's prescribing authority does so by reference to objective criteria such as "legitimate medical purpose" and "usual course" of "professional practice." 21 CFR §1306.04(a); see *Gonzales*, 546 U. S., at 285 , 126 S. Ct. 904 , 163 L. Ed. 2d 748 (Scalia, J., dissenting) ("The use of the word 'legitimate' connotes an *objective* standard of 'medicine'"); *Moore*, 423 U. S., at 141-142 , 96 S. Ct. 335 , 46 L. Ed. 2d 333 (describing Congress' intent "to confine authorized medical practice within *accepted* limits" (emphasis added)). As we have said before, "the more unreasonable" a defendant's

"asserted beliefs or misunderstandings are," especially as measured against objective criteria, "the more likely the jury . . . will find that the Government has carried its burden of proving knowledge." *Cheek* v. *United States*, 498 U. S. 192, 203-204 , 111 S. Ct. 604 , 112 L. Ed. 2d 617 (1991). But the Government must still carry this burden. And for purposes of a criminal conviction under §841, this requires proving that a defendant knew or intended that his or her conduct was unauthorized. . . .

In this case involving a pharmaceutical company's marketing of prescription opioids, federal prosecutors employed the RICO statute, with predicate violations including narcotics offenses, honest services fraud, and ordinary mail and wire fraud charges.

UNITED STATES v. SIMON, 12 F.4th 1 (1st Cir. 2021)

SELYA, Circuit Judge:

The tale told by this case chronicles the pernicious practices employed by a publicly held pharmaceutical firm, Insys Therapeutics, Inc. (Insys), with respect to the marketing and sale of Subsys, a fentanyl-laced medication approved by the United States Food and Drug Administration (FDA) for use in the treatment of breakthrough cancer pain. When the government got wind of these practices, it launched an investigation. That investigation produced evidence that led a federal grand jury to indict seven of the company's top executives on charges brought under the Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. § 1962(d). Two of the executives eventually entered into plea agreements, but the rest stood their ground. Following a fifty-one-day trial, the jury convicted the five remaining defendants as charged (with an exception described below), and the district court (again with an exception described below) declined to set aside the jury verdicts. The court then sentenced the defendants to prison terms of varying lengths, ordered defendant-specific restitution, and directed the forfeiture of certain assets. . . .

We begin with a snapshot of the relevant facts drawn from the evidence adduced at trial. . . . Insys is a pharmaceutical firm founded by one of the defendants, Dr. John Kapoor. Under the Insys umbrella, Kapoor sought to develop sublingual spray drug-delivery formulations. The firm explored various options, but soon concentrated on developing a sublingual fentanyl spray. This product came to be called "Subsys."

In early 2012, the FDA approved Subsys for the treatment of patients suffering from "breakthrough cancer pain." The term "breakthrough cancer pain" is a term of art: it refers to brief spikes in pain (typically lasting less than one hour) in patients with cancer who are already dealing with constant and relatively steady pain. All other uses of Subsys were deemed "off-label."

When Subsys went on the market, its FDA-approved label declared that "[t]he initial dose of Subsys to treat episodes of breakthrough cancer pain is always 100 micrograms." Moreover, the label warned that "Subsys contains fentanyl," which is a "Schedule II

controlled substance with an abuse liability similar to other opioid analgesics." Relatedly, the label carried a limitation on who could prescribe the drug: due to "the risk for misuse, abuse, addiction and overdose," Subsys could be prescribed "only through a restricted program ... called 'Risk Evaluation and Mitigation Strategy'" (REMS). This program formed part of the FDA's Transmucosal Immediate Release Fentanyl REMS Access Program, which required patients, prescribers, and pharmacists to sign a form stating that they understood the risks presented by the prescribed drug.

Subsys made its debut in the marketplace in March of 2012 (shortly after FDA approval was secured). At that point in time, Kapoor was serving as Insys's executive chairman, Michael Babich was serving as its chief executive officer, Shawn Simon was serving as its vice president of sales, and Matthew Napoletano was serving as its vice president of marketing.

Around the time of the Subsys launch, Insys assembled a marketing team. It proceeded to provide its sales force with access to data that ranked physicians "based on their history of prescribing within the opiate market, in particular, the fentanyl market." The ranking system assigned a number between 1 and 10 to each doctor — the higher the number the greater the volume of prescriptions written. Salespeople were instructed to target doctors ranked 5 or above and to give their "highest attention" to those assigned a 10. They were also told to employ a "switch strategy" aimed at persuading prescribers whose patients already had been determined to need a similar fentanyl product to jettison the similar product in favor of Subsys. Although the only approved use for Subsys was for treatment of breakthrough cancer pain, most of the prescribers listed in the database were pain-management specialists, not oncologists.

Notwithstanding Insys's strategic plan, Kapoor was disappointed with initial sales and revenue figures. He told colleagues that it was "the worst f*****g launch in pharmaceutical history he's ever seen." In Kapoor's view, the "main issue" was that the majority of patients who started on Subsys would stay on the drug only for the first month and would not refill their prescriptions. Napoletano hypothesized that patients were electing not to stick with Subsys because insurance companies were choosing not to cover it. Patients, he suggested, did not want to pay out of pocket to refill Subsys prescriptions.

Kapoor, though, had a different take: he attributed the widespread failure to refill Subsys prescriptions to patients "starting on too low of a dose." Because the Subsys label specified the initial dose as 100 micrograms, Kapoor expressed concern that patients who were used to a higher dose of a competing product would not be satisfied with the pain management offered by Subsys at that initial dosage. Consistent with Kapoor's concerns, sales data (which Insys executives analyzed daily) showed that the lower a patient's starting dose, the higher the "falloff rate."

By the fall of 2012, Insys had begun to overhaul its marketing team. Shawn Simon was cashiered, and Alec Burlakoff (previously a regional manager) replaced him as vice president of sales. Defendant Joseph A. Rowan was promoted into Burlakoff's former

role. Defendants Sunrise Lee and Richard M. Simon were installed as regional managers, and defendant Michael J. Gurry became vice president for managed markets

In addition to these executive-suite changes, Insys revamped its sales and marketing strategy. That fall, it hosted both a national sales meeting and a national sales call to train its sales force on a "new plan of attack." This plan had several components:

- A new "switch program" allowed patients who were transitioning to Subsys from a competing drug to receive vouchers to defray the cost of Subsys for as long as they needed it or until it was covered by their insurance.
- A new "super voucher" program offered a means of providing free product to patients.
- A specially crafted "effective dose" message informed prescribers that, despite the statements on the FDA-approved labelling, 100- or 200-microgram doses were not effective. To complement this "effective dose" messaging, sales representatives were notified "each and every time" a prescriber wrote a Subsys prescription for 100-or 200-micrograms; and they were instructed to report back within 24 hours both as to the reason why the doctor had prescribed the low dose and as to how the doctor planned to titrate the patient to the "effective dose."
- A revised compensation structure was put in place. This structure rewarded sales representatives for pushing doctors to prescribe higher doses of Subsys. Under it, larger prescribed doses yielded salespeople larger bonuses both because bonus percentages were higher for higher doses and because higher doses were more costly.

The icing on the cake was Insys's inauguration of a speaker program in August of 2012. The ostensible "objective of the program" was to provide "peer-to-peer education." To that end, Insys would invite physicians whom it envisioned as potential Subsys prescribers and the speaker (a fellow health-care provider) would "present the information [about the drug] to them." These presentations would take place through "online web hosting[s]" or at "dinner meetings." Each sales region was to host a roughly equal number of programs.

In its original incarnation, the speaker program never got off the ground. Instead, Kapoor transmogrified it. About a month after Napoletano announced the inauguration of the program, Kapoor "put on hold all speaker programs effective immediately." This directive emanated from Kapoor's disagreement with Napoletano about what the objective of the program ought to be: as Kapoor saw it, the speaker program "was designed for the speakers," not for the physicians who comprised the audience. Kapoor "wanted every speaker to write" Subsys prescriptions.

To accomplish this objective, Kapoor asked Napoletano for a list of the doctors who served as speakers, along with data as to "how many of them were writing [Subsys]" and data as to "what percentage of the prescriptions came from them." Napoletano balked,

responding that "it's the attendees that you measure" — not the speakers. Kapoor "was not in agreement with that" and continued to insist upon a restructuring of the program.

In September, Kapoor, Burlakoff, Babich, and Napoletano met to discuss the direction of the speaker program. Consistent with Kapoor's vision, Burlakoff argued against the original peer-to-peer education model. When Napoletano pointed out that "in accordance with pharma code" each event had to have "a minimum of two to four people" attend, Burlakoff replied that he "d[idn't] care if there are any attendees" and that "he expect[ed] every speaker to write" prescriptions. He said that the speaker program should be "about the speaker and getting return from the speaker." Although the meeting "was very contentious," Kapoor was satisfied that his message had been received and proceeded to lift his "hold" on the speaker program.

Burlakoff then emailed the sales force stating that speaker programs are "the number one opportunity to grow [their] business." He predicted that "[t]he hungry, motivated sales representatives will be facilitating as many speaker programs as humanly possible." He also suggested that a successful speaker program would require salespersons to seek out speakers who are "expert[s] with the utilization of Subsys in [their] clinical practice" and who "have at least 20 patients on Subsys."

Even with this sharp change in direction, Insys's top brass disagreed as to how to measure the program's success. In October, Kapoor, Napoletano, Babich, and Burlakoff met regarding that issue. Napoletano wanted to "track [the attendees] moving forward to see if the presentation had any impact and if they adopted the product in their practice." Burlakoff disagreed and reiterated that "the metric to track is the speaker." The meeting concluded with the issue still up in the air.

