From:	Abrams, Jill
To:	csmith@sch-llc.com
Cc:	Mishaan, Jessica
Subject:	Public Records Request for Information Pertaining to Opioid Settlements and Judgments
Date:	Friday, June 21, 2019 1:44:14 PM
Attachments:	Records Request.zip PR Response to Coopers Law Firm.pdf

Dear Ms. Smith,

Please see the attached letter and documents in response to your public records request. Feel free to contact me if you have any questions.

Jill

Jill S. Abrams
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STATE OF VERMONT
OFFICE OF THE ATTORNEY GENERAL
109 STATE STREET
MONTPELIER, VT
05609-1001

June 21, 2019

VIA EMAIL
Claris Smith
Cooper Law Firm
1525 Religious Street
New Orleans, Louisiana 70130

Dear Ms. Smith:

Attached please find, in a zipped file, records in response to your public record act request dated May 24, 2019.

As we discussed during our May 28, 2019 telephone conversation, and as confirmed by our May 28, 2019 email exchange, we searched for complaints filed by the Attorney General's Office ("AGO") against any opioid manufacturer listed on the spreadsheet you provided, the subject matter of which is an opioid listed on the spreadsheet you provided; and any settlement or judgment entered into by the AGO with any opioid manufacturer listed on the spreadsheet you provided, the subject matter of which is an opioid listed on the spreadsheet you provided. Because our matters are generally retained according to party names rather than product names, we performed our search using the manufacturer names you provided.

As I mentioned, our record retention policy requires us to retain records for six years after an enforcement action is completed or closed. We searched for records for the time period from May 24, 2013 to the present. As we agreed, the AGO has also produced the 2007 Consent Judgment we entered into with Purdue.

We hope the attached and above information is helpful to you.

Sincerely,

Jill S. Abrams
Assistant Attorney General
Director, Consumer Protection Division

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

STATE OF WISCONSIN
By Attorney General Brad D. Schimel

STATE OF ALABAMA
STATE OF ALASKA
STATE OF ARKANSAS
STATE OF CALIFORNIA
STATE OF COLORADO
DISTRICT OF COLUMBIA
STATE OF CONNECTICUT
STATE OF DELAWARE
STATE OF FLORIDA
STATE OF GEORGIA
STATE OF HAWAII
STATE OF IDAHO
STATE OF ILLINOIS
STATE OF IOWA
STATE OF KANSAS
COMMONWEALTH OF KENTUCKY
STATE OF LOUISIANA
STATE OF MAINE
STATE OF MARYLAND
COMMONWEALTH OF MASSACHUSETTS
STATE OF MICHIGAN
STATE OF MINNESOTA
STATE OF MISSISSIPPI
STATE OF MISSOURI
STATE OF NEBRASKA
STATE OF NEW HAMPSHIRE
STATE OF NEW MEXICO
STATE OF NEW YORK
STATE OF NORTH CAROLINA
STATE OF OHIO
STATE OF OKLAHOMA
STATE OF OREGON
COMMONWEALTH OF PENNSYLVANIA
STATE OF RHODE ISLAND
STATE OF SOUTH CAROLINA
STATE OF TENNESSEE
STATE OF UTAH
STATE OF VERMONT
COMMONWEALTH OF VIRGINIA
STATE OF WASHINGTON

No.2:16-CV-5073(MSG)

STATE OF WEST VIRGINIA

Plaintiffs,

v.

INDIVIOR INC. f/k/a RECKITT BENCKISER PHARMACEUTICALS, INC.;
RECKITT BENCKISER HEALTHCARE (UK) LTD.;
INDIVIOR PLC; and
MONOSOL RX, LLC

Defendants.

FIRST AMENDED COMPLAINT

The States of Wisconsin, Alabama, Alaska, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee, Utah, Vermont, Washington, West Virginia, the Commonwealths of Kentucky, Massachusetts, Pennsylvania, and Virginia, and the District of Columbia, by their Attorneys General, (collectively "Plaintiff States"), complain against Defendants Indivior Inc., f/k/a Reckitt Benckiser Pharmaceuticals, Inc.; Reckitt Benckiser Healthcare (UK) LTD.; Indivior PLC (collectively "Reckitt" or "Reckitt Defendants"); and MonoSol Rx, LLC ("MonoSol") as follows:

Nature of the Action

1. Plaintiff States bring this action with respect to the prescription drug Suboxone® ("Suboxone") and its generic equivalent, co-formulated buprenorphine hydrochloride and naloxone hydrochloride dehydrate ("co-formulated buprenorphine/naloxone").

2. Co-formulated buprenorphine/naloxone is a combination drug product consisting of two active pharmaceutical ingredients that are used together as an opioid replacement therapy for the treatment of opioid dependency (e.g., heroin addiction). Defendants are engaged in the manufacture or sale of co-formulated buprenorphine/naloxone under the brand-name Suboxone.

3. Plaintiff States allege that Defendants employed an unlawful, multi-pronged scheme designed to prevent or delay less expensive generic versions of Suboxone from entering the market to preserve their monopoly profits from the sale of Suboxone. The scheme included product hopping, unfounded allegations of safety issues with the Tablet form of Suboxone, intentional delays involving the U.S. Food and Drug Administration's (the "FDA") requirement of a Risk Evaluation and Mitigation Strategy ("REMS"), and filing a sham citizen petition to delay would-be competitors.

4. As a result of their unlawful scheme to keep generic versions of Suboxone off the market, and in violation of federal and state antitrust laws and state consumer-protection laws, Defendants illegally maintained monopoly power in the market for co-formulated buprenorphine/naloxone opioid treatments in the United States from October 8, 2009 until generic entry in March 2013, and continue to dominate the market for co-formulated buprenorphine/naloxone film.

5. Defendants' scheme to delay generic competition intended and had the purpose of, preventing generic substitution to Suboxone, and denying consumer choice for generic versions of Suboxone.

6. As a result of Defendants' anticompetitive conduct, consumers and state governments have been limited in their treatment options for opioid addiction and continue to be

deprived of the benefits of generic competition while Defendants continue to reap monopoly profits from the sale of Suboxone.

7. Defendants' conduct is deceptive and unconscionable, includes unfair trade practices and unfair methods of competition, or is otherwise unlawful under the antitrust and consumer protection laws of the Plaintiff States. Their conduct causes harm to Plaintiff States, governmental entities, and consumers by forcing them to pay more for Suboxone than they otherwise would in a competitive market, and limits their options for the treatment of opioid addiction.

8. Consequently the Plaintiff States, by and through their Attorneys General, bring this action to seek injunctive relief, penalties, and disgorgement for the Defendants' unlawful conspiracy and monopolization of the market for co-formulated buprenorphine/naloxone for treating opioid addiction.

Jurisdiction & Venue

9. This Court has subject matter jurisdiction under 15 U.S.C. §§ 1 and 2, 15 U.S.C. § 26, and 28 U.S.C. §§ 1331 and 1337 over the federal antitrust claims. This Court also has supplemental jurisdiction over the state law claims under 28 U.S.C. § 1367 because those claims are so related to the federal claims that they form part of the same case or controversy. The exercise of supplemental jurisdiction avoids unnecessary duplication and multiplicity of actions and is in the interests of judicial economy, convenience, and fairness.

10. Venue is proper in the Eastern District of Pennsylvania under 15 U.S.C. § 22 and 28 U.S.C. §§ 1391(b) and (c). Each Defendant transacts business or committed an illegal or tortious act in this district, or has an agent or can be found in this district, and the interstate trade and commerce, hereinafter described, is carried out in substantial part in this district.

Parties

11. Defendant Indivior Inc. f/k/a Reckitt Benckiser Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business located at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia 23235. Indivior Inc. is a wholly-owned subsidiary of Indivior PLC. Indivior Inc. is engaged in the development, manufacture, and sale of Suboxone throughout the United States, and is in whole or in part responsible for some or all of the conduct alleged in this Complaint and attributed to Reckitt.

12. Defendant Reckitt Benckiser Healthcare (UK) Ltd. is a British corporation incorporated under the laws of England and Wales, with its registered office located at 103-105 Bath Road, Slough, Berkshire, SL1 3UH. This defendant is engaged in the development and manufacture of pharmaceuticals, including Suboxone, and health care products and services made and sold subject to FDA approval, and is in whole or in part responsible for some or all of the conduct alleged in this Complaint and attributed to Reckitt. This conduct includes but is not limited to the execution of the initial contract with MonoSol Rx, LLC in December 2006 that initiated the joint venture to create and manufacture Suboxone Film. Reckitt Benckiser Healthcare (UK) Ltd. also established the parameters for the timing of the launch and the formulation of Suboxone film, gathers, and investigates all consumer complaints as to Suboxone products, trademarked the names for the financial programs to encourage the switch from Suboxone tablets to film, and obtained patents together with MonoSol related to Suboxone film development. Reckitt Benckiser Healthcare (UK) Ltd. monitored the taste and quality of Suboxone film, prepared materials for regulatory approval of Suboxone film, manufactured and supplied the ingredients for Suboxone film, and provided grants for the study of Suboxone.

13. Defendant Indivior PLC is a British corporation incorporated under the laws of England and Wales, with its registered office located at 103-105 Bath Road, Slough, Berkshire, SL1 3UH. This defendant is engaged in the development, manufacture, and sale of Suboxone throughout the United States, and is in whole or in part responsible for some or all of the conduct alleged in this Complaint and attributed to Reckitt. Indivior PLC was formed in 2014 as a new company. Shortly thereafter, Reckitt Benckiser Group plc ("RB Group") sold the assets of a collection of companies, including Defendant Indivior, Inc., from RB Group to Indivior PLC. By the terms of the sale, ownership of all assets and operations related to the production of Suboxone transferred to Indivior PLC. Additionally, RB Group shareholders received one share of stock in Indivior PLC for each share of RB Group stock that they owned. Indivior PLC has expressly agreed to indemnify RB Group in respect to any claims and expenses incurred by any company within the Indivior Group or the RB Group arising out of or associated with the Indivior business prior to the transfer. Indivior PLC holds itself out as the manufacturer of Suboxone, and describes itself as the successor company to Reckitt Benckiser Pharmaceuticals, Inc., which was the company that manufactured Suboxone during the period of time in which most of the relevant conduct occurred. Indivior PLC has current and former overlapping directors with Reckitt Benckiser Pharmaceuticals, Inc. and Indivior, Inc., and many of the individuals who participated in the conduct alleged herein are now employed by Indivior PLC. Indivior PLC, and Indivior Inc. completed work orders initially received by Reckitt Benckiser Pharmaceuticals, Inc. and inherited its customers. Unless identified individually, Reckitt Benckiser Healthcare (UK) Ltd., Indivior PLC, and Indivior, Inc., f/k/a Reckitt Benckiser Pharmaceuticals, Inc., are collectively referred to as "Reckitt."

14. Defendant MonoSol Rx, LLC is a Delaware limited liability company with its principal place of business located at 6560 Melton Road, Portage, Indiana, 46368. This defendant is engaged in the development, manufacture, and sale of pharmaceuticals, including Suboxone, throughout the United States.

15. Reckitt's actions described in this Complaint are part, and in furtherance of, the illegal monopolization, attempted monopolization, conspiracy to monopolize, restraint of trade, and unfair and deceptive trade practices alleged herein. All actions described herein were authorized, ordered, or performed by Reckitt's various officers, agents, employees or other representatives while actively engaged in the management of Reckitt's affairs, or that of their predecessors-in-interest, within the course and scope of their duties and employment, and with the actual, apparent, and ostensible authority of Reckitt.

16. MonoSol's actions described in this Complaint are part, and in furtherance of, the monopolization conspiracy and unfair and deceptive trade practices alleged herein. All actions described herein were authorized, ordered, or performed by MonoSol's various officers, agents, employees or other representatives while actively engaged in the management of MonoSol's affairs, or that of their predecessors-in-interest, within the course and scope of their duties and employment, and with the actual, apparent, and ostensible authority of MonoSol.

17. Government entities and consumers residing throughout the Plaintiff States purchased or provided reimbursement for Suboxone Film and Suboxone Tablets at supra-competitive prices as a result of Defendants' conduct alleged herein.

18. Plaintiff States bring this action, by and through their Attorneys General, in their sovereign and quasi-sovereign capacities to enforce their own laws and to protect the economic well-being of the States and their residents from the harm that results from the violations of law.

Relevant Market

19. The relevant product market is any drug with co-formulated buprenorphine/naloxone as the active ingredients for the treatment of opioid addiction. There are no feasible substitutes for co-formulated buprenorphine/naloxone in the pharmacological intervention of opioid dependence. This market includes Suboxone Film and Tablets and any AB-rated generics that can be substituted for them.

20. Suboxone Tablets and Suboxone Film do not exhibit significant, positive price cross-elasticity of demand with any opioid dependence treatment or other product other than AB-rated generic versions of buprenorphine/naloxone tablets. Suboxone is categorized as a schedule III drug and co-formulated with an opioid antagonist to deter abuse. Until 2013, Suboxone was the only replacement maintenance therapy that could be prescribed in an office setting and taken by patients at home. By contrast, Methadone, is a Schedule II drug and must be administered in a clinic. Subutex, another opioid treatment drug marketed by Reckitt, is not interchangeable because it lacks naloxone, the opioid antagonist that deters abuse. Zubsolv (a generic buprenorphine/naloxone tablet) and Bunavail (a generic buprenorphine/naloxone film) entered the market after generic Suboxone Tablets. Zubsolv and Bunavail are not AB-rated to the Film or Tablets.

21. The relevant geographic market is the United States and its territories.

22. Before October 8, 2009, Suboxone was the only co-formulated buprenorphine/naloxone opioid treatment because of its orphan drug status, so Reckitt enjoyed 100 percent market share in the United States and its territories. After the exclusivity period expired, Reckitt's branded Suboxone products, including the Suboxone Film it introduced in September 2010, remained the sole source of co-formulated buprenorphine/naloxone until two

generic manufacturers introduced generic tablets in March 2013. An additional generic tablet manufacturer was approved in September 2016. When Suboxone-branded Tablets and Film were sold alongside one another, Reckitt successfully converted most of the Suboxone market to its Film, for which there are no generic substitutes. After the introduction of the two generic tablet products in 2013, Reckitt's market share for co-formulated buprenorphine/naloxone dropped to 68 percent.