At a subsequent meeting, Kapoor resolved the issue. He stated that he "wanted to make sure every speaker wrote" Subsys prescriptions and "wanted a positive ROI" — a shorthand reference to return on investment. The ROI, as Kapoor measured it, would be the ratio between net revenue and the amount paid for speaker services. After a heated exchange, Napoletano capitulated and agreed to begin preparing reports tracking speakers and their corresponding ROIs. These reports allowed Kapoor to "see how successful [the] speakers were and how much product they were writing, based on how much money [Insys] had given them so far." Once this data became available, any speaker who "did not generate at least two times in revenue what was being paid to them" was "flagged" for a "temporary hold on programming." Refined to bare essence, the flagged speakers "wouldn't get programs" and, thus, would not receive honorariums.

This new protocol transformed the speaker programs from pedagogical exercises into funding mechanisms for a pay-for-play fandango. It is, therefore, unsurprising that with the new protocol in place, Burlakoff sought to identify "whales." He coined the term "whales" to refer to physicians who "ha[d] agreed in a very clear and concise manner that they [were] up for the deal, which [meant that] they [would] be compensated based on the number of prescriptions of Subsys they wr[ote]." A corollary to that deal was that "the more they wr[ote] and the more they increase[d] the dose, the more they'[d] get paid

to speak." At Burlakoff's urging, regional sales managers were to have a "candid conversation" with each potential whale and make clear that if the physician was going to receive payments from Insys, he was "going to write a significant amount of Subsys prescriptions to new patients as well as increase the doses of current patients." Burlakoff told sales managers to view speakers as their "business partner[s]. . . .

Without exception, the prescription numbers of these physicians increased when they joined the speaker program. In an email, Burlakoff described the doctors as "clueless" because they "prescribe strictly based on their relationship with the sales manager." As a result of that relationship and the pressure that sales representatives exerted, practitioners designated as "[s]peakers" generated approximately $4,200,000 in net revenue (60 percent of Insys's total net revenue) after receiving more than $550,000 in speakers' fees. Pleased with the success of the reconstituted speaker program, Kapoor raised the speaker budget in subsequent years.

Insys allocated speaker programs primarily to whales and other prolific Subsys prescribers. These practitioners were paid between $1,000 and $3,000 per event, depending on the particular practitioner's "résumé or ... influence." Speakers' payments were routinely sent by mail. Multiple speaker events featured the same practitioner. Insys initially capped annual speaking fees at $100,000 per practitioner but later raised the ceiling to $125,000. At a meeting in January of 2014, Babich, Burlakoff, and Richard Simon compiled a list of "doctors that had the highest potential to write." Burlakoff then "mobilized the sales force to go out and make sure that these 19 or 20 doctors reached their [fees] cap."

Despite the largess shown to speakers, the speaking events themselves had little to no attendance. Often, only the speaker, a friend or family member, and the sales representative were on hand. Even when more people were in attendance, the speaker programs were mostly "social outings" or "just a reason to gather people and have dinner and pay [the doctor]." Although sales representatives were required to submit sign-in forms and attendee evaluation forms to a third-party compliance firm (Sci Medica), they frequently submitted inaccurate documentation, including sign-in sheets with names and signatures of people who were not present, to give the speaking programs an aura of legitimacy. And when Kapoor replaced Sci Medica with an in-house compliance officer, the apocryphal documentation continued to flow.

While the revamped speakers' program drove up the volume of Subsys prescriptions, insurance coverage remained a problem. Medicare, Medicaid, and private insurance companies covered the cost of Subsys prescriptions only if a practitioner obtained prior authorization to prescribe the drug. And because of the FDA label, coverage was limited to patients with a current cancer diagnosis who both suffered from breakthrough cancer pain and already had tried other opioid medication.

Nor did the coverage limitations stop there. As a condition precedent to coverage, insurers required that a patient had tried a generic fentanyl product that had either failed to ameliorate the breakthrough cancer pain or proved difficult to ingest. To seek prior

authorization, a practitioner typically submitted patient and diagnosis information to the insurer, and the insurer relied upon the accuracy of the submitted information in its decisionmaking. When Insys launched Subsys, it processed prior authorization requests through a third party and achieved only a 30-35 percent success rate for prior authorization approvals.

To enhance the approval rate, Gurry suggested bringing the approval process in-house. With Kapoor's blessing, Gurry hired Elizabeth Gurrieri in October of 2012 to found the Insys Reimbursement Center (IRC), which operated out of Insys headquarters. Insys created an opt-in form through which Subsys prescribers could authorize the IRC to contact insurers and request prior authorizations. The form listed patient information that insurers typically would request during the prior authorization process, such as whether the patient had tried certain medications. Particular items from the list could be checked off as applying to a specific case. This streamlined the process: a prescriber would sign and fax an opt-in form to the IRC; the IRC would call the insurer; and if the insurer needed additional information, the IRC would reach out to the sales representative who would then follow up with the prescriber. Insys encouraged physicians to use the IRC, knowing that if the prior authorization was approved, "[t]he sales rep would get paid, Insys would get paid, and the script would get paid." A pilot program achieved an approval rate of 65-70 percent. As a result, Insys quickly transitioned the IRC out of its pilot phase and expanded it. Gurrieri was promoted to manager of reimbursement services in March of 2013.

The IRC proved to be a rousing success. It owed much of its success to the sales representatives. They interacted with the physicians and collected documentation requested by insurers during the prior-authorization process. A sales representative would often spend at least one day per week in a physician's office, reviewing patient files, assisting with authorizations, and completing the opt-in forms.

Another factor in the IRC's success was the hiring of "area business liaison[s]." These individuals were assigned to the physicians who prescribed Subsys in substantial volume. Each area business liaison worked in a physician's office processing authorizations, but was paid by Insys, thereby reducing the physician's overhead.

The third, and perhaps most impactful, factor in the IRC's success was Insys's decision to begin collecting data on each coverage decision. The IRC identified diagnoses and conditions that historically had prompted particular insurers to approve Subsys prescriptions. It proceeded to list these diagnoses and conditions on the opt-in form, and sales representatives encouraged physicians to employ them when seeking Subsys authorizations. For example, Gurrieri noted success using "the terminology 'history of cancer,' which means that they didn't have cancer at the time but they had a history of cancer." Once salespeople heard that use of that phrase could help obtain insurance approval, the IRC, "all of a sudden, saw more opt-ins having 'history of cancer' on them, which [led] to better approval ratings."

Management regularly discussed the IRC on the daily 8:30 a.m. calls. All updates about the IRC were communicated by Gurry during those calls. Although Insys had made great strides in upping its approval rate, Kapoor put constant pressure on the IRC to achieve a rate of 90 percent or higher. Striving to attain this benchmark, the IRC started to offer training sessions to sales representatives on "how to get the drug approved." Similarly, Gurry started to advise sales representatives about what diagnoses and conditions should be checked on the opt-in forms. He famously directed IRC employees "to ride the gray line," that is, to "work around the insurance companies" and "find ways around their questions." Following that direction, the IRC developed strategies to mislead insurers into granting prior authorizations for the use of Subsys. Some of these strategies included misleading the insurer into believing that the caller was calling from the physician's office rather than from the IRC; representing that a patient had cancer even if the available information reflected only a history of cancer; giving the ICD-9 diagnosis code as "338" to obscure the fact that the diagnosis was chronic pain (which uses code 338.29 or 338.4) and not cancer pain or neoplasm-related pain (which uses code 338.3); listing tried-and-failed medications that the patient had never used; and falsely stating that patients had dysphagia (difficulty swallowing).

Insys expected insurance companies to ask whether a physician had prescribed Subsys to treat "breakthrough cancer pain." Gurrieri instructed IRC staff to respond with "the spiel," which was pat phrasing designed to obfuscate the purpose of the prescription. The essence of the spiel was that "[t]he physician is aware that the medication is intended for the management of breakthrough pain in cancer patients, and the physician is treating the breakthrough pain." Phrased in this way, the expectation was that "the person on the other end of the phone would be misled to think the patient had cancer and approve the prior authorization."

The record makes manifest that the IRC, in practice, was more interested in transmitting information that would prompt favorable coverage determinations than it was in transmitting accurate information. Through the IRC, the insurers were fed a steady diet of deceptions, evasions, and half-truths.

Just as sales representatives were incentivized to push physicians to prescribe higher doses of Subsys, IRC staffers were incentivized to obtain insurance approvals. Goals known as "gates" were set weekly. If the gate was opened, the staff member (usually paid a low hourly wage) would receive a bonus.

The cocktail that Insys had mixed — including its revised marketing and sales strategies, its use of speaker programs as vehicles for bribes to physicians, its use of business liaisons, and its no-holds-barred tactics within the IRC — proved to be lucrative. Insys was able to go public only a year after introducing Subsys to the market. Within two years after the initial public offering, the company reached a market cap of over $3,000,000,000. And by the end of 2015, Insys's stock price had nearly quadrupled. Throughout, the defendants received substantial salaries, bonuses, and stock options.

But Insys's meteoric rise appeared too good to be true, and the company attracted unwanted attention. When federal authorities began probing the details of how Insys was marketing Subsys, the defendants' scheme began to unravel. . . .

The record is replete with support for the proposition that Kapoor intended physicians to write medically illegitimate prescriptions. Kapoor sought out pill mill doctors (that is, doctors who were notorious for their readiness to prescribe drugs regardless of medical necessity). See, e.g., United States v. Iriele, 977 F.3d 1155, 1161 (11th Cir. 2020) (describing as "pill mill" a clinic where people "could get prescriptions for their controlled substances of choice with few, if any, questions asked"). For instance, Burlakoff testified that, to increase sales, Kapoor wanted him to do "[w]hatever it took with whomever [they] called on, including pill mill doctors."

Perhaps the best illustration of Kapoor's intent is found in the evidence concerning his attitude toward Dr. Madison. Kapoor encouraged dealings with Dr. Madison despite having reviewed an email in which a sales representative wrote that "Dr. Madison runs a very shady pill mill and only accepts cash. ... He basically just shows up to sign his name on the prescription pad, if he shows up at all." Kapoor also knew that another sales representative had observed a "shady setup" in Dr. Madison's office with "many patients ... going in and out of there ... just seeking medication." As one expert witness put it, this prescribing behavior was inconsistent with a doctor's duty to carry out "those things that are necessary to reasonably diagnose the problem," such as "history taking, physical examination, and the obtaining and evaluation of diagnostic studies."

Although on unmistakable notice of the kind of operation that Dr. Madison appeared to be running, Kapoor pursued him. Babich testified that Kapoor "wanted [Dr. Madison] to write the drug" and awarded him speaker programs (and, thus, kickbacks) "as much as once a week." This was consistent both with Babich's description of Kapoor's avowed "philosophy" and with other evidence reflecting Kapoor's appetite for whales. The jury reasonably could have found that Kapoor's decision to continue courting and compensating Dr. Madison, notwithstanding his knowledge that the doctor was running a notorious pill mill, was proof of at least a tacit understanding of Kapoor's culpable role in the distribution scheme. See United States v. King, 898 F.3d 797, 809 (8th Cir. 2018).

Kapoor complains that this is a bridge too far. He laments that he received hundreds of emails a day, that he was busy with other business pursuits and charitable endeavors, and that Dr. Madison is only one of 13 doctors discussed in the four-page email. It follows, Kapoor suggests, that a reasonable jury could not infer that he read the sales representative's description of Dr. Madison.

This suggestion is little more than whistling past the graveyard. It conveniently overlooks that the jury heard evidence that Kapoor demanded information on "every [Subsys] script that was written" and "every doctor that wrote it." He demanded spreadsheets to parse doctor-level data and sought to identify "whales" — doctors who understood that, in exchange for speaker-program payments, they would prescribe "a significant amount of Subsys prescriptions."

What is more, Babich testified that Kapoor expressed great interest in these kinds of sales reports. Kapoor "want[ed] every single rep every Friday to e-mail [Babich] a list of all their top physicians and what happened with those top physicians that week." An assistant "print[ed] these out" and put "them on [Kapoor's] desk for Monday morning, so he c[ould] review" them. Given that level of attention to detail vis-à-vis prescribers, the inference that Kapoor read the email about Dr. Madison seems compelling.

Last — but surely not least — Babich confirmed that he gave the four-page email directly to Kapoor. He also testified that — several months after he had forwarded that email about Dr. Madison to Kapoor — the same sales representative again reiterated that Dr. Madison operated a pill mill and added that Dr. Madison faced possible legal action. Babich described this matter as "a serious issue" and testified that he personally reviewed this information with Kapoor. Kapoor responded that Dr. Madison "still has a medical license. I don't want him taken off the call list" for speaker programs.

We need not tarry. The evidence, taken in the light most hospitable to the verdict, plainly supports the inference that Kapoor knew of Dr. Madison's illegitimate prescribing habits yet took steps to ensure that he would continue prescribing Subsys. Indeed, the evidence warrants an inference that Kapoor sought to recruit Dr. Madison as a speaker (that is, as a kickback recipient) precisely because of these habits. Such an inference is consistent with other evidence that pill mill doctors were prized by Kapoor: he tracked physicians' prescription patterns, gave favorable treatment to the doctors who prescribed Subsys most profligately, and — according to Burlakoff — did "whatever it took" to increase Subsys sales. As Burlakoff put it, Kapoor's message to the sales force was that "pill mills for [Insys] meant dollar signs."

The evidence also showed that Kapoor led Insys's effort to influence physicians' prescription decisions through "effective dose" messaging. The FDA-approved label stated that "[t]he initial dose of Subsys to treat episodes of breakthrough cancer pain is always 100 micrograms." Doctors were supposed to "look at one patient at a time" and "titrate one patient at a time" to the dose of the drug that achieves "the desired effect." Noting that patients on higher doses were more likely to refill their Subsys prescriptions, Kapoor sought to ride roughshod over this regime and "move patients to higher doses." His mantra was to "push the dose." To that end, he incorporated into the speaker program kickbacks for dosage increases — the greater the increase, the greater the payout. Predictably, Kapoor's campaign to increase dosages resulted in the sales force negotiating dosage agreements with doctors. And Insys closely monitored these agreements: for example, when Dr. Somerville's dosage numbers appeared to be low, a sales representative was instructed to "[d]rill into [the medical assistant's] head that every refill has to be 180 to 240 [micrograms]" because "Dr. Somerville agreed to do this."

To sum up, the evidence plainly supports a finding that Kapoor intended practitioners to prescribe Subsys as much as possible, even when there was no medical necessity for the drug or the dosage prescribed. His "effective dose" campaign was designed to dissuade

doctors from prescribing medically appropriate lower dosages and to accelerate dose titration. A reasonable jury could infer that, by taking these actions, Kapoor pushed physicians — in Burlakoff's words — to "initiate a new habit" that would transform patients into repeat customers, quite apart from medical necessity. See United States v. Clough, 978 F.3d 810, 820-21 (1st Cir. 2020) (concluding that giving "opioid-dependent patients high dosages of this highly-addictive fentanyl drug, even when patients had no problems with their existing regimen" supported reasonable inference that defendant's "behavior was not reminiscent of a physician assistant prescribing based on need, but rather [that] of a drug pusher"). And having thrown medical necessity to the wind, Kapoor's "push the dose" message effectively directed Insys salespersons, who were not health-care professionals, to enforce mandatory ranges of dosages. Following Kapoor's lead, they shaped doctors' prescription decisions without regard to any individual patient information by getting the doctors to commit to meeting prescription-quantity numbers on a weekly basis. Jurors are allowed to use common sense and — surveying this unattractive tableau — a reasonable jury could have inferred that Kapoor, in "push[ing] the dose," intended doctors to increase doses of Subsys regardless of who the patient was or what the patient's medical needs might be. See United States v. Guzman, 571 F. App'x 356, 363 (6th Cir. 2014) ("[T]he jury could reasonably infer the requisite agreement to distribute controlled substances, as well as knowledge and participation" from "evidence showing that [defendants] tried to modify the prescribing practices of another nurse practitioner," including by directing a "nurse to prescribe short-acting rather than long-acting medications and to prescribe prednisone for all customers."). . . .

The district court admitted at trial testimony of nine patients who had received Subsys prescriptions from doctors who participated in the kickback scheme. All of the defendants challenge the admission of their testimony as irrelevant and unduly prejudicial. . . .

All in all, nine patients testified about the debilitating effects of addiction that they experienced while ingesting Subsys. We offer a representative sampling of this testimony:

- Cathy Avers testified that, as a result of taking Subsys, she "bec[a]me an addict" such that "[n]o matter how much [she] took, eventually it just wasn't enough." She testified to side effects such as "having a hard time functioning, standing up, going to sleep. It was such an impact on [her] being able to get up, out of bed, get dressed, and do anything." She confirmed that the information Insys had provided to her insurer — that she had a current cancer diagnosis, was taking morphine and hydromorphone, and was using a fentanyl patch — was apocryphal.

- Paul Lara testified that, while taking Subsys, he wound up "not finding [his] way home in a town [he'd] lived in all [his] life" and having "to call [his] wife to get directions home." He repeatedly hallucinated and "thought [he] was going crazy." He could not follow what customers were saying to him at work and once "literally

three or four" of his teeth "[fell] out right there [while] talking to a customer." He also confirmed that Insys's representations to his insurer that he had a current diagnosis of cancer were spurious.

- Sara Dawes testified that, while taking Subsys, she was "unable to function" and spent "most of [her] time in bed." When she stopped taking Subsys, she "was very, very, very sick and mentally couldn't hold it together" to the point that she had "a breakdown" and "drove off and left [her] kids on Christmas." She also testified that, contrary to what Insys had told her insurer, she never had cancer, never had taken methadone, and did not have difficulty ingesting generic fentanyl products.

- Betty Carrera testified that, while taking Subsys, she began having such phantasmagoric hallucinations that the police had to be called several times. She could not function and spent her days sleeping. She said that, when withdrawing from Subsys, she had nightmares and hallucinations, and she would "[wake] up at night screaming." She also contradicted Insys's representations to her insurer and testified that she never had issues swallowing.

- Woodrow Chestang described "slobber ... just run[ning] down [his] mouth," watching the clock, and craving more Subsys between doses. When he was unable to get Subsys, he experienced delirium tremens, nausea, and inability to eat or drink. He sometimes curled "into a fetal position" and realized that he was "burn[ing] up with fever." He added that, contrary to the information that Insys had given to his insurer, he neither had a history of cancer nor had previously been prescribed generic opioid containing fentanyl.

- Scott Byrd testified that Subsys was "life-changing" because "[i]t put [him] into an addiction state that [he] almost couldn't come out of." Because he used more than the quantity that his doctor had prescribed, he ran out early and experienced major withdrawal. He also swore that the signature on the opt-in form purportedly authorizing Insys to contact his insurer on his behalf was not his and, in fact, misspelled his name.

- Kendra Skalnican testified that she developed an addiction after starting on Subsys, and, as a result, began to take more of the medication than had been prescribed. When she ran out, she experienced severe withdrawal, sweating, vomiting, diarrhea, and pain all over her body. She told the jury that Subsys "made [her] addicted" and "[she] slept a lot of [her] life away." She also testified — contrary to information provided by Insys to her insurer — that she never had issue swallowing pills and never had tried other fentanyl products.

- Michelle DiLisio (previously Kamzyuk) testified that, while taking Subsys, she was lethargic, fatigued, dizzy, and felt "out of it." She reported that she suffered from severe withdrawal symptoms after she stopped taking the medication. And she made clear that the information that Insys had furnished to her insurer was false: she never had "any cancer ever" and, specifically, she never had ovarian cancer (indeed, she

had undergone ovary-removal surgery years before Subsys had been prescribed for her).

- Alicia Hinesley testified that Subsys made her "extremely sleepy" and led to difficulty in thinking. Sometimes she would sit or sleep all day. Belying Insys's statements that she was experiencing breakthrough cancer pain, she flatly denied that she ever had cancer. . . .