Trade and Commerce

23. Since 2002, Reckitt has sold Suboxone in interstate commerce throughout the United States.

24. Reckitt sold Suboxone in interstate commerce in each of the States. Reckitt's unlawful activities alleged in this Complaint occurred in and had a substantial effect upon interstate commerce. According to Reckitt's own annual reports, Reckitt's revenues for Suboxone sold in the United States surpassed $2 billion.

25. MonoSol entered into a series of agreements with Reckitt, beginning in 2006, for the development and manufacture of Suboxone Film. MonoSol manufactures all Suboxone Film sold in interstate commerce in each of the States. MonoSol's unlawful activities alleged in this Complaint have occurred in and have had a substantial effect on interstate commerce. MonoSol has received fixed payments as well as royalties associated with the sales of Suboxone Film.

Factual Background

I. Generic Drug Approval Process

26. The manufacture and commercial sale of pharmaceutical drugs are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. The manufacturer of a new drug must submit a new drug application ("NDA") that demonstrates,

among other things, a drug's safety, clinically proven effectiveness, composition, and patent coverage.

27. To speed the entry of generic drugs and to facilitate price competition with branded drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). Under the Hatch-Waxman Act, generic drug manufacturers may receive FDA approval for generic drugs without replicating the costly and time-consuming clinical trials involved in an NDA.

28. Instead of submitting an NDA, a generic drug manufacturer may submit an abbreviated new drug application ("ANDA") and incorporate data, such as clinical studies, that the NDA filer submitted to the FDA.

29. To be approved, an ANDA must demonstrate that the generic drug: (a) has the same active ingredients as; (b) is pharmaceutically equivalent to (same dosage form and strength); and (c) is bioequivalent to (exhibiting the same drug absorption characteristics) the previously approved drug.

30. Oral drugs that are proven to be both pharmaceutically equivalent and bioequivalent to a branded oral drug receive an "AB" rating from the FDA, indicating they are therapeutically equivalent to other drugs with the same rating in the same category. In most circumstances, only oral drugs that carry the FDA's AB generic rating in a particular category may be substituted by pharmacists for a physician's prescription for a brand-name drug without the physician's approval.

31. The FDA publishes a list of all approved drugs and therapeutic equivalents in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book").

32. Once the FDA approves an ANDA for a generic drug and determines that it is AB-rated to the branded drug, state laws govern how the generic may be substituted for the brand name drug prescribed by physicians. In most States and under most health plans, a pharmacist may (and often must) substitute an AB-rated generic drug for a prescribed brand name drug.

II. Suboxone's Orphan Drug Designation

33. In 2002, Reckitt introduced Suboxone as a sublingual tablet ("Suboxone Tablets"). At that time, the two component ingredients of Suboxone were not subject to any patent protection. Naloxone was first approved by the FDA in 1971, and buprenorphine was first approved by the FDA in 1982 as an injectable analgesic drug. Reckitt acknowledged that it had no knowledge of any existing patent protection for Suboxone Tablets at the time of its FDA application.

34. Instead of exclusivity through patent protection, Reckitt's Suboxone Tablets were granted a 7-year period of exclusivity as an "orphan drug" by the FDA.

35. A drug can be designated as an "orphan drug" when the FDA determines that either (a) the drug is intended for the safe and effective treatment, diagnosis or prevention of a rare disease or disorder that affects fewer than 200,000 people in the United States; or (b) the disease or disorder affects greater than 200,000 people, but the manufacturer is not reasonably expected to recover the costs of developing and marketing the treatment drug from sales in the United States.

36. Reckitt argued that its drug Suboxone would be used for the treatment of fewer than 200,000 people, but the FDA rejected that argument. Instead, the FDA granted orphan drug status to Suboxone Tablets based on Reckitt's representations that it would be unlikely to recover

the costs of developing and marketing the drug. After designation as an orphan drug by the FDA, the FDA approves the drug for marketing. It is then eligible for a period of orphan drug regulatory exclusivity for 7 years, allowing it to be marketed as a brand-name drug, free from generic competition.

37. Suboxone was designated as an orphan drug in 1994, but was not approved for 7-year marketing exclusivity until 2002. Reckitt's 7-year exclusivity expired on October 8, 2009. During that time, Reckitt was able to market sublingual tablet Suboxone without any threat of competition from any generic co-formulated buprenorphine/naloxone for the treatment of opioid addiction.

38. Although Reckitt secured an orphan drug designation for Suboxone Tablets on the basis of a cost recovery designation, Reckitt quickly began earning profits on Suboxone Tablets, earning more than $2 billion by 2010. Its successor in interest, Indivior Inc., derived almost all of its revenue from the sales of Suboxone.

III. Reckitt's Product-Hopping Scheme

A. Suboxone Tablet Market Share Threatened by Generic Entry

39. As the orphan drug exclusivity period for Suboxone Tablets neared expiration, Reckitt knew generic manufacturers would seek FDA approval to sell lower-priced generic versions of co-formulated buprenorphine/naloxone in direct competition to Suboxone Tablets.

40. As AB-rated generic drugs become available, lower-priced generic competitors are rapidly substituted for their brand-name counterparts because the Hatch-Waxman Act and most state drug product selection laws permit (or require) pharmacists to substitute an AB-rated generic drug for the branded version unless the prescription is specifically designated otherwise.

41. Manufacturers of brand-name drugs typically lose 80 percent or more of their sales to AB-rated generic competition soon after a generic competitor enters the market. Until an AB-rated generic becomes FDA approved, however, a branded manufacturer may continue to charge supra-competitive prices.

42. Reckitt was concerned that generic entry would significantly reduce the company's sales and revenue of its Suboxone Tablets. In its annual reports between 2008 and 2010, Reckitt stated:

- "As with all prescription drugs, the protection of this business has a finite term unless replaced with new treatments or forms. Therefore, the revenue and income of this business may not be sustained going forward unless replaced with new treatments or forms, on which the Company is actively working."
- "The Group continues to search for ways to offset the impact of the loss of exclusivity [of Suboxone] in the USA at the end of September 2009, up to 80% of the revenues and profits of that business might be lost to generic competition in 2010, with the possibility of further erosion thereafter."
- "It is well known that by far the largest part of the Pharmaceuticals business, the Suboxone Tablets in the USA, can become subject to generic competition at any time."
- "The expiry of the Group's exclusive license for Suboxone in the United States in 2009 and in the rest of the world in 2016 could expose the business to competition from generic variants."

43. FDA regulations allow branded manufacturers to seek FDA approval to modify the dosage form and strength of their existing products. Changing the dosage form and strength

of a branded drug changes its pharmaceutical equivalence and will alter the AB-rating of any proposed or available generic substitutes.

44. [redacted]

45. Faced with the impending loss of exclusivity and related drops in profit, [redacted]

B. Suboxone Film Enters the Market

46. In July 2007, Reckitt informed the FDA that it planned to file a new drug application to market Suboxone in a sublingual Film. [redacted]

47. [redacted]

48. MonoSol encouraged Reckitt and other pharmaceutical companies to engage in illegal and anticompetitive product-hopping on its website:

- "Patient-friendly delivery with no generic substitution"
- "Partnering with MonoSol Rx offers pharmaceutical companies the ability to introduce products that are highly differentiated from other dosage forms, both in performance and marketability, creating fresh, dynamic revenue-generating opportunities."
- Mock quote used in advertisement: "We launched this brand 5 years ago. We're not just letting it go over the cliff. It's time for the new strategy."
- "PharmFilm formulations represent revenue-life cycle extensions for products with patent lives that have expired or are approaching expiration."
- "If patient-friendly delivery, patent expiry, or launching the next blockbuster is on your agenda, the time is right to consider the advantages of PharmFilm."
- "Because PharmFilm is a unique, patent-protected delivery technology, it can be an ideal strategy for extending the life of a brand as generic incursion approaches."
- "PharmFilm drug technology allows: no generic substitution."

49. [redacted]

50. Reckitt and MonoSol's development of the new sublingual Film was intended to thwart generic entry, and to maintain Suboxone's market share by extending Reckitt's exclusivity on a co-formulated buprenorphine/naloxone product.

51. In April 2008, MonoSol applied for a patent, which was issued as patent number 8,017,150 entitled "Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom" and was listed by Reckitt in the FDA's Orange Book.

52. Reckitt listed the '150 patent as well as patent numbers 8,475,832, and 8,603,514 in the FDA Orange Book, and alleged that they cover Suboxone Film. The earliest patent expires in 2023, and all are the subject of several lawsuits brought by MonoSol and Reckitt against the many companies that sought FDA approval to make generic Suboxone Film. These patents are also the subject of multiple inter-partes proceedings challenging their validity. Reckitt and MonoSol have also sued their potential Suboxone Film rivals for infringement on two additional patents, patent numbers 8,900,497, and 8,906,277, which were not listed in the Orange Book. The U.S. District Court of Delaware has invalidated the '832 patent.

53. [redacted]

54. Throughout the Suboxone Film development process, MonoSol was aware that the timing of both FDA approval and final product development was crucial to bring the Suboxone Film to market prior to the entry of generic co-formulated buprenorphine/naloxone tablets. MonoSol actively strategized with Reckitt to minimize various manufacturing delays to beat the generic tablets to market.

55. On October 20, 2008, Reckitt submitted NDA 022410 to the FDA to market the sublingual Film version of Suboxone, which was received by the FDA on October 21, 2008. Because Suboxone Film is in a different dosage form than Suboxone Tablets, the two are not pharmaceutically equivalent.

56. Without pharmaceutical equivalency, drugs cannot be AB-rated substitutes for one another. Thus, any tablet form of generic co-formulated buprenorphine/naloxone would not be an AB-rated generic substitute for Suboxone Film, and typically a pharmacist may not automatically provide a patient with generic co-formulated buprenorphine/naloxone tablets when presented with a prescription for Suboxone Film.

57. On August 21, 2009, less than two months before the October 2009 expiration of exclusivity on the tablet formulation, the FDA rejected Reckitt's application to market Suboxone Film due to concerns that the Film could be abused by patients or others and could result in accidental exposure to children.

58. The Food and Drug Administration Amendments Act of 2007 gives the FDA the authority to require a Risk Evaluation and Mitigation Strategy ("REMS"), which is a document submitted by the manufacturer that contains a risk management plan or risk-minimization strategy that goes beyond the professional labeling to ensure that the benefits of a drug outweigh the risks.

59. In response to the FDA's rejection of the Suboxone Film application, Reckitt submitted a revised REMS to the FDA to address safety concerns related to the Film form.

60. The FDA approved Reckitt's NDA for Suboxone Film on August 30, 2010.

61. MonoSol remained active in the NDA-approval process and committed to doing everything possible to enable FDA approval as quickly as possible, [redacted]

62. Reckitt's Film offers no significant actual benefits for patients over its Tablet. FDA approval of Suboxone Film was based on the studies Reckitt used to establish safety and efficacy of the Tablets, and Reckitt's representation that the Film had sufficient equivalent

bioavailability to the Tablets. The FDA confirmed that Reckitt's NDA contained no new efficacy studies. In fact, Reckitt even represented to the FDA that any differences between the two formulations were "clinically insignificant." Until August 2012, the dosage strengths of the two Suboxone products were identical.

63. The most important factor identified by Reckitt in bringing Suboxone Film to market was avoiding competition from generic entrants.

64. Suboxone Film has disadvantages compared to Suboxone Tablets:

- Film is easier to conceal and smuggle into jails and prisons;
- Increased naloxone bioavailability in the Film version, increasing the risk of unwanted opioid withdrawal symptoms;
- Film's rapid dissolution creates barriers to removal if accidentally ingested.
- Film is more dangerous because less unpleasant taste compared to Tablets, making children less likely to spit it out;
- Film is more likely to become stuck on the tongue if accidentally ingested by a child;
- Film's increased strength of 12mg increased dosage exposure to children;

65. The FDA found that Suboxone Film had no demonstrable safety advantage over Suboxone Tablets. The FDA also concluded that the studies Reckitt offered to the contrary were flawed, stating:

- "Almost all of the safety experience with the proposed new formulation was derived from a single study. This study had a number of flaws, including inadequate training of personnel conducting safety exams, inconsistent

recording of findings, treatment of participants with dosing regimens not recommended in the proposed labeling, and a high drop-out rate;"

- "After review of the clinical study report and database for the study RB-US-07-0001 [used to support Reckitt's NDA for Suboxone Film], our overall conclusion is that the study was poorly designed and conducted and was not useful for demonstrating any difference in the safety profile or abuse potential of the two formulations;" and
- "There was no positive control arm (Suboxone Tablet group) in this study. So it would be impossible to claim any potential advantages of Suboxone strip [Film] over the current Suboxone Tablet product."

66. Furthermore, the FDA expressed concerns that the Suboxone Film actually presented increased safety issues: "It should be noted that the proposed filmstrip product cannot be spit out easily and dissolves quickly. Therefore, to the extent that some cases may be mitigated by the child spitting out the Tablet before full absorption, the filmstrip product could be more hazardous than the Tablet." This concern was based upon the fact that once in the mouth, the Suboxone Film hydrates into a gel in 30 seconds and is completely absorbed in 3 minutes, releasing all of the buprenorphine contained in the Film. Suboxone Tablets, however, may take up to 10 minutes to fully dissolve. Many children who accidentally ingest Suboxone Tablets spit them out quickly, but even when they do succeed in swallowing the Tablets, the buprenorphine is absorbed to a far lesser extent in the tablet formulation than in the Film. These factors make Suboxone Tablets potentially less dangerous than Film in accidental pediatric exposure.