The district court appropriately found that the patient-harm testimony was relevant. To prove the CSA predicates, the government had to show that the defendants agreed that a healthcare practitioner would prescribe Subsys outside the usual course of medical practice and without any legitimate medical purpose. See Volkman, 797 F.3d at 391. The evidence of the patients' altered behavior, addiction, and withdrawal symptoms was plainly relevant to show that the doctors' treatment was outside the course of professional practice. This is particularly true where, as here, each doctor continued to prescribe Subsys to his or her patient despite knowing of the patient's addiction. Taking a practical view of what had transpired, the jury reasonably could have regarded the patient-harm testimony as powerful proof both that the coconspirator doctors prescribed Subsys in the absence of any medical necessity and that they failed to minimize the risk of adverse effects when setting dosages. In fine, the patient-harm testimony was relevant to show that the doctors contravened their professional obligations. See United States v. Singh, 54 F.3d 1182, 1187 (4th Cir. 1995). And we think it obvious that evidence that the doctors prescribed Subsys outside the usual course of professional practice while receiving kickbacks constitutes evidence relevant to show that the defendants had entered into an agreement to bring about exactly that result. See United States v. Rivera-Santiago, 872 F.2d 1073, 1079 (1st Cir. 1989) (explaining that "[t]he actions, as well as the words of the [coconspirators], are evidence of the existence and scope of a conspiracy"). On this record, evidence about the exploitation of addiction was relevant to show that all of the coconspirators, including the defendants, viewed addiction less as a societal problem and more as a pathway to predatory profits. . . .

The defendants erect a straw man. They submit that the patient-harm testimony "said nothing about what [they], who had no contact with any of these patients and no knowledge of [what] they were affected by Subsys, specifically intended." But as we already have discussed, a core component of the conspiracy to distribute Subsys was influencing doctors to "push the dose." The most logical reason for the defendants' unremitting efforts to increase dosages was their knowledge that patients on higher doses would refill their Subsys prescriptions while patients on lower doses would not. The patient-harm testimony showed vividly just how the "effective dose" messaging furthered the scheme. . .

To be sure, the patient-harm testimony packed a punch. Nevertheless, the issue is not prejudice simpliciter but, rather, whether particular evidence crosses the line into the forbidden realm of unfair prejudice. See United States v. Pitrone, 115 F.3d 1, 8 (1st Cir. 1997) ("[I]t is only unfair prejudice against which the law protects." (emphasis in

original)). The fact that addiction is ugly does not bar the government from offering evidence about it when — as in this case — the defendants' scheme has made addiction relevant and probative. See, e.g., United States v. Morales-Aldahondo, 524 F.3d 115, 120 (1st Cir. 2008) (holding that, although admitted images of child pornography "undoubtedly had an emotional impact on jurors," district court "properly balanced the competing concerns of Rule 403" when evidence was probative and court "limit[ed] the number of images presented"). In the last analysis, a "court is not required to scrub the trial clean of all evidence that may have an emotional impact, where the evidence is part of the Government's narrative." Id. at 120 (internal quotation omitted). . . .

Of course, any treatment of the opioid catastrophe in the field of corporate crime must include the most publicized case, the investigation and prosecution of Purdue Pharma, a private company long controlled by the Sackler family. As to the company, the Purdue matter concluded in 2020 with a massive "global" settlement involving a corporate guilty plea and the resolution of many related civil proceedings. Because the company was subject to a bankruptcy proceeding at the time of the settlements, the particulars of the relevant agreements are too long and complicated to tackle here.

The most important element of the Purdue settlement, of course, is the description of the criminal conduct in the case. Below is a portion of the summary of the facts included in the settlement agreement. The government's theory for Purdue's criminal liability was based principally on a conspiracy to defraud the U.S. government (specifically the DEA) and a conspiracy to violate the anti-kickback statute excerpted at the outset of this chapter. For by far the best comprehensive account to date, see PATRICK RADDEN KEEFE, EMPIRE OF PAIN: THE SECRET HISTORY OF THE SACKLER DYNASTY (2021).

ADDENDUM A TO SETTLEMENT AGREEMENT

I. Introduction

1. Purdue Pharma L.P.'s ("Purdue") profits declined precipitously in 2010 after the introduction of its Reformulated OxyContin, which was intended to be more difficult (though not impossible) to crush or manipulate for purposes of abuse and misuse.

2. Purdue attributed the majority of the decline to two trends: (i) individuals abusing opioids moving from OxyContin to opioids that were easier to abuse through insufflation or injection and (ii) increased scrutiny of prescribers, pharmacists, and other actors in the opioid distribution chain.

3. Purdue sought to recapture lost sales and increase Purdue's share of the opioid market.

4. As a result, from 2010 through approximately February 2018, Purdue developed and implemented several strategies to ensure that the revenues generated from its opioid prescriptions, including those that Purdue knew or should have known were not medically necessary, would continue to flow to Purdue.

5. At the center of these strategies was Purdue's aggressive marketing program that focused on detailing over 100,000 doctors and nurse practitioners nationwide each year, including thousands of prescribers that Purdue knew or should have known were prescribing opioids for uses many of which were not for a medically accepted indication, were unsafe, ineffective, and medically unnecessary, and/or were diverted for uses that lacked a legitimate medical purpose. By 2013, Purdue intensified its detailing of the very highest-volume prescribers, *i.e.*, those writing "25 times as many OxyContin scripts" as their similarly situated peers, because it knew that its detailing was highly effective in causing these prescribers to write more prescriptions for Purdue's opioids. This strategy was referred to as the "Evolve to Excellence" or "E2E" program.

6. Purdue also rewarded and induced prescriptions from some of its most lucrative prescribers by paying kickbacks through its Key Opinion Leader corporate advisor and speaker programs. Indeed, some of the prescribers whom Purdue paid through these programs were poor speakers, showed indicia of abuse and diversion, or, in at least one case, requested an express *quid pro quo* from Purdue employees.

7. Increasingly concerned that pharmacies would not fill OxyContin prescriptions as pharmacies and regulators increased safeguards against the filling of medically unnecessary prescriptions, Purdue developed and implemented a strategy to detail the pharmacies of its highest volume prescribers, including those that Purdue knew were writing medically unnecessary prescriptions, to ensure that Purdue opioids would be dispensed. Further, after Purdue determined that a large number of its prescriptions were still being rejected, Purdue considered an "alternative distribution strategy" and later developed a program focused on Hysingla through which it paid kickbacks to three specialty pharmacies to dispense prescriptions for Purdue's opioids that traditional pharmacies refused to fill.

8. Finally, from April 2016 through December 2016, Purdue paid kickbacks to Practice Fusion, an electronic health records company ("EHR"), to induce it to recommend and arrange for prescriptions of opioids by creating alerts that would appear within Practice Fusion's software while providers were seeing patients. Purdue did so with the intent that these alerts would cause more prescriptions for extended release opioids like those manufactured and sold by Purdue.

9. Through its marketing and kickbacks, from 2010 through 2018, Purdue knowingly caused the submission of false and fraudulent claims to Federal healthcare programs for its opioid drugs that were: (1) prescribed for uses that were not for a medically accepted indication, were unsafe, ineffective, and medically unnecessary, and that were often diverted for uses that lacked a legitimate medical purpose; or (2) tainted by illegal kickbacks.

II. Prior Resolution

10. In 2007, The Purdue Frederick Company, Inc. ("Purdue Frederick"), an affiliate of Purdue, pled guilty to misbranding OxyContin by falsely marketing it as less

addictive, less subject to abuse and diversion, and less likely to cause dependence and withdrawal than other pain medications. Purdue and Purdue Frederick also agreed to pay more than $600 million, of which over $100 million was paid to settle civil False Claims Act liability for knowingly causing the submission of false claims to Federal healthcare programs for OxyContin. In conjunction with the resolution, Purdue entered into a five-year Corporate Integrity Agreement with the Department of Health and Human Services, Office of Inspector General (OIG-HHS). OIG-HHS closed the corporate integrity agreement in January 2013.

III. Organization of Purdue Pharma

11. Purdue Pharma L.P. carries on operations, including distributing and selling the extended-release opioid drugs OxyContin, Butrans, and Hysingla. Prior to February 2018, it employed a sales force of, at times, over five hundred representatives to market its opioid drugs.

12. Purdue was owned (through trusts) and controlled by members of the Sackler family. Several members of the Sackler family served on the Board of Directors of Purdue Pharma Inc., which oversaw Purdue and certain related companies during the relevant time period.

13. The Sacklers, as members of the Purdue Board, exercised substantial oversight over management's operations of Purdue. For instance, in February of 2011, a memorandum observed: "There seems to be a consensus that the role of the board and that of the management is blurred compared with the distinctions made by other major corporations," and, historically, certain members of Sackler family functioned as "executives, management, board, and shareholders all-in-one [and] worked collaboratively with other managers on a daily basis."

14. As late as 2017, a high-level Purdue executive commented: "Three distinct business types (branded Rx [including Purdue]/biosimilars, consumer/OTC, generics) are being run through four separate regions (five if Rhodes is included), with the Board of Directors serving as the 'de-facto' CEO."

IV. The Opioid Drugs Purdue Manufactured, Marketed, Promoted, and Sold

A. OxyContin

15. Oxycodone is an opioid agonist with a morphine milligram equivalent ("MME") of 1.5 and a high potential for abuse similar to other opioids including fentanyl, hydromorphone, methadone, morphine, and oxymorphone.

16. It is classified as a Schedule II narcotic under the Controlled Substances Act, 21 U.S.C. § 801, *et seq*. ("CSA").

17. Purdue manufactured, marketed, promoted, sold, and distributed OxyContin, an extended-release oxycodone tablet, nationwide, including by sending sales

representatives to prescribers' offices and pharmacies, to persuade healthcare providers to prescribe and pharmacists to dispense OxyContin.