67. The FDA also noted the possible increase of potential for abuse with the Film; that the Film is both easier to conceal or divert, and that it is easier to dissolve and inject. "Taken together, these findings suggest that expanded use of this product will result in significant abuse and diversion that needs to be considered with any anticipated benefits the drug may offer." In fact, almost 6,000 Suboxone Film strips (46 percent of those dispensed to study subjects) were "missing" after the limited clinical studies performed by Reckitt to gain FDA approval.

68. Reckitt is aware of the advantages that Suboxone Tablets have over Suboxone Film, as evidenced by the fact that Reckitt markets Suboxone exclusively in tablet form in almost all of the countries where it is sold. This continues to be true even after Reckitt removed the Tablets from the U.S. market. For instance, Reckitt is currently applying to sell Suboxone Tablets in China, rather than in the Film.

C. Reckitt Converts the Market From Tablets to Film

69. Reckitt's reformulation, as devised by MonoSol, was designed for the purpose of defeating the AB-rated substitutability that generic co-formulated buprenorphine/naloxone tablets would enjoy once Suboxone's orphan drug exclusivity period expired October 8, 2009.

[redacted]

70. [redacted]

[redacted]

[redacted]

71. [redacted]

[redacted]

72. To complete their plan to extend Suboxone's exclusivity by the patent protection claimed for the Film, Reckitt then engaged in a multi-faceted campaign to convert the co-formulated buprenorphine/naloxone market to Suboxone Film.

73. Reckitt purposefully based its campaign to convert the market on unfounded safety concerns about the Tablets, including concerns regarding accidental exposure to children. These concerns were a sham developed to convince prescribers and payors that the Suboxone Film provided increased safety and efficacy over the Tablets. [redacted]

[redacted]

74. Reckitt communicated to the public and to the medical community that single-dose or unit-dose packaging was necessary to prevent potential exposure to multiple doses in the case of accidental pediatric exposure. Reckitt then began marketing Suboxone Film in unit-dose packaging.

75. Reckitt partnered with consulting firm Venebio Group, LLC to develop its "Film is safer" platform. Venebio's website states that the project "evaluated effectiveness of innovative pharmaceutical packaging in reducing pediatric exposure." [redacted]

76. Reckitt's Suboxone Tablets have been sold in unit-dose packaging outside of the United States since 2005. Reckitt did not make any attempt to convert its tablet packaging to unit-dose packaging in the United States. Rather, despite its claimed safety concerns, Reckitt continued to sell Tablets in multi-unit bottles, contrary to its practices in other countries, until it withdrew its Tablets from the United States market upon the entry of generic versions.

77. Reckitt began a multi-front offensive to drive the Film to market before the generics could enter with their version of the Suboxone Tablet. [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

78. [redacted]

79. [redacted]

80. [redacted]

81. In September 2012, Reckitt issued a press release advising the public and prescribing physicians that Reckitt intended to withdraw the Tablets from the market within the next six months. Reckitt's press release falsely stated that the withdrawal was due to the "pediatric exposure safety issue." Reckitt was aware that its assertions of pediatric safety concerns regarding the Tablet formulation were unfounded.

82. Reckitt also sought a declaration from the FDA that Suboxone Tablets were being voluntarily pulled from the market by Reckitt due to safety issues.

83. As another part of its plan to convert the market from Tablets to Film, Reckitt utilized a patient assistance program called "Here to Help," that provided qualified individuals with free or low-cost drugs. [redacted]

[redacted]

84. Finally, Reckitt induced conversion of the market to the Film by raising the price of its Suboxone Tablets before the introduction of the AB-rated generic tablet product into the market. As a result, the Film was initially cheaper than the branded tablets. Reckitt also developed programs that provided discounts and rebates to consumers who purchased the Film.

85. [redacted]

86. Reckitt engaged in each of these actions with the purpose of converting the prescription market for Suboxone from Tablets to the Film to thwart generic competition once AB-rated generic substitutes became available for Suboxone Tablets. [redacted]

87. Reckitt's product-hopping scheme was successful. By mid-2012, the Film accounted for over 70 percent of Suboxone prescriptions, and by the time the generic tablets

received FDA approval in February 2013, 85 percent of Suboxone prescriptions were written for the Film instead of for Suboxone Tablets.

88. Reckitt withdrew Suboxone Tablets from the market on March 18, 2013.

IV. Reckitt Delays Generic Entry

89. ANDAs for approval to sell generic Suboxone were filed in 2009. Although the orphan drug exclusivity period on branded Suboxone Tablets expired on October 8, 2009, generic buprenorphine/naloxone tablets did not gain FDA approval until February 2013. This delay was due in large part to Reckitt's tactics, which were intended to delay generic entry while Reckitt continued and completed its product-hopping scheme.

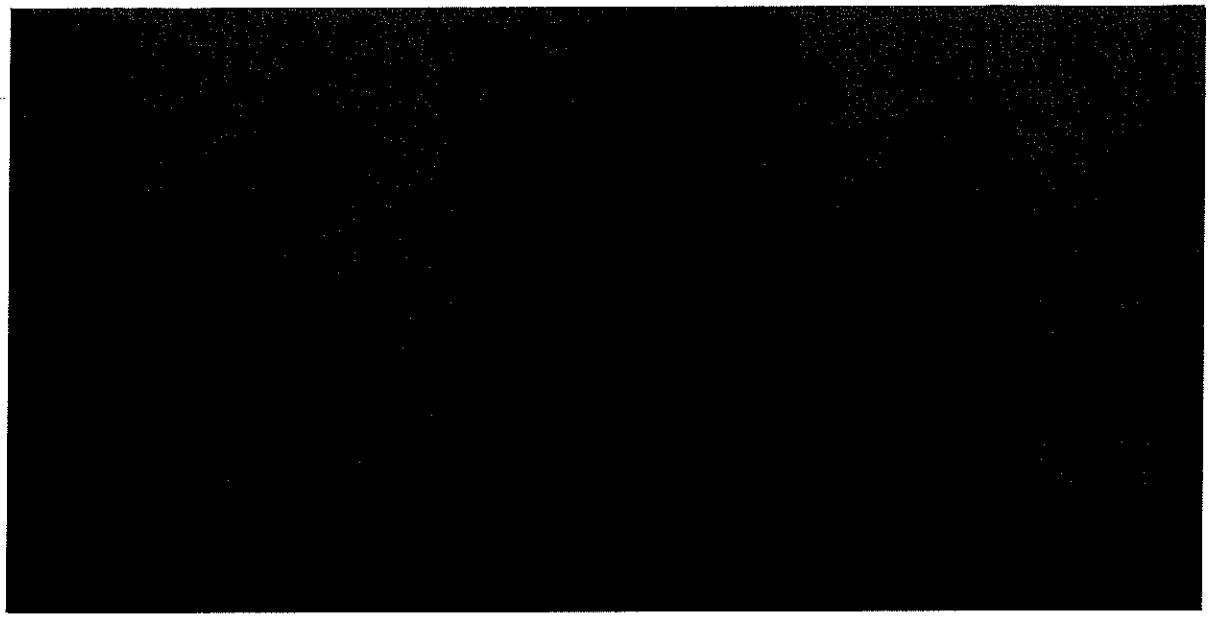
90. In late 2011, while certain potential generic competitors (referred to collectively as "Buprenorphine Products Manufacturers Group") were awaiting FDA approval of their ANDAs for generic co-formulated buprenorphine/naloxone tablets, Reckitt submitted a REMS for Suboxone Tablets, which was approved by the FDA in December 2011.

91. On January 6, 2012, the FDA ordered Reckitt to cooperate with the Buprenorphine Products Manufacturers Group in a shared REMS. Shared REMS are utilized like individual REMS—to address safety concerns of pharmaceutical products. When multiple manufacturers are marketing a generic product that is an AB-rated substitute for a reference drug, the FDA requires that the manufacturers work together to submit a shared REMS. The companies' filing ANDAs and comprising the Buprenorphine Products Manufacturers Group were Actavis, Inc.; Amneal Pharmaceuticals LLC; Ethypharm USA Corp.; Mylan Inc.; Roxane Laboratories Inc.; Sandoz Inc.; Sun Pharmaceuticals Industries, Ltd; and Teva Pharmaceuticals USA, Inc.

92. Approved NDA holders must participate in a shared REMS process with ANDA applicants, and NDA holders may not use safety concerns to block or delay ANDA approval under 21 U.S.C. § 355-1(f).

93. Although Reckitt's Suboxone Tablet REMS was only approved by the FDA in December 2011, Reckitt did not cooperate with the generic manufacturers in the finalization and submission of a shared REMS. Reckitt also did not indicate outright that it refused to participate in the shared REMS process. Instead, Reckitt engaged in multiple delay tactics and made misleading statements to conceal its true intent, which was to prolong the approval of the ANDAs for generic Suboxone Tablets.

94. [redacted]



95. Reckitt falsely represented to the FDA and the Buprenorphine Products Manufacturers Group that it would cooperate. Reckitt never intended to participate in a single shared REMS program with the generic manufacturers, engaging in the process for the sole purpose of delaying generic approval.

96. Because the FDA could not approve the ANDA applications without an approved REMS, Reckitt's refusal to cooperate was intended to and did in fact delay generic entry past the date when entry otherwise would have occurred.

97. Reckitt's refusal to cooperate successfully delayed submission of the shared REMS until August of 2012, when the generic ANDA filers finally obtained an unprecedented waiver allowing them to submit a shared REMS program of their own without Reckitt's cooperation. Absent such delay tactics, the shared REMS program would have been completed no later than May 6, 2012.

98. Reckitt knew that once the FDA approved the ANDAs, generic Suboxone Tablets would become available and immediately substitutable for branded Suboxone Tablets. To gain

more time to complete its product hop scheme, Reckitt engaged in another delay tactic by filing a citizen petition with the FDA.

99. Under § 505(q) of the Food, Drug and Cosmetic Act, any individual may submit a petition, commonly known as a "citizen petition," asking the FDA take, or refrain from taking, certain administrative action. Citizen petitions are commonly used to express concerns about the safety or legality of a product.

100. The FDA is granted a 150-day period to respond to each citizen petition under 21 C.F.R. § 10.30.

101. During the 150-day period, FDA approval of any ANDA pending for a product that is the subject of the citizen petition is typically delayed. Although 21 U.S.C. § 355(q)(1)(A) provides that the Secretary "shall not delay approval" of a pending ANDA, subpart (ii) requires that "the Secretary, upon reviewing the petition," must determine whether a further delay is necessary to protect public health. Thus, the filing of a citizen petition in and of itself creates a delay insofar as the FDA must actually review the allegations made in the petition, enabling brand-name manufacturers to file a baseless citizen petition to prolong their monopoly on a particular branded drug. This abuse of the petition process has been repeatedly acknowledged by FDA officials.

102. On September 25, 2012, Reckitt filed a citizen petition asking the FDA to withhold approval of the ANDAs for generic Suboxone Tablets unless: (1) the ANDA contained a targeted pediatric exposure education program; (2) the ANDA product had child-resistant unit-dose packaging; and (3) the FDA had determined whether Reckitt had discontinued Suboxone Tablets for safety reasons.

103. In the same week that it filed the citizen petition, Reckitt announced its intent to permanently withdraw Suboxone Tablets from the market for purported safety reasons even though the FDA stated that it could not determine whether the Film was safer, and that the cause for any alleged decline in unintended pediatric exposures to the Film was unverified.

104. Reckitt did not disclose these alleged safety concerns about Suboxone Tablets to the generic manufacturers during the shared REMS negotiation process, and refused to engage in any meaningful way with the generics during that process even after being ordered to do so by the FDA. In fact, Reckitt used information gained from the generic manufacturers through the shared REMS negotiation to form its citizen petition and time its filing to increase delay.

105. The same alleged safety concerns raised in its citizen petition regarding the generic manufacturers' tablet product was dismissed by Reckitt less than a month prior with regard to its own Suboxone Tablets. Specifically, on August 30, 2012 Reckitt represented to the FDA in a combined REMS assessment that its tablet REMS was successful and needed no further changes. In fact, Reckitt considered and rejected converting its Suboxone Tablets to unit-dose packaging for pediatric safety reasons as early as February 2008.

106. [redacted]

107. [redacted]

108. The FDA ultimately denied Reckitt's citizen petition on February 22, 2013, noting that it was not supported by evidence and was inconsistent with Reckitt's own behavior. The FDA also said that it did not have the authority to issue some of the relief requested by Reckitt. The FDA acknowledged in its ruling that it had no authority to grant Reckitt's request to have Suboxone ANDAs contain targeted pediatric exposure program because the labeling for an ANDA must be the same as the labeling for the approved listed drug, pursuant to 21 U.S.C. § 355(j)(2)(A)(v) and (4)(G).

109. The FDA further stated in its denial that the close proximity of Reckitt's withdrawal of Suboxone Tablets to the "period in which generic competition for this product was expected to begin cannot be ignored."

110. The FDA referred Reckitt's conduct to the FTC for antitrust investigation.

111. Reckitt's baseless citizen petition did, in fact, delay the approval of the pending ANDAs—even though the FDA ultimately determined that a further delay was not necessary to protect public health—due to the passage of the 150-day period allowed for the FDA to review the petition under 21 U.S.C. § 355(q)(1)(A)(ii).

112. [redacted]

113. Reckitt's conduct in submitting and pursuing the baseless citizen petition had the intended effect of delaying FDA approval of the pending ANDAs and the entry of generic competition for co-formulated buprenorphine/naloxone tablets. But for Reckitt's baseless citizen petition, coupled with its dilatory and deceptive conduct with regard to the shared REMS that

caused the generic group's REMS approval to be delayed, competitors would have marketed generic co-formulated buprenorphine/naloxone tablets before they actually did.

114. On February 22, 2013, the FDA granted the generics-only, waiver-based REMS and approved Amneal and Activis' ANDAs for tablet sales.