18. In April 2010, Purdue received FDA approval to market a reformulated version of OxyContin.

19. Reformulated OxyContin was more difficult to crush or dissolve, but FDA cautioned that Reformulated OxyContin "is not completely tamper-resistant and those intent on abusing this new formulation will likely find a means to do so. In addition, the product can still be misused or abused and result in overdose by simply administering or ingesting larger than recommended oral doses."

20. In August 2010, Purdue discontinued the original version of OxyContin.

B. Butrans

21. Buprenorphine is an opioid partial agonist with an MME of 12.6 that exposes users to the risks of addiction, abuse, and misuse. It is classified as a Schedule III narcotic under the CSA.

22. In June 2010, Purdue received FDA approval to market Butrans, a buprenorphine patch, and began manufacturing, marketing, promoting, and selling Butrans nationwide.

C. Hysingla

23. Hydrocodone is an opioid agonist with an MME of 1.0 that exposes users to the risks of addiction, abuse, and misuse. It is classified as a Schedule II narcotic under the CSA.

24. In November 2014, Purdue received FDA approval to market Hysingla, an extended-release hydrocodone tablet, which is formulated with abuse-deterrent properties, and began manufacturing, marketing, promoting, and selling Hysingla nationwide.

V. Purdue Knowingly Caused Medically Unnecessary Prescription to be Submitted to Federal Healthcare Programs

25. From 2010 to February 2018, Purdue engaged in strategies that resulted in prescriptions of its drugs for uses that were not for a medically accepted indication, were unsafe, ineffective, and medically unnecessary, and that were diverted for uses that lacked a legitimate medical purpose. Such prescriptions are not reimbursable by Federal healthcare programs.

26. The paragraphs below describe the fraudulent scheme to cause extreme high-volume prescribers to write medically unnecessary OxyContin prescriptions for Federal healthcare program beneficiaries.

A. "Calling On" and "Detailing" Prescribers Causes Them to Write More Prescriptions

27. Until it stopped marketing opioids in February 2018, Purdue sought to increase and maintain opioid sales by sending sales representatives to prescribers' offices and pharmacies to meet with prescribers in person; deliver company-developed messaging; give the prescribers meals (such as coffee, breakfast, and lunch) and marketing materials (such as articles, brochures, posters, and other media); and provide information about pharmacies stocking Purdue opioids and prescription coverage, including coverage under Federal healthcare benefit programs.

28. This practice is known in the pharmaceutical industry as "calling on" or "detailing" healthcare providers and pharmacies.

29. Purdue knew that calling on or detailing healthcare providers and pharmacies caused them to prescribe and dispense, respectively, more of Purdue's opioid drugs.

30. In September 2010, at a presentation to Purdue's sales supervisors, a Purdue executive explained: "As I have stated several times, we know increases in the prescriber call average will have the single largest impact of anything you can do to increase prescriptions of Purdue products with our core and super core prescribers."

31. Additionally, presentations related to E2E recognized: "Increased calls have a significant impact on OxyContin TRx."

32. Likewise, Purdue prepared return-on-investment analyses comparing the cost of detailing as compared to the OxyContin prescriptions that would not have been written but for Purdue's in-person marketing, as well as "sensitivity" analyses showing the impact of Purdue's detailing on OxyContin prescribing.

B. The Sales Revenue Purdue Calculated from Federal Healthcare Programs

33. Purdue knew that Federal healthcare programs paid claims for Purdue's opioid drugs, including OxyContin, and those payments accounted for a significant percentage of Purdue's revenue.

34. For example, an April 11, 2012, budget presentation to Purdue's Board of Directors showed that certain Federal healthcare programs accounted for over 30% of Purdue's revenue from sales of OxyContin.

35. Additionally, Purdue developed messaging and marketing materials associated with prescription coverage for OxyContin, including Federal healthcare program coverage, to induce prescribers to write OxyContin prescriptions for Federal healthcare program beneficiaries.

36. Purdue knew that it was reasonably foreseeable that its promotional activities for its drugs were a substantial factor in claims being submitted to Federal healthcare programs.

C. Purdue's Marketing of OxyContin After Reformulation.

37. Shortly after the introduction of Reformulated OxyContin, Purdue's profits declined, in large part, because some individuals who abused OxyContin moved to more easily manipulated opioids.

38. Purdue executives closely analyzed Purdue's internal data, including data purchased from vendors, in order to target high-volume prescribers and monitor their prescriptions.

39. Purdue ranked the prescribers based on their aggregate opioid prescriptions in deciles from numbers 1 through 10, with 10 being the highest.

40. From 2010 to 2013, Purdue instructed its sales force to primarily focus on the top three deciles of prescribers.

41. The purpose of focusing the sales force on these highest deciles of prescribers was to cause an even higher volume of prescriptions to be written by them.

42. Purdue knew, at that time, that the three highest deciles of prescribers combined accounted for only 1.5% of all opioid prescribers nationwide, but wrote 80% of all OxyContin prescriptions nationwide. Purdue also knew that these prescribers were the most responsive to Purdue's detailing.

43. Specifically, in June 2010, Purdue executives discussed instructing sales representatives to "build their target list with a focus on the highest prescribers across all three categories (Tier 1), and then fill in target list with the next highest potential and keep in front of OER [opioid extended release] high prescribers." . . .

44. While the targeting strategies and terminology differed over time, from 2010 through 2013, sales representatives were instructed to develop call plans around these high volume prescribers and detail them with the most frequency. In turn, sales representatives were rewarded with incentive compensation tied to the volume of OxyContin prescriptions generated from the health care providers they had detailed and faced corrective action plans, such as performance improvement plans, when they did not meet their sales goals. . . .

45. Purdue also found that, if it stopped detailing those extreme high-volume prescribers, the number of Purdue prescriptions written by them would not just have stayed stagnant - it would have declined. For example, on September 16, 2011, a Purdue executive stated that high-volume prescribers' OxyContin prescriptions decreased between 23 to 28% without detailing.

46. Approximately a year later, on July 13, 2012, a Purdue executive advised others that "OxyContin base sales will most likely erode with time when marketing programs are removed" and that incremental prescription lift was 32% after detailing by Purdue sales representatives.

D. Declining Sales and Higher Sales Goals

47. From 2010 to 2018, Purdue's profits were almost entirely driven by its success in selling OxyContin.

48. On January 25, 2010, Richard Sackler emailed other members of Purdue's Board: “By way of background, the most important driver of our sales growth or decline is the performance of all the oxycodone extended release forms in the market (called OER); this is comprised of OxyContin® tablets plus all the generics in the space.” By virtue of OxyContin's importance, certain of the Sacklers placed pressure on executives to meet OxyContin sales goals set by the Board and participated in decision-making regarding Purdue's sales strategies for OxyContin, at times overruling the targets set by Purdue's executives.

49. For example, in January 2010, Purdue executives and certain of the Sacklers engaged in an exchange regarding the executives' proposed 2010 budget.

50. The executives proposed that OxyContin growth should be pegged at 3%. Richard Sackler thought this target was too low and would "lead to an OxyContin[] tablets forecast that is almost the same as our sales in 2009." A Purdue executive informed Richard Sackler that "in looking at the recent [oxycodone extended release] prescription growth trends and knowing the overall dynamics of the market OxyContin competes in - I just can't see a way of the prescription growth tracking to a level substantially higher than the 3% on which this budget is based" and that the higher target suggested by Richard Sackler would "be interpreted as an imposition as opposed to an action that will stimulate the type of business building behaviors we want to encourage."

51. In response, Richard Sackler, who believed that Purdue's OxyContin growth target should be much higher, told a Purdue executive "I'm disappointed and don't agree with you. This is a matter that the Board will have to take up and give you a settled direction."

52. Later that month, on January 25, 2010, Richard Sackler emailed the Board and informed them that he had "engaged management on this subject," referring to the proposed 2010 budget, and explained his view that management's number was "unduly conservative."

53. On the same day, Mortimer D.A. Sackler followed up with Theresa Sackler regarding Richard's proposal, stating "we should push management to agree to a higher target."

54. After the release of Reformulated OxyContin in August 2010, OxyContin sales immediately began to decline.

55. Purdue management presented information regarding the slipping demand for Purdue's OxyContin to Purdue's Board in December 2010, showing that the total weekly kilograms dispensed of branded OxyContin declined from August to November 2010.

56. This downward trend continued the following year. On or about June 15, 2011, a Purdue executive prepared a memorandum to a Purdue executive, among others, identifying an expected budget shortfall of over $1 billion. The memorandum stated that "Kilograms dispensed have declined since the transition to the reformulated, primarily due to fewer 40mg and 80mg tablets being dispensed."

57. In or around June 20, 2011, a Purdue executive shared this information with the Board in a presentation stating, "Since the transition, 40 and 80mg tablet prescriptions have decreased significantly. The 10mg and 20mg tablet prescriptions initially increased, but given their lower value not enough to offset the higher strength decline." The presentation went on to revise the forecast of projected OxyContin sales from $3.9 billion to $2.8 billion.

58. Sales continued to trend downward in 2012.

59. On April 15, 2012, Richard Sackler emailed a Purdue executive, stating, "We should . . . discuss the sudden decline in [OxyContin] sales in the past year or two. What are we doing to identify corrective actions?" The following day, a Purdue executive forwarded Richard Sackler's email to another Purdue executive, among others, stating, "I am surprised that Dr. Richard is asking this. Since the decline is related to reformulation I'm not sure how to proceed with him."

60. On July 17, 2012, Mortimer D.A. Sackler emailed fellow Purdue Board members stating that Purdue should "start a search asap for a new CEO" and consider "replacing the head of sales and marketing."

61. In November 2012, looking back at the time period since Reformulated OxyContin replaced original OxyContin, a Purdue executive reported to Purdue's Board of Directors that there was a "Decline in OxyContin [Prescriptions] From Late 2010 Through 2011." The executive added that 2012 gross sales of OxyContin were "3.7%[] below budget" and 2012 net sales of OxyContin were "4.3% below budget due to lower prescription demand, lower trade inventory, and higher returns than budgeted."