115. On March 6, 2013, generic co-formulated buprenorphine/naloxone tablets entered the market. By that time, Reckitt had successfully converted the vast majority of co-formulated buprenorphine/naloxone prescriptions being written in the United States from its branded Suboxone Tablet to the patent-protected Film, for which the newly approved generic competitors are not AB-rated substitutes.

Effects on Competition

116. Generic versions of brand-name drugs are typically priced significantly lower than the brand-name versions. As AB-rated generic competition enters the market for a particular drug, the brand-name versions are quickly replaced by the lower-priced generics. Under most state laws, this generic substitution occurs automatically, unless the prescribing physician has indicated that the brand-name product must be "dispensed as written."

117. The introduction of generic competition results in significant losses in profit for the brand-name manufacturers as consumers are switched to the lower-priced generics and the brand-name drug is no longer able to command a higher price. Conversely, the longer a branded manufacturer is able to delay the entry of generic competition to the market, the longer it can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its brand-name sales.

118. Reckitt's conspiracy with MonoSol and its acts, practices, and scheme described herein were for the purposes of, and had the effect of, restraining competition unreasonably by

preventing the entry of generic co-formulated buprenorphine/naloxone and destroying the market for the tablet formulation by the time the generic competitors gained FDA approval.

119. But for Reckitt and MonoSol's illegal conduct, generic competition to Suboxone Tablets would have been available after orphan exclusivity expired in October, 2009. Thus, Defendants' conduct delayed and prevented the savings that Suboxone purchasers would have enjoyed from that point until present date.

120. By causing a hard product switch, Reckitt avoided, and continues to avoid, automatic substitution of AB-rated generics under state generic substitution laws and, therefore, has limited, and continues to limit, competition with generic substitutes for Suboxone Tablets.

121. Had generic competition to Suboxone Tablets entered the market earlier—and not been delayed while Defendants converted the market to Suboxone Film—government entities and consumers would have substituted lower-priced generic Suboxone Tablets for the higher-priced branded Suboxone Tablets, and would have paid lower prices for some or all of their branded Suboxone purchases.

122. Reckitt's anticompetitive scheme to delay FDA approval of generic Suboxone Tablets while converting the Suboxone market to its patent-protected Suboxone Film unlawfully enabled, and continues to enable, Reckitt to sell Suboxone at supra-competitive prices, and allowed, and continues to allow, Reckitt and MonoSol to enjoy ill-gotten gains from the sales of Suboxone Film and branded Tablets, while Suboxone tablets were on the market.

123. By delaying generic competitors' entry into the market, Reckitt and MonoSol have deprived Plaintiff States, government entities, and consumers the benefits of competition in violation of the federal and state antitrust laws, consumer protection laws, and unfair competition statutes.

Injury

124. As a direct and proximate result of the unlawful conduct alleged above, government entities and consumers in Plaintiff States were not and are not able to purchase, or pay reimbursements for purchases of co-formulated buprenorphine/naloxone at prices determined by a market unhindered by the impact of Defendants' anticompetitive behavior. Instead, they have been and continue to be forced to pay artificially high monopoly prices. Consequently, they have suffered substantial injury in their business and property, and have suffered harms to their general economies in that, *inter alia*, they have paid more and continue to pay more for co-formulated buprenorphine/naloxone than they would have paid in a competitive market.

125. As a direct and proximate result of the unlawful conduct alleged above, the general economies of the States have sustained injury and the Plaintiff States are threatened with continuing injury to their business and property unless Reckitt and MonoSol are enjoined from this unlawful conduct.

126. As a direct and proximate result of the unlawful conduct alleged above, Reckitt and MonoSol have unjustly profited through inflated profit margins and will continue to do so.

127. Reckitt's unlawful conduct is continuing and will continue unless the injunctive and equitable relief requested by the Plaintiff States is granted.

128. MonoSol's unlawful conduct is continuing and will continue unless the injunctive and equitable relief requested by the Plaintiff States is granted.

129. Plaintiff States do not have an adequate remedy at law.

130. All conditions precedent necessary to the filing of this action have been fulfilled, waived or excused.

Count I: Monopolization under Sherman Act § 2 Against Reckitt Defendants

131. The preceding paragraphs are incorporated as if set forth herein.

132. From 2002 until the present, Indivior Inc., f/k/a Reckitt Benckiser Pharmaceuticals Inc., now wholly owned by Indivior PLC; Indivior PLC, as alleged above, a successor company to Reckitt Benckiser Pharmaceuticals Inc.; and Reckitt Benckiser Healthcare (UK) Ltd., (as described above, collectively referred to as "Reckitt") have possessed monopoly power in the relevant market of co-formulated buprenorphine/naloxone in the United States as owners or licensees to use Suboxone intellectual property, or their role in the development, manufacture, and sale of Suboxone.

133. The relevant product market is any drug with co-formulated buprenorphine/naloxone as the active ingredients for the treatment of opioid addiction. This market includes Suboxone Film and Tablets and any AB-rated generics that can be substituted for them.

134. The relevant geographic market is the United States and its territories.

135. The conspiracy substantially affected and still affects interstate commerce.

136. Reckitt willfully and unlawfully maintained its monopoly power by engaging in exclusionary conduct which had the intent, purpose, and effect of illegally preventing and blocking competition in the United States co-formulated buprenorphine/naloxone market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

137. Beginning in 2002, Reckitt engaged in exclusionary conduct including, but not limited to: devising and implementing an anti-generic strategy by intentionally causing delays to FDA approval of ANDAs for generic co-formulated buprenorphine/naloxone, filing a baseless citizen petition to delay ANDA approval, and alleging unfounded concerns regarding the safety

of the generic product while engaging in a campaign to convert the co-formulated buprenorphine/naloxone market from tablet formulations to their patent-protected Film.

138. As a direct and proximate result of Reckitt's exclusionary scheme, Plaintiff States have suffered harm to their general economies because government entities and consumers have had to purchase Suboxone at supra-competitive prices without the reasonable availability of a lower-priced generic alternative, and Reckitt has enjoyed ill-gotten gains from the sales of Suboxone Film and Tablets.

Count II: Attempted Monopolization Under Sherman Act § 2 Against Reckitt Defendants

139. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

140. The relevant product market is any drug with co-formulated buprenorphine/naloxone as the active ingredients for the treatment of opioid addiction. This market includes Suboxone Film and Tablets and any AB-rated generics that can be substituted for them.

141. Reckitt, through its overarching anticompetitive scheme, specifically intended to maintain its pre-existing monopoly power in the relevant market. It was Reckitt's conscious objective to control prices or to exclude competition in the relevant market.

142. The natural, intended and foreseeable consequence of Reckitt's overarching anticompetitive scheme was to control prices and exclude competition in the relevant market.

143. There was, and continues to be, a substantial and real chance, a reasonable likelihood, or a dangerous probability that Reckitt will succeed in and achieve its goal of maintaining monopoly power in the relevant market.

144. As a direct and proximate result of Reckitt's exclusionary scheme, Plaintiff States have suffered harm to their general economies because government entities and consumers have had to purchase Suboxone at supra-competitive prices without the reasonable availability of a lower-priced generic alternative, and Reckitt has enjoyed ill-gotten gains from the sales of Suboxone Film and Tablets.

Count III: Conspiracy to Monopolize under Sherman Act § 2 Against All Defendants

145. The preceding paragraphs are incorporated as if set forth herein.

146. The relevant product market is any drug with co-formulated buprenorphine/naloxone as the active ingredients for the treatment of opioid addiction. This market includes Suboxone Film and Tablets and any AB-rated generics that can be substituted for them.

147. The relevant product market is the United States and its territories.

148. The conspiracy substantially affected and still affects interstate commerce.

149. Defendants Reckitt and MonoSol conspired to monopolize and did unlawfully monopolize the relevant market for co-formulated buprenorphine/naloxone products in the United States, thereby violating Section 2 of the Sherman Act, 15 U.S.C. § 2.

150. Defendants Reckitt Benckiser Healthcare UK, Ltd. and MonoSol entered into a development agreement whereby MonoSol granted Reckitt the right to use its patented sublingual film technology to manufacture Suboxone in a film version.

151. Defendant MonoSol marketed itself specifically to companies looking to extend their period of exclusivity in an illegal and anticompetitive manner.

152. Defendants Reckitt and MonoSol entered into the agreement with the specific intent and for the purpose of extending Reckitt's monopoly power, which was due to expire at

the end of Reckitt's FDA-granted "orphan status" period, and for the purpose of preventing generic competition with its branded product.

153. Defendants have acted in concert to willfully and unlawfully maintain Reckitt's monopoly power in the relevant market for co-formulated buprenorphine/naloxone drugs in the United States by engaging in unlawful exclusionary conduct, which had the purpose and effect of unreasonably restraining competition.

154. Defendants Reckitt and MonoSol engaged in their conspiracy with the specific intent to prevent generic competition in the United States co-formulated buprenorphine/naloxone market.

155. Defendant Reckitt had the specific intent to monopolize the Suboxone market when it conspired with and utilized MonoSol's services to extend its monopoly power through the use of sublingual film because this technology would not allow automatic retail generic substitution for Suboxone Tablets.

156. Defendant Reckitt committed a series of acts in furtherance of the conspiracy, including, but not limited to: devising and implementing an anti-generic strategy by intentionally causing delays to FDA approval of ANDAs for generic co-formulated buprenorphine/naloxone, filing a baseless citizen petition to delay ANDA approval, alleging unfounded concerns regarding the safety of the generic product while engaging in a campaign to convert the co-formulated buprenorphine/naloxone market from tablet formulations to its patent-protected Film, and ultimately announcing the withdrawal of Suboxone Tablets from the market.

157. The Defendants' conspiracy created a realistic threat to competition in the United States co-formulated buprenorphine/naloxone market.

158. As a direct and proximate result of Reckitt and MonoSol's conspiracy, Plaintiff States have suffered harm to their general economies because government entities and consumers have had to purchase Suboxone at supra-competitive prices without the reasonable availability of a lower-priced generic alternative, and Reckitt and MonoSol have enjoyed ill-gotten gains from the sales of Suboxone Film and Tablets.

Count IV: Illegal Restraint of Trade under Sherman Act § 1 Against All Defendants

159. The preceding paragraphs are incorporated as if set forth herein.

160. The relevant product market is any drug with co-formulated buprenorphine/naloxone as the active ingredients for the treatment of opioid addiction. This market includes Suboxone Film and Tablets and any AB-rated generics that can be substituted for them.

161. From 2006 to the present, the Reckitt Defendants entered into and maintained a contract, combination, or conspiracy with MonoSol to restrain trade in the U.S. market for co-formulated buprenorphine/naloxone drugs, and thereby violated Section 1 of the Sherman Act, 15 U.S.C. § 1.

162. From 2006 to the present, MonoSol entered into and maintained a contract, combination, or conspiracy with the Reckitt Defendants to restrain trade in the U.S. market for co-formulated buprenorphine/naloxone drugs, and thereby violated Section 1 of the Sherman Act, 15 U.S.C. § 1.

163. The contract, combination or conspiracy substantially affected and still affects interstate commerce.

164. As a direct and proximate result of Reckitt and MonoSol's scheme, Plaintiff States have suffered harm to their general economies because government entities and consumers

have had to purchase Suboxone at supra-competitive prices without the reasonable availability of a lower-priced generic alternative, and Reckitt and MonoSol have enjoyed ill-gotten gains from the sales of Suboxone Film and Tablets.

165. The anti-competitive effects of Defendants' conspiracy outweigh pro-competitive effects, if any, that their conduct may have had.

Count V: State Law Claims Against Reckitt and MonoSol Defendants

Alabama

166. Plaintiff State of Alabama repeats and realleges every preceding allegation.

167. The acts and practices by Defendants constitute unconscionable acts in violation of the Alabama Deceptive Trade Practices Act, Code of Alabama, 1975, § 8-19-5(27) for which the State of Alabama is entitled to relief.

Alaska

168. The State of Alaska repeats and realleges every preceding allegation.

169. The aforementioned practices by Defendants are in violation of the Alaska Restraint of Trade Act, AS 45.50.562 *et seq.*, and Plaintiff State of Alaska is entitled to relief for these violations under AS 45.50.576 - .578.

170. The aforementioned practices by Defendants are in violation of the Alaska Unfair Trade Practices and Consumer Protection Act, AS 45.50.471 *et seq.*, and Plaintiff State of Alaska is entitled to relief for these violations under AS 45.50.501, .531, and .537.

Arkansas

171. The Plaintiff State of Arkansas repeats and realleges each and every allegation contained in paragraphs 1 through 165.

172. Defendants' acts violate, and Plaintiff State of Arkansas is entitled to relief under, The Arkansas Unfair Practices Act, Arkansas Code Annotated § 4-75-201 *et seq.*, The Arkansas Statute on Monopolies, Ark. Code Ann. § 4-75-301 et seq., The Arkansas Deceptive Trade Practices Act, §4-88-101 *et seq.*, and the Common Law of Arkansas.

California

173. California realleges and incorporates all of the allegations above from paragraphs 1 through 165.

174. The aforementioned conduct practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code sections 16700, *et seq.*, and the California Unfair Competition Act, Cal. Bus. & Prof. Code sections 17200, *et seq*. The afore-alleged representations and statements of Reckitt to doctors, payors, providers, pharmacists and others regarding the existence of safety concerns of the Suboxone Tablets, which representations Reckitt knew or by the exercise of reasonable care should have known to be unfounded, untrue and misleading also constitute violations of Cal. Bus. & Prof. Code sections 17500 *et seq*.