62. In October 2013, Mortimer D.A. Sackler inquired directly with Purdue's leadership to request additional data concerning the downward trend in sales by dosage, requesting a chart to "show the breakdown of the OxyContin market share by strength against competitors. I would like to understand more the recent dynamics of the market and where the patients are shifting to that we are losing." Later that same day, responses to Mortimer's questions explained that the loss of sales was due to "the recent dynamics of the market," the pressures of increased government regulation, and that there were "fewer patients titrating to the higher strengths from the lower ones."

E. Post-Reformulation Decline Attributed, in Large Part, to Medically Unnecessary Prescriptions

63. Purdue studied the drivers of the post-reformulation OxyContin sales decline, and it attributed the decline, in large part, to a reduction in prescriptions written for

individuals who abused OxyContin through insufflation or injection and increases in safeguards intended to hinder medically unnecessary prescribing.

64. Purdue also conducted a number of post-marketing studies of Reformulated OxyContin.

65. Purdue's studies and analyses showed that the decline in overall OxyContin prescriptions was most pronounced among both extreme high-volume opioid prescribers and its highest dosage tablets, the 40 mg and 80 mg tablets.

66. Purdue also attributed approximately 40% of the decline in OxyContin prescriptions in 2010 to 2011 to "Region Zero" prescribers. Region Zero prescribers were prescribers that Purdue instructed sales representatives not to call on because, based on information maintained by its Abuse and Diversion Detection ("ADD") Program, Purdue determined that "there is a concern about potential abuse or diversion related activities" by them. Purdue had detailed information (down to the number of prescriptions written, product, and dosage) of Purdue products prescribed by all prescribers, including Region Zero doctors from which it could determine that Purdue had been making substantial profits from these prescriptions.

67. Purdue knew that the remainder of prescribers who experienced a significant drop in sales post-reformulation were not on Purdue's Region Zero do-not-call list, meaning representatives could continue detailing them.

68. At the December 2010 Board briefing, a Purdue executive discussed a chart stating that "Region 0 Accounts For Much Of The TRx Decline At The Regional Level."

69. In April 2011, Purdue prepared an excel sheet showing prescribers who experienced significant drops in prescriptions post-reformulation. Among the 134 prescribers listed in the prescription change analysis, Purdue was continuing to detail about one-third of them. The spreadsheet specifically identified substantial declines in prescriptions for 80 mg tablets.

70. On October 25, 2011, Purdue's Board received a copy of Purdue's September Executive Committee Meeting Notes & Actions, which provided Board members with information regarding the impact of Reformulated OxyContin on abuse.

71. Among the Board materials was a presentation stating that there was a "[d]ecline in 80 mg prescriptions, esp[ecially] among 'Do not Call' prescribers," and a "[s]hift in routes of abuse, especially injecting and snorting."

72. The study, which surveyed individuals being treated for opioid use disorder who reported abusing OxyContin through any route, also found that while the overall rate of OxyContin abuse decreased, some users continued to abuse Reformulated OxyContin through insufflation or injection-albeit with more difficulty-and that the percentage of users who reported abusing OxyContin through oral ingestion increased from 54% to 76% following the introduction of Reformulated OxyContin.

73. The materials provided to the Board in October 2011 also included a study, "Changes in Prescribing Patterns Following Introduction of Reformulated OxyContin: A Window into Diversion." The study examined a two-year period, August 2009 to July 2011, and found that data for Region Zero prescribers showed an 86% decline in their OxyContin prescriptions after Purdue's introduction of its reformulated version, and especially at the highest dosages, 40 and 80 mg tablets. The study found that prescribers suspected of abuse and diversion also prescribed the highest dose (80 mg) of OxyContin more frequently than other prescribers.

74. The study also found that Region Zero prescribers accounted for only 38.4% of the overall decline in sales post-reformulation, which Purdue attributed to reduced abuse of OxyContin. The remaining 61.6% of the decline was among other prescribers that were not on Purdue's Region Zero lists, meaning that sales representatives either were continuing to call on these prescribers or were permitted to do so.

75. Figures in the presentation further showed that immediate-release oxycodone prescribing increased at a similar rate (an approximately 32% increase) to the decline in 80 mg and 40 mg tablets of Reformulated OxyContin prescriptions (which experienced a 24% decrease and 26% decrease, respectively) among the non-Region Zero comparator prescribers, indicating that patients who had been abusing OxyContin may have been shifted to a non-reformulated oxycodone product that they could continue to misuse.

76. Versions of the presentation, including at least one provided to Richard Sackler in August 2013, repeated key findings, including: "Greater declines for doctors that were potentially problematic prescribers"; "Greater declines for high versus low dosage strengths"; "A small number of prescribers contribute to a large proportion of potential diversion of opioids from legal to illegal channels"; and "there were doctors in the [Purdue's] database who were prescribing painkillers 'for what appears to be the wrong reasons.'"

77. In sum, Purdue knew that, after the release of its Reformulated OxyContin, the product continued to be abused, but the method of abuse shifted to abuse through oral ingestion. Furthermore, Purdue knew that abuse and diversion appeared concentrated among a cohort of high-volume prescribers. As described below, certain of Purdue's marketing efforts were concentrated on extreme high-volume prescribers.

F. Decline in OxyContin Revenue Also Attributed to Safeguards Intended to Curb Abuse and Diversion.

78. At the same time, Purdue also attributed declines in OxyContin prescription revenue post-reformulation to safeguards intended to reduce medically unnecessary opioid sales, including increased scrutiny of opioid prescribing by law enforcement, wholesalers, distributors, and retail pharmacies.

79. For example, a Business Condition Report from a May 2-3, 2013 Board of

Directors Meeting described sales as being "$144mm behind Q12013 budget" with "$36mm attributed to lower Rx demand" and stated that "[p]ossible causes of fewer tabs/Rx in the market" include "Increased State Regulations"; "Anti-opioid environment"; and "Increased DEA/law enforcement scrutiny of physicians, pharmacies and wholesalers."

80. A consulting company that worked for Purdue since approximately the mid-2000s similarly attributed the decline in sales, in large part, to both the reformulation and safeguards against medically unnecessary prescriptions.

81. In 2013, the consulting company informed Purdue and its Board, that "[t]he retail channel, both pharmacies and distributors, is under intense scrutiny and direct risk."

82. More specifically, the consulting company explained "[t]here are reports of wholesalers stopping shipments entirely to an increasing number of pharmacies," "[m]any wholesalers are also imposing hard quantity limits on orders based on prior purchase levels," and "[p]harmacy chains are implementing guidelines for which patients can fill opioid prescriptions."

83. Later, Purdue's 2014 budget presentation to the Board listed these safeguards - intended to prevent medically unnecessary prescriptions of opioids, including OxyContin - among the "challenges" to achieving revenue goals.

G. Re-catalyzing Medically Unnecessary Prescriptions: Turbocharging Sales Through E2E.

84. On May 25, 2013 Richard Sackler had a call with a senior executive from the consulting company to discuss various business opportunities, including opportunities related to OxyContin.

85. On May 28, 2013, Purdue entered into a contract with the consulting company to "conduct a rapid assessment of the underlying drivers of current OxyContin performance, identify key opportunities to increase near-term OxyContin revenue and develop plans to capture priority opportunities."

86. Between July 18 and August 8, 2013, the consulting company provided several reports to a Purdue executive, at least two of which were provided to the Board, including the Sacklers.

87. The consulting company proposed that Purdue adopt what was later referred to as the "Evolve to Excellence" initiative, or "E2E."

88. The reports concluded that there existed a "significant opportunity to improve sales through better targeting."

89. "Better targeting" meant focusing sales calls on extreme high-volume opioid prescribers and removing sales representative discretion with respect to call plans.

90. Purdue and the consulting company analyzed Purdue prescription data and other Purdue data sources broken down by deciles based on, primarily, their opioid prescribing. According to Purdue and the consulting company's deciling calculations, the prescribers writing “25 times as many OxyContin prescriptions as" other providers - those within the top five deciles - comprised less than seven percent of all prescribers nationwide, but wrote approximately as many opioid prescriptions as the remaining 93 percent of prescribers combined.

91. The consulting company contended that, in contrast to the decile ranking undertaken by Purdue from 2010 to 2012, its rankings focused on "value deciles," which purported to be qualitatively different. In practice, the value decile ranking only enhanced Purdue's marketing focus on extreme high-volume prescribers and ensured a focus on Federal healthcare program beneficiaries.

92. The "value decile" analysis purported to use the following metrics: (1) overall opioid prescriptions, including number of branded versus generic prescriptions; (2) whether the prescriber had rules in place prohibiting sales representatives from calling on them; (3) managed care access, including access to Federal healthcare program beneficiaries; and (4) the number of the prescriber's new to brand prescriptions (including new opioid patients and switches from other opioid products).

93. The consulting company reports showed that the highest-volume prescribers were the most susceptible to marketing: detailing resulted in a 53% increase in prescriptions compared to only 33% for the middle decile prescribers. They also showed that, in the absence of detailing, high-volume prescribers' Purdue prescriptions would decline considerably.

94. The consulting company told Purdue and its Board that its proposed marketing plan would slow or reverse that decline and recapture those sales.

95. The memoranda asked Purdue to "make a clear go or no go decision on Turbocharging the Sales Engine," meaning implementing E2E.

96. On August 15, 2013, two Purdue executives discussed the consulting company's progress on evaluating growth opportunities for OxyContin with the Board. Their presentation noted that the analysis would include an examination of "relatively more sudden declines in tablets per prescriptions and prescriptions for 40 mg and 80 mg strengths" and "prescriber segmentation and targeting."

97. Later that same day, Richard Sackler emailed Mortimer D. A. Sackler: "The 'discoveries' of [the consulting company] are astonishing."

98. Richard Sackler subsequently arranged for a face-to-face meeting for the Board with the consulting company outside of the presence of Purdue executives.

99. On August 23, 2013, certain Sackler family members met with the consulting company and examined its "unvarnished" findings and recommendations.