175. Accordingly, the State of California in its law enforcement capacity, seeks all relief available under California's Cartwright Act and the Unfair Competition Act, including all available monetary and equitable relief, injunctive relief pursuant to Cal. Bus & Prof. Code § 16754.5 to restore and preserve fair competition and bar any continued conduct that is wrongful, among other things, civil penalties pursuant to Cal. Bus. & Prof. Code § 17206 of $2,500 per each and every act, prescription and victim of any violation of the California Unfair Competition Act (and under Cal. Civil Code § 3345, trebled for senior citizens and disabled victims of the violation), and disgorgement of all revenues, profits, and gains achieved in whole or in part through the violations of the Acts complained of herein, including disgorgement, unjust

enrichment, injunctions, costs, reasonable attorneys' fees, and civil penalties, and any such other relief that might be available under statute or equity, penalties, and any such other equitable or monetary relief that might be available under statute or equity.

Colorado

176. Plaintiff State of Colorado repeats and realleges each and every allegation contained in paragraphs 1 through 165.

177. Defendants' acts violate, and Plaintiff State of Colorado is entitled to relief under, the Colorado Antitrust Act of 1992, § 6-4-101, *et seq.*, Colo. Rev. Stat.

Connecticut

178. Plaintiff State of Connecticut repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

179. Defendants' actions as alleged herein violate the Connecticut Antitrust Act, Conn. Gen. Stat. §§ 35-26 and 35-28, in that they have the purpose and/or effect of unreasonably restraining trade and commerce within the State of Connecticut and elsewhere.

180. Defendants' actions as alleged herein violate Conn. Gen. Stat. §§ 35-27 and 35-29 in that they represent monopolization of or attempts to monopolize trade or commerce within the State of Connecticut and elsewhere and/or have the purpose and effect of substantially lessening competition within the State of Connecticut and elsewhere.

181. Defendants' acts and practices as alleged herein constitute unfair methods of competition in violation of the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat § 42-110b.

182. The State of Connecticut seeks injunctive relief pursuant to Conn. Gen. Stat. § 35-34, civil penalties pursuant to Conn. Gen. Stat. § 35-38 for each and every violation of the

Connecticut Antitrust Act, civil penalties pursuant to Conn. Gen. Stat. § 42-110o of $5,000 for each and every willful violation of the Connecticut Unfair Trade Practices Act, and disgorgement of all revenues, profits, and gains achieved in whole or in part through the unfair methods of competition complained of herein, pursuant to Conn. Gen. Stat. § 42-110m.

Delaware

183. Plaintiff State of Delaware repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

184. The aforementioned practices by Defendants are in violation of Section 2103 of the Delaware Antitrust Act, 6 Del. c. § 2101, *et seq.*

185. The State of Delaware through the Attorney General brings this action pursuant to Sections 2105 and 2107, and seeks civil penalties and equitable relief pursuant to Section 2107 of the Delaware Antitrust Act, 6 Del. C. § 2101, *et seq.*

District of Columbia

186. Plaintiff District of Columbia repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

187. The aforementioned practices by Defendants are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4502 and 28-4503.

188. Plaintiff District of Columbia has been and continues to be injured by Defendants' actions, and is entitled to relief for these violations under D.C. Code § 28-4507(a).

Florida

189. Plaintiff State of Florida repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

190. Defendants' acts violate Section 542.18, Florida Statutes, for their contract, combination, or conspiracy in restraint of trade or commerce in Florida as alleged in Count IV. Plaintiff State of Florida is entitled to relief under the Florida Antitrust Act of 1980, Section 542.15, Florida Statutes, *et seq.*

191. Defendants' acts violate Section 542.19, Florida Statutes, because they monopolized, attempted to monopolize, and combined or conspired with each other to monopolize any part of trade or commerce in Florida as alleged in Counts I, II and III. Plaintiff State of Florida is entitled to relief under the Florida Antitrust Act of 1980, Section 542.15, Florida Statutes, *et seq.*

192. Defendants' acts violate Florida Deceptive and Unfair Trade Practices Act, Section 501.204, Florida Statutes, because they constituted unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of trade or commerce in Florida, as alleged in Counts I through IV. Plaintiff State of Florida is entitled to relief under the Florida Deceptive and Unfair Trade Practices Act, Section 501.201, Florida Statutes, *et seq.*

Georgia

193. Plaintiff State of Georgia repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

194. The aforementioned practices by Defendants violate, and Plaintiff State of Georgia is entitled to relief under, O.C.G.A. §§ 10-1-390, *et seq.*

Hawaii

195. Plaintiff State of Hawaii repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

196. The aforementioned practices by Defendants were and are in violation of the Hawaii Antitrust Act, Hawaii Revised Statutes section 480-1 *et seq.*

197. Plaintiff State of Hawaii is entitled to injunctive relief, disgorgement to deprive defendants of ill-gotten gains unjustly obtained, civil penalties of not less than $500 nor more than $10,000 for each violation pursuant to Hawaii Revised Statutes section 480-3.1, attorney's fees together with the costs of suit, and any other remedies available under the Hawaii Antitrust Act, Hawaii Revised Statutes section 480-1 *et seq.* and any other provision in the Hawaii Revised Statutes.

Idaho

198. Plaintiff State of Idaho repeats and realleges each and every allegation contained in paragraphs 1 through 165.

199. Defendants' actions violate the Idaho Competition Act (the "Act"), Idaho Code § 48-104, in that they have the purpose or the effect (or both) of unreasonably restraining Idaho commerce, as that term is defined by Idaho Code § 48-103(1) of the Act.

200. Defendants' actions violate the Act, Idaho Code § 48-105, in that they represent monopolization of, or attempts to monopolize, or a conspiracy to monopolize, a line of Idaho commerce, as that term is defined by Idaho Code § 48-103(1) of the Act.

201. Plaintiff State of Idaho is entitled to all relief available under the Act, Idaho Code §§ 48-108, 48-112, for those violations, including, but not limited to, injunctive relief, civil penalties, disgorgement, attorneys' fees, and costs.

Illinois

202. Plaintiff State of Illinois repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

203. By engaging in the conduct described above, the Defendants violate sections 3(2) and 3(3) of the Illinois Antitrust Act, 740 ILCS 10/1 *et seq.* and cause the State and its residents to pay more for Suboxone.

204. Plaintiff State of Illinois, under its antitrust enforcement authority in 740 ILCS 10/7, is entitled to an injunction, disgorgement, civil penalties, and any other remedy available at law for these violations under sections 7(1), 7(2), and 7(4) of the Illinois Antitrust Act.

Iowa

205. Plaintiff State of Iowa repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

206. The alleged practices by Defendants violate the Iowa Competition Law, Iowa Code Chapter 553.

207. Iowa seeks an injunction for these practices pursuant to Iowa Code § 553.12, and civil penalties pursuant to Iowa Code § 553.13.

208. Defendants' acts and practices as alleged herein also constitute an unfair practice in violation of the Iowa Consumer Fraud Act, Iowa Code § 714.16(1)(n)

209. Pursuant to Iowa Code § 714.16(7), the State of Iowa, seeks disgorgement and other equitable relief for these violations. In addition, pursuant to Iowa Code § 714.16(11) the Attorney General seeks reasonable fees and costs for the investigation and court action.

Kansas

210. Plaintiff State of Kansas repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

211. The aforementioned acts and practices by the Defendants violate the Kansas Restraint of Trade Act, Kan. Stat. Ann. §§ 50-101, *et seq.*, and Plaintiff State of Kansas is entitled to relief under Kan. Stat. Ann. §§ 50-103, 50-160, 50-161, and 50-163.

Kentucky

212. Plaintiff Commonwealth of Kentucky repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

213. The aforementioned acts or practices by Defendants violate the Consumer Protection Act Kentucky Rev. Stat. Ann. 367.110 *et seq*. The violations were willfully done.

214. Plaintiff Commonwealth of Kentucky, under its statutes, is entitled to injunction, disgorgement, civil penalties, and any other relief the court deems proper.

Louisiana

215. The State of Louisiana repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

216. The practices of Defendants described herein are in violation of the Louisiana Monopolies Act, LSA-R.S. 51:121 *et seq.*, and the Louisiana Unfair Trade Practices Act, LSA-R.S. 51:1401 *et seq.*

217. The State of Louisiana is entitled to injunctive relief and civil penalties under LSA-R.S. 51:1407 as well as disgorgement and any other equitable relief that the court deems proper under LSA-R.S. 51:1408.

Maine

218. Plaintiff State of Maine repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

219. The aforementioned practices by Defendants are in violation of the Maine Monopolies and Profiteering Law, 10 M.R.S. §§ 1101 and 1102, and Plaintiff State of Maine is entitled to relief for these violations under 10 M.R.S. § 1104.

220. The aforementioned practices by Defendants are intentional and in violation of the Maine Unfair Trade Practices Act, 5 M.R.S. § 207, and Plaintiff State of Maine is entitled to relief for these violations under 5 M.R.S. § 209.

Maryland

221. Plaintiff State of Maryland repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

222. The aforementioned practices by Defendants are in violation of the Maryland Antitrust Act, Md. Commercial Law Code Ann. § 11-201 *et seq.*

223. Further, § 11-209(a)(3) provides that the court may exercise all equitable powers necessary to remove the effects of any violation including injunction, restitution, disgorgement and divestiture. The Plaintiff State of Maryland is entitled to costs, reasonable attorney's fees and civil penalties. §§ 11-209(b)(3), 11-209(a)(4).

Massachusetts

224. Plaintiff Commonwealth of Massachusetts repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

225. The aforementioned practices by Defendants constitute unfair methods of competition or unfair or deceptive acts or practices in violation of the Massachusetts Consumer Protection Act, M.G.L c. 93A, § 2 *et seq.*

226. Plaintiff Commonwealth of Massachusetts is entitled to relief under M.G.L. c. 93A, § 4.

227. Plaintiff Commonwealth of Massachusetts notified the defendants of this intended action more than five days prior to the commencement of this action and gave the Defendants an opportunity to confer in accordance with M.G. L. c. 93A, § 4.

Michigan

228. Plaintiff State of Michigan repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

229. The aforementioned practices by Defendants constitute violations of the Michigan Antitrust Reform Act, MCL 445.771 *et seq.*

230. Plaintiff State of Michigan is entitled to disgorgement of profits, penalties, costs, and fees under Section 8 of the Michigan Antitrust Reform Act, MCL 445.778.

Minnesota

231. Plaintiff State of Minnesota repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

232. Defendants' acts violate, and Plaintiff State of Minnesota is entitled to an injunction, disgorgement, and civil penalties and any other remedy available at law for these violations under the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.46-.66, the Uniform Deceptive Trade Practices Act of 1973, Minn. Stat. §§ 325D.43-.48, Minn. Stat. Ch. 8, and Minnesota common law for unjust enrichment.

Mississippi

233. Plaintiff State of Mississippi repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

234. Defendants' acts violate Miss. Code Ann. § 75- 21-1 *et seq.*, and Plaintiff State of Mississippi is entitled to relief under Miss. Code Ann. § 75- 21-1 *et seq.*

235. Defendants' acts violate the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1, *et seq.*, and Plaintiff State of Mississippi is entitled to relief under the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1, *et seq.*

236. Pursuant to Miss. Code Ann. § 75-21-1 *et seq.*, and the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1, *et seq.*, Plaintiff State of Mississippi seeks and is entitled to injunctive relief, disgorgement, civil penalties, costs, and any other just and equitable relief which this Court deems appropriate.

Missouri

237. Plaintiff State of Missouri repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

238. The aforementioned practices by Defendants violate the Missouri Antitrust Law, Missouri Rev. Stat. §§ 416.011 *et seq.*, and Missouri's Merchandising Practices Act, Missouri Rev. Stat. §§ 407.010 et seq., as further interpreted by 15 CSR 60-8.010 *et seq.* and 15 CSR 60-9.01 *et seq.*, and the State of Missouri is entitled to an injunction, disgorgement, civil penalties and any other relief available under the aforementioned Missouri statutes and regulations.

239. The State of Missouri also seeks its costs and attorney fees incurred in the prosecution of this action.

Nebraska

240. Plaintiff State of Nebraska repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

241. The aforementioned acts and practices by Defendants were, and are, in violation of the following Nebraska statutes: Unlawful Restraint of Trade Act, Neb. Rev. Stat. § 59-801 *et seq.*; Consumer Protection Act, Neb. Rev. Stat. § 59-1601 *et seq.*; and Uniform Deceptive Trade

Practices Act, Neb. Rev. Stat. § 87-301 *et seq.* Specifically, Defendants' acts and practices were, and are, in violation of Neb. Rev. Stat. §§ 59-801, 59-802, 59-1602, 59-1603, 59-1604, 87-302(5), 87-302(6), 87-302(8), 87-303.01. Defendants' acts and practices as alleged herein have had an impact, directly and indirectly, upon the public interest of the State of Nebraska.

242. Accordingly, Plaintiff State of Nebraska seeks all relief available under the Unlawful Restraint of Trade Act, the Consumer Protection Act, the Uniform Deceptive Trade Practices Act, and Neb. Rev. Stat. § 84-212. Plaintiff State of Nebraska is entitled to relief including but not limited to: disgorgement, injunctions, civil penalties, and its costs and attorney's fees pursuant to Neb. Rev. Stat. §§ 59-803, 59-819, 59-821, 59-1608, 59-1609, 59-1614, 84-212, 87-303, 87-303.05, and 87-303.11.

New Hampshire

243. New Hampshire realleges and incorporates all of the allegations above from paragraphs 1 through 165.

244. The aforementioned practices by Defendants were and are in violation of the New Hampshire Antitrust Provisions, Revised Statutes Annotated (RSA), 356:1 *et seq.*

245. Plaintiff State of New Hampshire is entitled to relief under N.H. RSA 356:4 *et seq.*

New Mexico

246. Plaintiff State of New Mexico repeats and re-alleges each and every allegation contained in paragraphs 1 to 165.

247. The aforementioned actions and practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. § 57-1-1 *et seq.*, and the New Mexico Unfair Practices Act, § 57-12-1 *et seq.*

248. Accordingly, the State of New Mexico is entitled to remedies available to it under the New Mexico Antitrust Act and the New Mexico Unfair Practices Act, including injunctive relief, restitution, disgorgement, unjust enrichment, civil penalties, costs, attorney's fees, and any other appropriate monetary and injunctive relief. *See* N.M. Stat. Ann. §§ 57-1-3, -7, -8; N.M. Stat. Ann. § 57-12-8, -10, -11.

New York

249. Plaintiff State of New York realleges and incorporates each and every allegation contained in paragraphs 1 through 165 as if fully set forth herein.

250. Defendants' acts violate the Donnelly Act, New York's antitrust law, N.Y. Gen. Bus. Law § 340 *et seq.*

251. Defendants have engaged in repeated fraudulent or illegal acts in the carrying on, conducting, or transaction of business, in violation of Section 63(12) of the New York Executive Law, N.Y. Exec. Law § 63(12).

252. Because of Defendants' illegal conduct, New York State is entitled to legal and equitable remedies including but not limited to injunctive relief, equitable monetary relief, and penalties pursuant to Sections 340-342(c) of the New York General Business Law and Section 63(12) of the New York Executive Law.

North Carolina

253. Plaintiff State of North Carolina repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

254. Defendants' acts violate North Carolina's Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. § 75-1 *et seq.* Plaintiff State of North Carolina is entitled to relief under N.C. Gen. Stat. § 75-1 *et seq.*

255. Plaintiff State of North Carolina is entitled to recover its costs and attorneys' fees pursuant to N.C. Gen. Stat. § 75-16.1.

Ohio

256. Plaintiff State of Ohio repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

257. The Attorney General brings this action in his sovereign capacity as the chief law enforcement officer of the State of Ohio.

258. Pursuant to Ohio Rev. Code § 1331.11, the Ohio Attorney General is authorized to institute and prosecute actions on behalf of the State to enforce the provisions and remedies of Ohio's antitrust law, the Ohio Valentine Act, codified in Ohio Rev. Code Chapter 1331.

259. The aforementioned practices by Defendants violate Ohio Rev. Code §§ 1331.01 *et seq.* These violations substantially affect the people of Ohio and have impacts within the State of Ohio.

260. Pursuant to Ohio Rev. Code § 109.81, the Ohio Attorney General is authorized to do all things necessary to properly conduct any antitrust case and to seek equitable relief as provided in Revised Code §§ 109.81 and 1331.11. Based on Defendant's conduct, the State of Ohio is entitled to an injunction, disgorgement, and civil penalties and any other remedy available at law or equity for these violations under Ohio law or the laws of the United States.

Oklahoma

261. Plaintiff State of Oklahoma repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

262. The aforementioned practices by the Defendants are in violation of the Oklahoma Antitrust Reform Act, 79 O.S. § 201 *et seq.*, and the Oklahoma Consumer Protection Act, 15 O.S. § 751 *et seq.*, and Plaintiff State of Oklahoma is entitled to relief under 79 O.S. § 205 and 15 O.S. § 756.1 respectively.

Oregon

263. Oregon realleges and incorporates all of the allegations above from paragraphs 1 through 165.

264. The aforementioned practices by Defendants were and are in violation of the Oregon Antitrust Law, Oregon Revised Statutes ("ORS") 646.705, *et seq.* These violations had impacts within the State of Oregon and substantially affected the people of Oregon.

265. Plaintiff State of Oregon seeks all relief available under the Oregon Antitrust Act, including injunction, civil penalties, equitable relief including but not limited to disgorgement and unjust enrichment, the State of Oregon's costs incurred in bringing this action, plus reasonable attorney fees, expert witness fees, and costs of investigation, and any other remedy available at law for these violations under ORS 646.760, ORS 646.770, ORS 646.775, and ORS 646.780.

Pennsylvania

266. Plaintiff Commonwealth of Pennsylvania repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

267. The aforementioned practices by Defendants violate the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1, *et seq.* ("PUTPCPL") and Pennsylvania antitrust common law. The Pennsylvania Office of Attorney General has reason to believe that the Defendants have engaged in a method, act or practice declared by 73 P.S. § 201-3 to be unlawful, and that this proceeding would be in the public interest pursuant to 71 P.S. § 201-4.

268. On behalf of the Commonwealth and its citizens pursuant to 71 Pa. C.S.A. § 732-204 (c), Pennsylvania seeks injunctive relief, restoration, disgorgement and attorneys' fees and costs pursuant to 73 P.S. § 201-4 and 4.1 and civil penalties of not exceeding $3,000 for each such willful violation pursuant to 73 P.S. § 201-8 (b). Pennsylvania also seeks injunctive relief and disgorgement under antitrust common law.

Rhode Island

269. Rhode Island realleges and incorporates all of the allegations above from paragraphs 1 through 165.

270. Defendant's acts violate the Rhode Island Antitrust Act, and Plaintiff State of Rhode Island is entitled to injunctive relief, civil penalties, reasonable attorneys' fees, costs and statutory interest pursuant to R.I. Gen. Laws § 6-36-1 *et seq.* These violations substantially affect the people of Rhode Island and have impacts within the State of Rhode Island.

271. Defendant's acts violate the Rhode Island Deceptive Trade Practices Act, and Plaintiff State of Rhode Island is entitled to injunctive relief, civil penalties, reasonable attorneys' fees, costs and statutory interest pursuant to R.I. Gen. Laws § 6-13.1-1 *et seq.* These violations substantially affect the people of Rhode Island and have impacts within the State of Rhode Island.

South Carolina

272. Plaintiff State of South Carolina repeats and realleges every preceding allegation.

273. The aforementioned practices by Defendants constitute an "unfair method of competition and unfair or deceptive acts or practices" under §39-5-20 of the South Carolina Code of Laws. Plaintiff State of South Carolina, as parens patriae for the citizens of South Carolina, is entitled to relief for these violations under §39-5-50, §39-5-110(a) and any other remedy available at law or equity.

274. South Carolina seeks attorneys' fees and costs under §39-5-50(a).

Tennessee

275. Plaintiff State of Tennessee repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

276. The aforementioned practices by Defendants are in violation of Tennessee's antitrust law, the Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101 *et seq.*

277. Defendants' aforementioned practices are in violation of the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. §§ 47-18-101 *et seq.*

278. By Defendants' actions or omissions during the FDA approval process and by Defendants' actions or omissions when converting the market from Suboxone Tablets to Suboxone Film, Defendants in numerous instances represented, directly or indirectly, expressly or by implication, that there were legitimate health and safety concerns with Suboxone Tablets that warranted a switch to Suboxone Film, which Defendants represented did not pose similar health and safety risks. These representations were made in connection with the federal approval application, advertising, marketing, promotion, offering for sale, or sale of Suboxone Film.

279. In truth and in fact, the health and safety concerns that Defendants represented with respect to Suboxone Tablets were inaccurate and unfounded, the Suboxone Tablets did not present the negative characteristics that the Defendants represented, the Suboxone Film did present health and safety concerns, and the Suboxone Tablets were potentially safer than the Suboxone Film.

280. Defendants failed to accurately and reasonably represent the characteristics of Suboxone Tablets and Suboxone Film to the FDA, doctors, payers, and pharmacists.

281. Defendants' practices caused or are likely to cause substantial injury to consumers that consumers cannot reasonably avoid themselves and that is not outweighed by countervailing benefits to consumers or competition.

282. Specifically, Defendants violated the following statutory provisions:

- Tenn. Code Ann. § 47-18-104(a), which prohibits unfair or deceptive acts or practices affecting the conduct of any trade or commerce;
- Tenn. Code Ann. § 47-18-104(b)(5), which prohibits representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have, or that a person has a sponsorship approval, status, affiliation or connection that the person does not have;
- Tenn. Code Ann. § 47-18-104(b)(7), which prohibits representing that goods or services are of a particular standard, quality, or grade, if they are of another; and
- Tenn. Code Ann. § 47-18-104(b)(27), which prohibits engaging in any other act or practice which is deceptive to the consumer or to any other person.

Utah

283. Plaintiff State of Utah repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

284. Defendants' acts violate the Utah Antitrust Act, Utah Code §§ 76-10-3101, *et seq.* (the "Act"), and Plaintiff State of Utah is entitled to all relief available under the Act for those violations, including, but not limited to, injunctive relief, civil penalties, disgorgement, attorneys' fees, and costs.

Vermont

285. Plaintiff State of Vermont repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

286. The aforementioned practices by Defendants are in violation of the Vermont Consumer Protection Act, 9 V.S.A § 2453, and Plaintiff State of Vermont is entitled to relief for these violations under 9 V.S.A. §§ 2458 and 2465.

Virginia

287. The aforementioned practices by Defendants are in violation of the Virginia Antitrust Act, Va. Code Ann. §§ 59.1-9.1 *et seq.* These violations had impacts within the Commonwealth of Virginia and substantially affected the people of Virginia.

288. Plaintiff Commonwealth of Virginia is entitled to relief under the Virginia Antitrust Act, Va. Code Ann. §§ 59.1-9.11 and 59.1-9.15.

Washington

289. Plaintiff State of Washington repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

290. The aforementioned practices by Defendants were, and are in, violation of the Washington Consumer Protection Act, Wash. Rev. Code 19.86 *et seq.* These violations had impacts within the State of Washington and substantially affected the people of Washington. Plaintiff State of Washington is entitled to an injunction, disgorgement, and civil penalties under the Consumer Protection Act, Wash. Rev. Code 19.86.080 and 19.86.140.

West Virginia

291. Plaintiff State of West Virginia repeats and re-alleges each and every allegation contained in paragraph 1 through 165.

292. Defendants' acts violate the West Virginia Antitrust Act, *see* W. Va. Code § 47–18–1 *et seq.* These violations substantially affected the State of West Virginia and had impacts within the State of West Virginia. In addition, defendants were unjustly enriched by their violations of West Virginia law.

293. Plaintiff State of West Virginia is entitled all equitable relief (including injunctive relief and disgorgement), as well as civil penalties (including treble damages), under West Virginia Code § 47–18–1 *et seq.*

294. Plaintiff State of West Virginia is also entitled to recover its costs and attorneys' fees under West Virginia Code § 47–18–9.

Wisconsin

295. Plaintiff State of Wisconsin repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

296. The aforementioned practices by Defendants are in violation of Wisconsin's Antitrust Act, Wis. Stat. Ch. § 133.03 *et seq.* These violations substantially affect the people of Wisconsin and have impacts within the State of Wisconsin.

297. Plaintiff State of Wisconsin, under its antitrust enforcement authority in Wis. Stat. Ch. 133, is entitled to an injunction, disgorgement, and civil penalties and any other remedy available at law for these violations under Wis. Stat. §§ 133.03, 133.14, 133.16, 133.17, and 133.18.

Prayer for Relief

Accordingly, the Plaintiff States request that this Court:

1. Adjudge and decree that Defendants violated sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2;
2. Adjudge and decree that the foregoing activities violated each of the State statutes enumerated in this Complaint;
3. Enjoin and restrain, pursuant to 15 U.S.C. §26 and state law, Defendants, their affiliates, assignees, subsidiaries, successors, and transferees, and their officers, directors, partners, agents and employees, and all other persons acting or claiming to act on their behalf or in concert with them, from continuing to engage in any anticompetitive conduct and from adopting in the future any practice, plan, program, or device having a similar purpose or effect to the anticompetitive actions set forth above;
4. Award to each Plaintiff State statutory or equitable disgorgement or any other relief as the court finds appropriate to redress violations for state antitrust or consumer protection laws or to restore competition;
5. Award to each Plaintiff State the maximum civil penalties allowed by law;
6. Award to each Plaintiff State its costs, including reasonable attorneys' fees; and
7. Order any other relief that this Court deems proper.

Jury Demand

298. Pursuant to Fed. R. Civ. P. 39(b), Plaintiff States request a trial by the Court.

Dated: November ___, 2016

Respectfully submitted,

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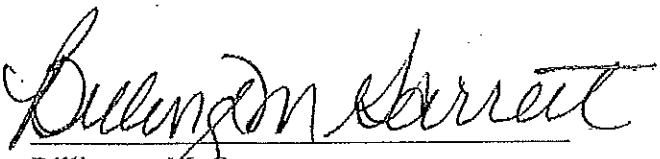

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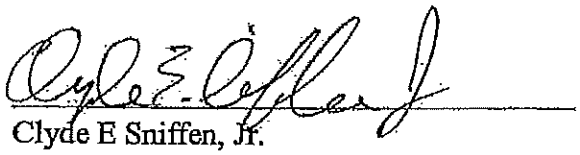

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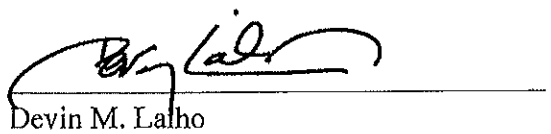

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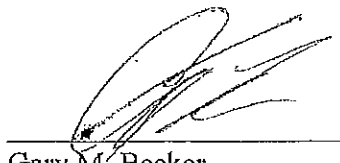

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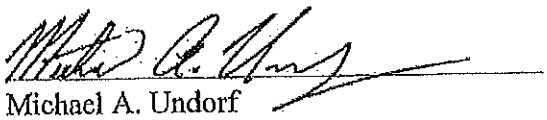

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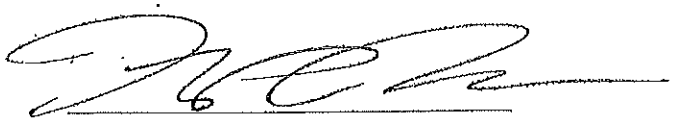

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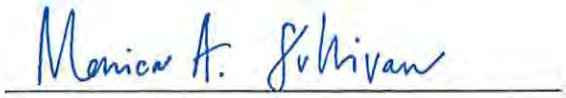

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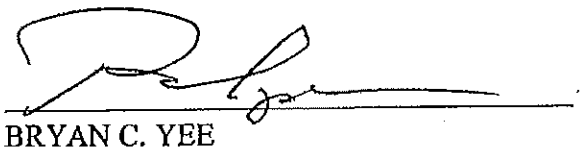