100. Following the meeting, one of the consulting company partners that led the meeting with the Sacklers memorialized in an email: "[T]he room was filled with only family, including the elder statesman Dr. Raymond [Sackler]. We went through exhibit by exhibit for about 2 hrs. . . . They were extremely supportive of the findings and our recommendations . . . and wanted to strongly endorse getting going on our recommendations."

101. Another consulting company partner further remarked in the email correspondence that their "findings were crystal clear to" the Sacklers "and [the Sacklers] gave a ringing endorsement of 'moving forward fast.'"

102. After the "ringing endorsement" by the Sacklers, Purdue, in collaboration with the consulting company, implemented many of the consulting company's recommendations.

103. The Board received a presentation on E2E's implementation at the September 2013 Board meeting.

104. In September 2013, Richard Sackler emailed an advisor asking when Purdue could reach out to a newly-hired Purdue executive to brief him on E2E.

105. E2E took a multifaceted approach to increasing OxyContin prescribing and Purdue's profits. The consulting company recommended, among other strategies, refreshing Purdue's marketing messaging - particularly around titration to higher, more lucrative dosages -- and undertaking strategies to ensure prescriptions would be filled. At its core, however, E2E focused on intensifying marketing to the very highest-volume prescribers in the country by targeting them with increased frequency and minimizing sales representative discretion in identifying prescribers to target. The E2E call plans targeted the highest-volume prescribers in the country, and the program demanded stricter adherence with call plans than had existed in years past.

106. In late 2013, the Board received a 2014 Budget presentation again reviewing E2E's implementation. Board notes show the Board discussed ensuring E2E's funding at that meeting.

107. In sum, Purdue understood E2E's core strategies, namely, that it relied on generating prescriptions from extreme high-volume prescribers, and implemented it anyway.

H. E2E's Aggressive OxyContin Sales and Marketing Strategies.

108. E2E was overseen by the consulting company and some of Purdue's top executives through the creation of the E2E Executive Oversight Team ("EOT") and Project Management Office ("PMO").

a. Increasing the Frequency of Calls on Extreme High-Volume Prescribers

109. Based on a study showing that providers in deciles 7-10 were most responsive

to sales calls and were the most prolific writers, the E2E call plans instructed sales representatives to call on the very highest deciles of high-volume prescribers with the most frequency.

110. Specifically, Purdue instructed its sales representatives to call on the highest volume OxyContin prescribers (*i.e.*, those in so-called "deciles" 7 through 10) at least 24 times a year and "heavily favor" promoting OxyContin over other Purdue opioids in their messaging.

111. Purdue executives also emphasized the focus of E2E at national sales meetings: "The single core objective of E2E.is to make sure that we're making calls on the highest potential customers with the right frequency to maximize prescribing potential."

112. An email between two Purdue executives dated October 23, 2013, entitled "S&P Final Version" attached Board presentations, a 2014 Budget Presentation to the Board on OxyContin Tablets, which reflected that the extreme high-volume prescribers that E2E targeted were most sensitive to Purdue's marketing:

113. Speaker notes to this presentation discussed focusing on these top tier prescribers because "Increased calls with decile 8-10 prescribers have a significant impact on OxyContin® TRx growth" - an over 39% increase as compared to a decline of approximately 17% among prescribers receiving fewer calls.

b. Messaging to Cause High Volume Prescribers to Get More Patients on OxyContin and Titrate Patients to Higher Dosages

114. Purdue's sales and marketing departments prepared scripts, visual aids, brochures, and messaging for representatives to use with the providers they called on. A large part of this marketing was intended to cause the highest volume prescribers in the nation to "commit" to writing more OxyContin prescriptions.

115. At the same time, Purdue also refined its marketing message through the S.T.A.R.T. (Supplement, Titrate, Adjust, Reassess, Tailor) initiative by focusing sales conversations with prescribers on titrating patients to dosages.

116. The goal of the program was to discourage patient discontinuation of OxyContin due to perceived lack of pain relief by encouraging providers to increase the OxyContin dosage, or "titrate up."

117. For example, a 2011 script stated: "We discussed the discontinuation rate of extended-release opioids by day 35. One of the potential reasons for discontinuation is the lack of efficacy perhaps as a result of lack of titration." E2E created a refreshed 2014 version of the script that stated: "According to an analysis . 57% of patients initiated on some commonly prescribed extended-release opioids are no longer on those products by day 35," "Assuming a patient discontinues therapy by day 35 due to their perceived lack of pain relief, what is the impact on your patient, you and your staff? (pause for effect),"

and then "Doctor, working with you and your staff, I can provide support to you when initiating and titrating dosages on my products."

118. In addition, representatives were trained to "[o]vercome . . . objection[s]" raised by providers and get physicians to "commit" to prescribe more Purdue products. Specifically, representatives were trained to pivot from legitimate physician concerns about addiction to statements about "dependence" and opioid "tolerance." When asked about the safety of high dosages, representatives were instructed to respond that OxyContin "does not have a ceiling dose."

119. The Board received information concerning "OxyContin strength Rx history as well as statistical projections" that attributed the decline in sales of the high dosage tablets to "DEA pressures and 'good faith dispensing policies' at large chain pharmacies, *fewer patients switching into the ERO market from other products*, and there are *fewer patients titrating to the higher strengths from the lower ones*" (emphasis in original).

120. At the November 2013 meeting concerning Purdue's 2014 budget, a Purdue executive discussed with the Board the company's plan to "refine the message" of the company's titration up marketing campaign and specifically referenced the "Individualize the Dose" campaign, a Conversion & Titration Guide, and the S.T.A.R.T. principles to "highlight important elements of titration throughout the course of treatment."

121. Briefings to the Board also showed that the E2E marketing pushed by sales representatives in these calls specifically discussed titrating to higher dosages, initiating opioid naive patients on opioid therapy, and switching patients from immediate release opioids to Reformulated OxyContin.

122. In December 2013 correspondence, a Purdue executive told the Board that "[t]he E2E sales force focus/effectiveness initiatives [that] are being implemented starting October 2013 through April 2014 are already showing positive results."

I. Purdue's Internal Systems Confirm That E2E Caused Medically Unnecessary Prescribing

123. Purdue's Abuse and Diversion Detection ("ADD") program and Region Zero list contain examples of high-volume prescribers detailed during E2E that Purdue's own employees suspected were writing medically unnecessary prescriptions.

124. At all relevant times, Purdue maintained an ADD program, through which Purdue had the means and ability to identify prescribers suspected of engaging in abuse and diversion.

125. The ADD program began in or around 2002 and ended in or around February 2018. It was governed during most of that time period by Standard Operating Procedure ("SOP") 1.7.1.

126. SOP 1.7.1 instructed Purdue employees to refer prescribers who displayed indicia of abuse and diversion to ADD. Employees referred these prescribers to ADD by issuing a Report of Concern ("ROC").

127. The indicia of abuse and diversion in SOP 1.7.1 were amended over time and included, among other things, excessive numbers of patients; brief or nonexistent contact with patients; high numbers of cash pay patients; information that a prescriber or his or her patients may be diverting opioids; allegations of patient overdoses; allegations of unauthorized individuals signing prescriptions; large numbers of patients traveling long distances; and allegations that a prescriber is under investigation.

128. After prescribers were referred to ADD, Purdue reviewed information concerning the prescribers to determine whether Purdue should continue to market its opioids to them.

129. If Purdue determined a sales representative should not continue to call on a prescriber, the prescriber was placed on the Region Zero list.

130. Purdue was aware that Region Zero providers were responsible for a major drop in sales after Reformulated OxyContin was released, and that there were also declines among prescribers that were not on Region Zero that Purdue sales representatives could continue to detail.

131. Purdue sales representatives were trained to report prescribers suspected of abuse and diversion to ADD, and some sales representatives did so.

132. However, high-volume prescribers were often not reported and, even if they were, they were sometimes not added to Region Zero until they lost the ability to prescribe through legal or medical board action. In addition, certain Purdue policies resulted in high-volume prescribers not being reported to ADD, and thus not being added to Region Zero. For example, Purdue trained its sales representatives to only report clear instances of abuse and diversion, and sales representatives were instructed to discuss the reports with their district managers prior to filing. In addition, although Purdue's policy stated that it required timely reporting, Purdue had few, if any, effective compliance measures to address an employee's failure to report, and very few sales representatives were penalized for failing to timely report.

133. Purdue's Sales and Marketing Department tracked prescribing of opioids by all health care providers, including providers included in ADD and Region Zero, placing them into deciles as described above. ADD contained a field that reflected whether a health care provider was a high-volume prescriber. When the sales force petitioned for a prescriber to be removed from Region Zero so that detailing of him or her could resume, and when ADD reviewed such petitions, both the sales force and ADD were aware of the volume of sales generated by that prescriber.

134. From 2002 through the end of 2012, Purdue conducted various data analyses to identify prescribers with red flags for abuse and diversion. The red flags included

prescribers with high numbers of prescriptions for 80mg tablets; prescribers with large numbers of patients that used multiple prescribers or pharmacies; and prescribers with large numbers of cash paying patients.

135. Purdue also evaluated prescribers whose prescriptions declined sharply following reformulation.

136. Although the analyses identified many red flag prescribers, only a fraction were reviewed as part of the ADD program and Purdue knowingly continued detailing others without any further scrutiny.

137. Further, even for those prescribers who were placed on Region Zero, Purdue engaged in other practices to increase those prescribers' opioid prescriptions.

a. Purdue permitted sales representatives to continue calling on other members of the exact same practice, although doing so could increase the prescriptions of the Region Zero prescriber;

b. Purdue detailed its highest-volume prescribers' pharmacies in order to increase the likelihood that Region Zero prescriptions would be filled; and

c. Purdue permitted sales representatives and managers to petition to have Region Zero status reversed so they could resume calling on Region Zero prescribers. These petitions were sometimes granted.