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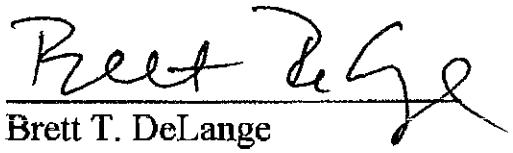

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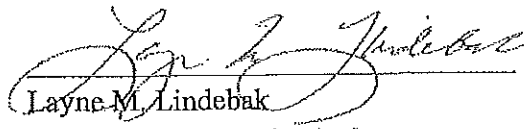

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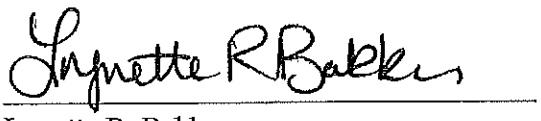

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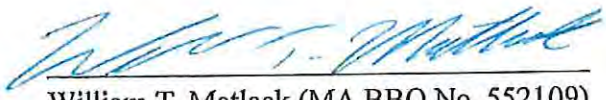

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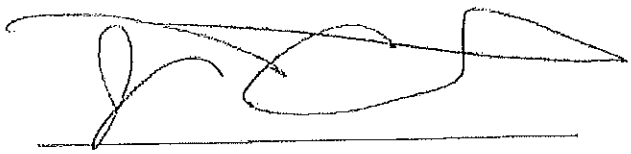

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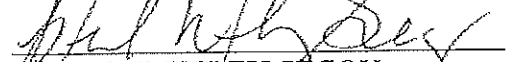
BY: 

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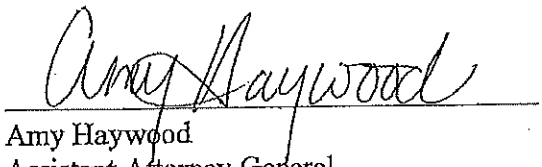

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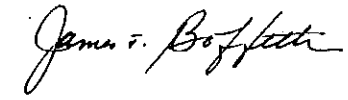

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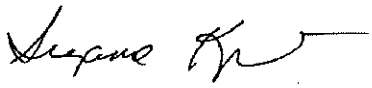

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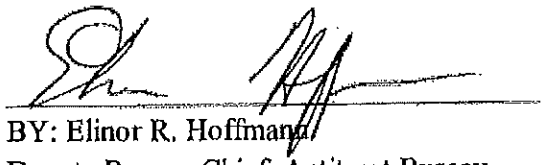

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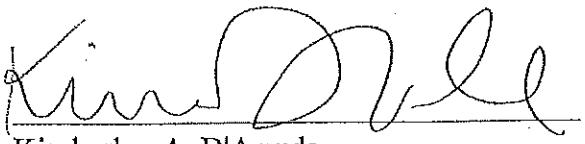

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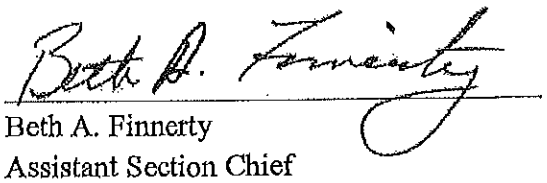

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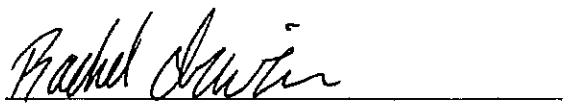

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STATE OF VERMONT

SUPERIOR COURT
CHITTENDEN UNIT

CIVIL DIVISION
DOCKET NO. 757-9-18

STATE OF VERMONT,

Plaintiff,

v.

PURDUE PHARMA L.P., PURDUE PHARMA INC., and THE PURDUE FREDERICK COMPANY,

Defendants.

COMPLAINT

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COMPLAINT

The Vermont Attorney General brings this suit against Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company (collectively, "Purdue") for violations of Vermont's Consumer Protection Act and creating a public nuisance. Defendants have violated the Vermont Consumer Protection Act by engaging in unfair and deceptive trade practices, including making misleading marketing claims about their long-acting opioid products, during the period of April 2010 to present ("the Relevant Period"), and created a public nuisance in the State of Vermont through their deceptive marketing of opioids for the treatment of chronic pain, for which the Attorney General seeks civil penalties, injunctive relief, disgorgement, fees and costs, and other appropriate relief.

INTRODUCTION

A. Purdue Succeeded in Mainstreaming Opioids Prescribing

1. For 20 years, Purdue has been the leading force in the prescription opioid market, both nationwide and in Vermont. During this time, the pharmaceutical giant Purdue manufactured, sold, and aggressively marketed prescription opioids, including the brand-name drugs OxyContin, Butrans, and Hysingla ER.

2. Before the 1990s, opioids were not widely prescribed because it was correctly believed that their use involved serious risks—including addiction, withdrawal, and overdose—that were not justified by the benefits. Opioids typically were used only to treat short-term, acute pain (*e.g.*, trauma and post-surgical) or for palliative care (*e.g.*, end-of-life) because they were considered too addictive and debilitating for long-term use. This prevailing medical and popular understanding operated as an appropriate constraint on the market for prescription opioids.

3. Beginning in the late 1990s, Purdue set out to effect a sweeping change in the public and medical community's perception of opioids—by downplaying the risks and

aggressively encouraging much broader use. Purdue orchestrated and enacted a plan of massive expansion—designed to change opioids' limited use from acute and palliative care to become a wide-ranging and often front-line option for *long-term, chronic conditions* like back pain, migraines, and arthritis.

4. Purdue exploited a new emphasis in medicine on patient-centered care to advocate that pain was an undertreated priority. Purdue helped to institutionalize this patient-centric shift, and then Purdue capitalized on the platform it had created to push its message that health care providers should prescribe more opioids to treat this undertreated chronic pain. Purdue designed an array of deceptive messages that reduced concerns about opioids generally, and that promoted Purdue's opioids specifically as safe, effective, and appropriate for long-term use and for moderate pain conditions. Purdue's massive marketing scheme, which occurred alongside similar efforts of other industry players, was profoundly successful at shifting the medical and public consensus regarding the use of opioids.

5. Before the introduction of OxyContin in 1996, the opioid market was for post-surgical, end-of-life, or cancer pain. By 2012, opioids were among the most prescribed drugs; approximately 90% of prescription opioids were given for chronic pain conditions, and only 10% of prescription opioids were dispensed for post-surgical, palliative, and cancer pain treatments.[1] This was an almost complete reversal of long-standing medical practice.

6. According to the Centers for Disease Control and Prevention ("CDC"), nearly 62 million Americans received at least one opioid prescription in 2016.[2]

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[1] Laxmaiah Manchikanti *et al.*, *Opioid Epidemic in the United States*, 15 Pain Physician ES9-ES38, at ES27 (2012).

[2] Centers for Disease Control and Prevention, Annual Surveillance Report of Drug-Related Risks and Outcomes (2017), https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf, at 7.

7. In 2007, Purdue and three of its executives pleaded guilty to federal criminal charges for deceptive conduct in the sale and marketing of opioids. Purdue paid more than $600 million to resolve the government enforcement actions. But by then, long-term opioid therapy for chronic pain had become established as a commonplace, often first-line, treatment.

8. Although Purdue made some concessionary adjustments to the marketing statements that had prompted its prosecution, it never stopped misrepresenting the risks and benefits of its blockbuster drug, OxyContin, and other opioids. Purdue failed to correct, and actually persisted in building upon and profiting from, its earlier deceptions and the platform of misunderstanding it had created. Even worse, Purdue began directing its deceptive marketing in pursuit of new target patients: specifically, it began focusing its efforts on the elderly and patients who had not previously used these powerful drugs (labeled by Purdue as the "opioid naïve").

9. Since 2007, Purdue, nationwide and in Vermont, has engaged in unfair, false, and misleading conduct, including from April 2010 to present ("the Relevant Period"), by continuing to: (a) omit or minimize the serious risk of addiction; (b) overstate the effectiveness of screening tools for preventing addiction, which gave prescribers unwarranted confidence that they could safely prescribe opioids; (c) deny or fail to disclose that the dangers of opioids increase as dose increases, which increase the risk of addiction and overdose; and (d) exaggerate the effectiveness of abuse-deterrent formulations at preventing abuse and addiction.

10. There is not now, and has never been, <u>any science</u> to support Purdue's distorted symphony of misrepresentations about the benefits and safety of long-term opioid use. Purdue falsely promoted long-term opioid use as an appropriate and effective therapy that would improve patients' function and quality of life. Year after year, Purdue promoted these

unsubstantiated claims to patients—via unbranded websites and other promotional materials—and to prescribers—through in-person sales calls, branded and unbranded marketing materials, speaker presentations, and other means. Purdue made these deceptive statements without disclosing the critical fact that there was no scientific evidence to support the safety or efficacy of opioid use for longer than 12 weeks. In fact, Purdue made the unconscionable decision not to pursue studies about the use of opioids for longer than 12 weeks. The Food and Drug Administration ("FDA") ordered Purdue and other manufacturers to undertake such studies in September 2013.[3]

11. At the same time, Purdue methodically minimized the very real risks of addiction in its sales calls and marketing materials, as alleged herein. These two pieces went hand-in-glove: (a) convincing the medical community and public to believe scientifically unsubstantiated statements about the safety and benefits of long-term opioid use, and (b) inappropriately minimizing the serious risks of addiction. These formed the lynchpins of Purdue's successful and deceptive scheme.

B. The Proliferation of Prescription Opioids Has Been Devastating to Vermont

12. In 2010, 482,572 opioid prescriptions were dispensed in Vermont, a state with a population of just over 625,000.[4] That number continued to rise. In 2015, the number of opioid

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[3] Food and Drug Administration PMR 2065-5, Opioid Post-Marketing Requirement Consortium (available at https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm363722.htm).

[4] Anne VanDonsel, Shayla Livingston, and John Searles (Vermont Department of Health), *Opioids in Vermont: Prevalence, Risk, and Impact* (October 27, 2016), http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Prevalence_Risk_Impact.pdf, at 30 ("Number of Prescriptions by Drug Type and Year"); Vermont Department of Health, *Special Report: Opioid Prescriptions and Benzodiazepines, 2014* (February 2016), http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Benzodiazepenes_Report.pdf, at 3.

prescriptions increased to 498,973[5]—the equivalent of giving a prescription to every 1.3 people living in Vermont, including infants.

13. There is no question that this volume of opioids leads to increased incidence of dependence and addiction. In a 2014 survey by the U.S. Department of Health and Human Services, more than three percent of Vermonters—approximately 18,000 people—reported a dependence on a controlled substance.[6] Vermont ranks as the 8th-highest state for drug dependence nationwide,[7] despite other favorable health indicators like better access to health care and insurance coverage as compared to other states.[8]

14. Opioids are killing Vermont citizens at a skyrocketing rate, and a common origin is prescription opioids. Drug-related fatalities involving opioids nearly doubled between 2012 and 2016.[9] While the national average of opioid-related overdose deaths in 2016 was 13.3 per 100,000 persons, the rate in Vermont was 18.4 – 38% higher than the national average.[10] And these overdose deaths have a broad impact. In a state like Vermont, there are no anonymous deaths.

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[5] *Id.*

[6] amfAR Opioid & Health Indicators Database, *Percent of people 12+ Reporting Drug Dependence*, http://opioid.amfar.org/indicator/drugdep.

[7] *Id.*

[8] *See State Health Assessment Plan - Healthy Vermonters 2020* (December 2012), http://www.healthvermont.gov/sites/default/files/documents/2016/11/Healthy%20Vermonters%202020%20Report.pdf, at 13, 5, 27.

[9] Vermont Department of Health, *Opioid-Related Fatalities Among Vermonters* (updated August 2018), http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Data_Brief_Opioid_Related_Fatalities.pdf.

[10] National Institute on Drug Abuse, *Vermont Opioid Summary* (March 2018), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/vermont-opioid-summary.

15. The link between prescription opioids and "street drugs" like heroin and fentanyl fuels the opioid crisis. Many addicts begin with a legal opioid prescription from their doctor or by taking a pill from a prescription bottle belonging to a family member or friend.[11] Prescription opioid users also are far likelier to use illegal opioids like heroin and fentanyl. U.S. Centers for Disease Control and Prevention ("CDC") statistics show that people addicted to prescription opioids are 40x more likely also to be addicted to heroin. The same CDC report shows that nearly half (45%) of people who used heroin also were addicted to prescription opioid painkillers.[12] In 2017, the Vermont Department of Health reported that 80% of new heroin users also had a history of misusing prescription opioids.[13]

16. The heroin/fentanyl problem in Vermont is acute—fentanyl is involved in two-thirds of all opiate-related fatalities, and heroin is involved in one-third of all opiate-related fatalities.[14] The number of fatal overdoses involving fentanyl, in particular, has skyrocketed in recent years—a tenfold increase from 6 fatalities in 2012 to 67 fatalities in 2017.[15]

17. Beyond just addiction, there are additional and serious health dangers associated with illicit heroin and fentanyl use, including collapsed veins, bacterial infections of the blood

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[11] Nora Volkow and Francis Collins, National Institute on Drug Abuse, *"All Scientific Hands On Deck" to End the Opioid Crisis*, May 31, 2017, https://www.drugabuse.gov/about-nida/noras-blog/2017/05/all-scientific-hands-deck-to-end-opioid-crisis ("While there were nearly 20,000 overdoses in 2015 due to heroin or fentanyl, the trajectory of opioid addiction usually begins with prescription opioid misuse. Some people with opioid addiction began by taking diverted pills from friends and family members, but others began with an opioid prescription of their own").

[12] Centers for Disease Control and Prevention, *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/.

[13] Vermont Department of Health, *Opioid Misuse, Abuse & Dependence in Vermont Data Brief, April 2017*, http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_data_brief_opiodmisuse.pdf.