138. For example, in 2012, Purdue employees petitioned for over 180 mid to high-decile Region Zero providers to be reinstated.

139. Purdue also failed to maintain updated and complete Region Zero lists.

140. Purdue knowingly continued detailing prescribers suspected of abuse and diversion, including at times after a ROC was filed with ADD.

Doctor-1

141. From January 2010 through May 2018, Purdue representatives detailed Doctor-1 at least 300 times, although calls after February 2018 did not promote opioid products. During this time, the doctor caused the submission of a high number of OxyContin claims to Medicare.

142. Purdue knew that Doctor-1 was prescribing medically unnecessary opioids. From 2009 through 2011, Purdue received at least three different ROCs about Doctor-1.

143. In October 2009, a Purdue sales representative reported: "Pharmacist . . . says they've had all kinds of problems with abuse and diversion of Oxycontin . . . [Pharmacist] said [he] and [other doctor] are too lose [sic] when writing prescriptions of Oxycontin. He says of the patients he thinks are selling their prescriptions, he has notified the

doctors, but nothing has changed."

144. In June 2010, the sales representative further reported: "the pharmacy manager, says [the doctor] is known as the "Candyman" . . . because she will immediately put every patient on the highest dose of narcotics she can, whether it's Oxycontin or another product. He says when he goes to local pharmacist meetings, when her name comes up everyone in the room cringes and moans because of her practices. He says she is doing all kinds of wacky dosing and tablet strengths. He says he feels like she is not doing what she should be doing with medications. On occasion he has refused to fill prescriptions from her office. He said he's been seeing some crazy dosing of Oxycontin coming in, especially from [Doctor-1]."

145. In July 2010, a Purdue sales representative reported: Another physician "said he had a patient from [the doctor] who was on 80 mg 5 times per day. He thought this was over the top and asked me today what the maximum dose was. He felt this patient was definitely exceeding it. I told him since it was a single entity opioid, there is no ceiling dose. It is only limited by side effects. He said he would not continue this type of dose."

146. The same representative "became concerned on March 18, 2010, when she realized that patients were being treated by . . . a registered nurse without prescribing privileges, in [the doctor's] absence. According to [the representative], this 'was not an isolated incident.'"

147. The representatives' call notes showed other instances where Doctor-1 was absent during business hours, including a February 2010 incident when the doctor left in the middle of the day to get a tattoo.

148. The ADD program placed Doctor-1 on Region Zero and instructed sales representatives to cease calling on the doctor in August 2010.

149. However, in October 2011, Purdue informed sales representatives that they may resume calling on Doctor-1, and the sales representatives did so until the spring of 2018.

150. Purdue's detailing caused Doctor-1 to write medically unnecessary prescriptions for OxyContin, claims for which were submitted to Federal healthcare programs.

Doctor-2

151. From January 2010 to May 2018, Purdue representatives detailed Doctor-2 at least 260 times, although calls after February 2018 did not promote opioid products.

152. During this time, Doctor-2 caused Medicare claims for OxyContin, the overwhelming majority of which were for OxyContin 80mg tablets.

153. On September 23, 2003, a Purdue employee flagged Doctor-2 for ADD review stating, "Have you looked at the doctor with [the doctor's ME number]? This person is in specialty decile 7 and has about twice the volume as anyone else in that decile."

154. Purdue performed an ADD review in July 2004 after reviewing information showing the doctor had abnormally high opioid volume and a high percentage of cash-paying patients, and receiving reports that the doctor was under investigation for his opioid prescribing. The ADD team did not place Doctor-2 on the Region Zero list at that time.

155. Doctor-2's name came up again in 2008 and 2009 in connection with Purdue's internal investigation of a diverting pharmacy. The investigation revealed, in part, the following red flags regarding the pharmacy, including: it was a high traffic pharmacy; cars observed at the pharmacy had out of state plates; it had pharmacy clients loitering outside; it had pharmacy clients entering and exiting vehicles not their own; and it had pharmacy clients exchanging prescription drugs. As part of the investigation, Purdue identified Doctor-2 as one of the "Three (3) Main Doctors who prescribe for [pharmacy]," but undertook no further review of the doctor after this event.

156. Purdue sales representatives' call notes also identified ongoing concerns regarding abuse by the doctor's patients. For example, a 2010 call note stated: "Had a patient that died this week that was taking OxyContin (2 tablets of 80mg at Q12h). She was 45-48 years old and had been seen by [the doctor] for 10 years. The patient had complained previously (was reported) that the reformulation made her sick and tried to get a refund for the reformulation (the pharmacy refused). She did find generic OxyContin. Patient was found dead sitting at the kitchen table with a syringe beside her. It has been ruled as an accidental death by the police."

157. Following the reformulation of OxyContin, Doctor-2 was flagged for review by a December 2010 data analysis due to the doctor's drop in Reformulated OxyContin prescription rates. Months after the analysis, on August 1, 2011, Purdue completed an ADD review, deciding to take no action based on Doctor-2's explanation for why he stopped prescribing Reformulated OxyContin.

158. In early 2013, the state Board of Medical Examiners filed a complaint against Doctor-2 outlining his practice of prescribing OxyContin and other opioids outside the course of legitimate medical practice, which detailed the excessive amounts of OxyContin he prescribed to certain patients.

159. On February 27, 2013, a Purdue sales representative filed a ROC that Doctor-2 was subject to disciplinary action by the Board of Medical Examiners. On April 5, 2013, Doctor-2 was placed on the Region Zero list. Purdue representatives had detailed Doctor-3 146 times between 2007 and his addition to Region Zero in April 2013.

160. Although under ADD review since February 27, 2013, Purdue sales representatives called on Doctor-2 several more times until April 5, 2013.

161. Four months later, on August 26, 2013, a Purdue sales representative requested to resume calling on the doctor. In response, the ADD program wondered if it was "[t]oo soon to put him back on the list." It initially recommended a "resume call" status due to

a "lack of progress on the resolution of the board's complaint and the doctor's continuation in practice," but, after further discussion, kept him on Region Zero.

162. In February 2015, the same Purdue sales representative again requested that the doctor be removed from the Region Zero list. The doctor was removed from the list on March 2015 after an "Expedited Review" of requests to resume calling on several high-volume doctors. Purdue sales representatives detailed Doctor-2 an additional 117 times between March 2015 and spring 2018, although calls after February 2018 did not promote opioid medications.

163. In sum, Purdue's detailing caused Doctor-2 to write medically unnecessary prescriptions for OxyContin, claims for which were submitted to Federal healthcare programs.

Doctor-3

164. From January 2010 through March 2013, Purdue sales representatives detailed Doctor-3, who was, at one time, the highest volume Medicare prescriber of opioids in the nation, over 100 times. The majority of Doctor-3's prescriptions were for 80 mg tablets.

165. Doctor-3 surrendered his medical and DEA licenses in 2013. In October 2016, Doctor-3 pled guilty to distribution of a controlled substance and healthcare fraud.

166. Over the course of a little over a year, Purdue's ADD program received at least five ROCs concerning Doctor-3. Additionally, Doctor-3's practice had numerous, easily identifiable indicia of abuse and diversion, including large numbers of high dosage patients, long lines of patients waiting outside his clinic, brief or nonexistent patient examinations, and drug transactions in the parking lot. Yet, Doctor-3 was not placed on Region Zero during this time period and sales representatives were directed to continue calling on him.

167. In fact, Doctor-3 was not placed on Region Zero at all until he lost his medical license and could no longer prescribe Purdue's opioids.

168. Purdue's detailing caused Doctor-3 to write medically unnecessary prescriptions for OxyContin, claims for which were submitted to Federal healthcare programs. . . .

VI. Kickbacks to Doctors to Induce and Reward Prescriptions

169. As an additional means to induce doctors to prescribe Purdue's opioid drugs, from 2010 through at least March 2018, Purdue paid kickbacks to certain prescribers in the form of speaker programs, advisory board memberships, research programs and honoraria.

170. Purdue allowed its sales and marketing personnel, who had data on each doctor's prescribing of Purdue's drugs and whose compensation depended on increasing their assigned doctors' prescribing of Purdue's drugs, to select speakers instead of Purdue's

medical education staff.

171. Purdue also allowed its sales representatives to relay and endorse doctors' requests to be retained, and the doctors could be selected even if they had not been identified by the consulting company Purdue had retained for this purpose. Within Purdue, these were known as "unsolicited requests."

172. Purdue vested final authority to select doctors in Purdue's Marketing department, which had data on each doctor's Purdue prescriptions.

173. Purdue's list of speakers included providers that Purdue knew or should have known were writing prescriptions that were not for a medically accepted indication; for uses that were unsafe, ineffective, and medically unnecessary; and/or that were diverted for uses that lacked a legitimate medical purpose.

174. Under the processes described above, Purdue knowingly and willfully selected doctors to retain as paid corporate advisors and speakers specifically to induce them to prescribe and reward them for prescribing Purdue's drugs in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (AKS).

175. For example:

a. Purdue paid the highest-volume OxyContin prescriber in the United States over $160,000 between 2013 and May 2018 because he was, in the words of Purdue's employees, "the biggest prescriber in CT," "the #3 prescriber of opioids nationally," and "very important to our success," even after he indicated that if he stopped receiving speaking assignments from Purdue, "the love may be lost."

b. Purdue paid the highest-volume OxyContin prescriber in Medicare approximately $475,000 between 2013 and January 2017 to deliver speeches and advice even though Purdue observed he was "not a strong speaker or presenter" and "attendees couldn't follow him," he engaged in "heavy prescribing, particularly in large doses for long periods of time," and was excluded by Florida Medicaid.

Purdue paid more than $110,000 to a high-volume prescriber who demanded speaking assignments or else he would "re-evaluate the use of [Purdue's] products.". . .

Problem 6-3

Much more has been written, and remains to be written, about the opioid scandal, of course. Based on just the information in this chapter, what might this particular and massive problem teach us about the matter of corporate crime generally—as a matter of law, enforcement policy, corporate management, politics, etc.?