[14] *Opioid-Related Fatalities Among Vermonters*, *supra* n.9, at 1.

[15] *Id.* at 5.

and heart, lung complications, and depression. When heroin is administered by injection, the sharing of needles or bodily fluids puts users at heightened risk for HIV and Hepatitis B and C—serious diseases that can be transmitted to sexual partners and children.[16] The concern about rising rates of HIV and Hepatitis C is very real in Vermont: in 2016, the CDC identified two Vermont counties—Essex and Windham—out of the more than 3,100 counties across the entire United States as among those in the 95th percentile (top 5% nationwide) at greatest risk for outbreaks of HIV and Hepatitis C.[17]

18. While heroin and fentanyl have contributed to the increasing number of opioid deaths in Vermont, the majority of opioid fatalities are causally linked to opioid prescriptions—which many heroin and fentanyl abusers have in their system at the time of their fatal overdose or have used at some point prior to their fatal overdose. A study by the Vermont Prescription Monitoring System found that 85% of opioid-related accidental fatalities in Vermont had received an opioid prescription within the last five years[18] and that 25% percent had received an opioid prescription within 30 days prior to their death.[19]

19. In Vermont, 90.6% of opioid-related fatalities in 2015 occurred in people who had controlled substance prescription histories. Of the decedents who had been given an opioid

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[16] National Institute on Drug Abuse, *What are the medical complications of chronic heroin use?* (March 28, 2018) at 11, https://www.drugabuse.gov/publications/research-reports/heroin/what-are-medical-complications-chronic-heroin-use.

[17] Michelle M. Van Handel et al., *County-level Vulnerability Assessment for Rapid Dissemination of HIV or HCV Infects among Persons who Inject Drugs, United States*, Journal of Acquired Immune Deficiency Syndromes, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5479631/; American Foundation for AIDS Research, *Vermont Opioid Epidemic*, http://opioid.amfar.org/VT.

[18] Vermont Prescription Monitoring System, *Controlled Substance Prescription Histories for Opioid-Related Accidental Fatalities in 2015* at 3, http://www.healthvermont.gov/sites/default/files/documents/2017/01/HSRV_VPMS_10_28_16_opioid_related_accidental_fatality_brief.pdf.

[19] *Id.*

prescription during the year prior to their death, the average opioid prescription supply was 261 days.[20]

20. In the most recent years for which data from the Vermont Department of Health is available (2015, 2016 and 2017), prescription opioids have been involved in roughly one-third of opioid-related deaths in Vermont.[21]

21. The demand for opioid addiction treatment has risen dramatically. In 2006, 1,897 Vermonters were treated for opioid use in state-funded treatment facilities. By 2015, that number had more than tripled, to 6,084.[22]

22. The effects of the opioid epidemic are widely felt in Vermont. In a 2016 poll commissioned by Vermont Public Radio, 53% of respondents said that they or someone they knew had been personally affected by opiate addiction.[23]

The devastating effects on infants and young children

23. Opioid use disorder in pregnant women has become prevalent in Vermont, as opioid use has proliferated more broadly, with potentially devastating health consequences for them and their infants. The number of women with diagnosed opioid use disorder at the time of delivery has increased dramatically over time in Vermont: from 0.5 per 1,000 deliveries in 2001 to 48.6 per 1,000 deliveries in 2014—over seven times the national average, and the highest

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[20] *Opioids in Vermont: Prevalence, Risk, and Impact, supra* n.4, at 31 ("Prescription History of Individuals with Opioid-related Accidental Fatalities").

[21] *Opioid-Related Fatalities Among Vermonters, supra* n.9, at 1.

[22] Vermont Department of Health, *People Treated for Opiate Use in Vermont by Fiscal Year*, http://www.healthvermont.gov/sites/default/files/documents/2016/12/adap_TotalOpiatebyFY.pdf.

[23] Vermont Public Radio, *The VPR Poll: The Issues, The Races and The Full Results* (July 27, 2016), http://digital.vpr.net/post/vpr-poll-issues-races-and-full-results#stream/0.

among the 30 states that have compiled this data.[24] This widespread prevalence of opioid use disorder in pregnant Vermonters is a major public health concern, because of the serious potential adverse maternal and neonatal outcomes associated with opioid use during pregnancy: preterm labor, stillbirth, neonatal abstinence syndrome, and maternal mortality.[25]

24. The number of infants born in Vermont who are diagnosed with Neonatal Abstinence Syndrome ("NAS")—a condition in which a newborn baby suffers withdrawal symptoms—also far exceeds the national average. Based on available data from 2012, the Vermont Department of Health estimated that the rate of NAS in Vermont was five times higher than the national average, and the Vermont statistics have continued to rise.[26]

25. In 2008, there were 17.0 infants with NAS per 1,000 live births (to Vermont residents in Vermont hospitals). By comparison, in 2014, that number had more than doubled to 35.3 per 1,000 live births (to Vermont residents in Vermont hospitals).[27]

26. Infants exposed to opioids *in utero* also face serious health consequences. At least 60–80% of these babies will experience symptoms such as seizures, respiratory distress, diarrhea, hypertonia, feeding intolerance, tremors, and vomiting because of their exposure to opioids in the womb.[28]

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[24] *Opioid Use Disorder Documented at Delivery Hospitalization—United States, 1999-2014*, CDC Morbidity and Mortality Weekly Report (August 10, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6731a1.htm?s_cid=mm6731a1_e, at 847.

[25] *Id.* at 845.

[26] *Opioids in Vermont: Prevalence, Risk, and Impact*, *supra* n.4, at 44 ("Improved treatment and screening have helped to identify more infants exposed to opioids").

[27] Vermont Department of Health, *Neonates Exposed to Opioids in Vermont* (April 2017), http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Opioids_Neonate_Exposure.pdf, at 1.

[28] Stephen W. Patrick *et al.*, *Neonatal Abstinence Syndrome and Associated Health Care Expenditures*, Journal of the American Medical Association (2012), https://www.ncbi.nlm.nih.gov/pubmed/ 22546608.

27. Infants born with NAS require longer and costlier hospital stays than those who are born without exposure to opioids. In 2012, the average length of hospital stay for non-NAS infants born to Vermont residents in Vermont hospitals was 3.0 days, at a cost of $5,590. But Vermont infants with NAS faced hospital stays more than 2x longer and nearly 3x more expensive, averaging 7.4 days and $15,456 (respectively).[29]

28. More than 50% of Vermont children under the age of five who have been taken into the custody of the Vermont Department of Children and Families (DCF) have been removed from their homes because of opioid-related issues.[30] As reported in 2016, the reporting of incidences to DCF's Child Protection Line have increased by 30%—from 15,760 reports in 2012 to 20,583 in 2016—and during those same years, approximately 30% of the calls related to substance abuse.[31]

The financial cost to our communities

29. Opioid overprescribing, misuse, and prescription diversion are draining Vermont's health care system. For example, one study estimated the 2007 total health care spending associated with opioid abuse in Vermont as exceeding $38 million.[32] From 2007 to

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[29] Vermont Department of Health, *Neonates Exposed to Opioids in Vermont*, *supra* n.27, at 2.

[30] Vermont Opioid Coordination Council, *Initial Report of Recommended Strategies* (January 2018), http://www.healthvermont.gov/sites/default/files/documents/pdf/OCC%202018%20Report%202018-1-9.Final_.pdf, at 3 n.1.

[31] Howard Weiss-Tisman, *Opioid Abuse Continues to Strain Vermont's Child Welfare System*, Vermont Public Radio (December 5, 2017), http://digital.vpr.net/post/opioid-abuse-continues-strain-vermonts-child-welfare-system#stream/0; Vermont Dept. for Children and Families Family Services Div., *2016 Report on Child Protection in Vermont*, http://legislature.vermont.gov/assets/Legislative-Reports/Child-Protection-Report-2016.pdf.

[32] Matrix Global Advisors, *Health Care Costs from Opioid Abuse: A State-by-State Analysis* (April 2015), https://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf, at 5.

2018, opioid prescribing rose dramatically, as did the numbers of persons using, misusing, and abusing both prescription and illegal opioids.

30. The health care costs associated with opioid overprescribing, addiction, and abuse are crushing. Vermont consumers—individuals, employers, and private insurers—have paid millions for opioid prescriptions. Vermont's opioid treatment programs cost more than $70 million between 2012 and 2017 alone.[33] Vermont consumers have likewise borne substantial healthcare costs due to this epidemic of addiction.

31. It is well-established that health care costs for persons addicted to opioids are much higher than health care costs for the general population. For example, overall health care costs are approximately 3x higher among patients receiving Medication Assisted Treatment for opioid addiction than is true for the general Medicaid population.[34] The average national private payer cost per person with opioid use disorder was $63,356 (in 2015).[35]

32. The prevalence of opioids in Vermont also places a greater burden on law enforcement – increased costs associated with investigating and prosecuting crimes related to opioid use and abuse, as well as increased costs for treating incarcerated residents for opioid use disorder.

33. The costs of incarceration—which include Medication Assisted Treatment for addiction and other related costs—are largely paid by the State. Crimes associated with

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[33] Harry Chen, MD (Commissioner, Vermont Dept. of Health), *Status of Opioid Treatment Efforts* – Health Reform Oversight Committee (October 25, 2016), http://www.leg.state.vt.us/jfo/healthcare/Health%20Reform%20Oversight%20Committee/2016_10_25/Status%20of%20Opioid%20Treatment%20Efforts%20-%20Chen.pdf, at 22.

[34] Vermont Department of Health, *The Opioid Addiction Treatment System* (January 13, 2013), http://www.leg.state.vt.us/reports/2013externalreports/285154.pdf, at 9.

[35] *Status of Opioid Treatment Efforts*, *supra* n.33.

prescription drugs—chiefly robbery and burglary—have risen.[36] Data collected by the Vermont Intelligence Center show that law enforcement consistently averages between one and two seizures of illicit opioids per day.[37] In a small state like Vermont, this steady drumbeat of opioid seizures has become a focal point of police time and attention.

34. Purdue's prescription opioids continue to be a central cause of the opioid crisis in Vermont, and Purdue also has retained a significant market share of the dollars spent by the State on opioid prescriptions. Using the Vermont State Employees' health plan data as just one example, Purdue's opioids alone account for more than 55% of the State of Vermont's total opioid prescription spending, from April 2010 to June 2018.

C. Vermont Is Leading the Nation with Its Innovative and Effective Approach to Combatting the Opioid Crisis

35. In 2012, Vermont passed legislation[38] authorizing its Department of Health to establish a state-wide integrated care system for opioid addiction treatment, creating the treatment "Hubs" (for high intensity Medication Assisted Treatment and counseling) and "Spokes" (for treatment by a team consisting of Community Drug Addiction Treatment Act-waivered prescribers—which include physicians, nurse practitioners, and physician assistants—

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[36] Vermont Department of Health, *Issue Brief: Prescription Drug Misuse in Vermont,* at 12 (Feb. 12, 2013), http://thehungryheartmovie.org/wp-content/uploads/2013/09/SEOW_Rx_Issue_Brief_Final_02_12_13.pdf.

[37] *Opioid Seizures: Number of Opioid Seizures as Reported by Vermont Law Enforcement*, Vermont Intelligence Center (January 2017), last updated June 2015, last on website May 18, 2018 (available at https://webcache.googleusercontent.com/search?q=cache:u92N642SthsJ:https://app.resultsscorecard.com/perfmeasure/embed/101519+&cd=2&hl=en&ct=clnk&gl=us).

[38] Act No. 135 (available at https://legislature.vermont.gov/assets/Documents/2012/Docs/ACTS/ACT135/ACT135%20As%20Enacted.pdf).

supported by a treatment team consisting of a nurse and a credentialed substance abuse counselor for every 100 persons receiving MAT).[39]

36. The Hub-and-Spoke System is unique in its comprehensiveness and has been recognized nationally as "visionary."[40] Vermont's success is the result of state and local actors working cooperatively to design and implement a multi-faceted, cutting-edge approach to addressing opioid addiction that reaches even the most rural areas in the State.[41] Despite Vermont's success in developing and administering these programs, the problem of opiate addiction is overwhelming, and the demand for these treatment programs continues to increase. Vermont's Blueprint for Health reports that more than 6,000 Vermonters are participating in the Hub and Spoke treatment system through the State's Medicaid program,[42] and additional Vermonters are treated in the Hub & Spoke system through private insurance and Medicare. Demand for opioid treatment in Vermont has continued to rise.[43] Vermont has engaged in an ongoing effort to keep up with the need and reduce wait times for patients seeking treatment.[44]

37. Vermont has elected to invest its treatment funds in evidence-based approaches, and is the nation's most proactive state at providing buprenorphine (a key component of

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[39] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, March 2017 (available at http://www.healthvermont.gov/sites/default/files/documents/2017/03/ADAP_Opioid_Strategy_Brief.pdf).

[40] Vermont Opioid Coordination Council, *Initial Report of Recommended Strategies*, *supra* n. 30, at 3.

[41] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, *supra* n.39.

[42] Pat Bradley, *Vermont Governor Testifies in Washington on Opioid Treatment Programs* (Feb. 7, 2018), http://wamc.org/post/vermont-governor-testifies-washington-opioid-treatment-programs; State of Vermont, *Blueprint for Health*, http://blueprintforhealth.vermont.gov/about-blueprint/hub-and-spoke.

[43] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, *supra* n.39.

[44] Chen (Vermont Department of Health), *Status of Opioid Treatment Efforts*, *supra* n.33, at 11 ("Hub Census and Waitlist: September 26, 2016").

Medication Assisted Treatment) to patients in need. The State averages 204 buprenorphine prescriptions per 1,000 persons, which is 524% higher than the national average of 39 per 1,000.[45] Vermont also leads the nation in funding access to buprenorphine for its citizens. Medicaid funding is used by patients filling over 68% of the total buprenorphine prescriptions in Vermont—nearly 3x the national average of 24.2%.[46]

38. Vermont also has elevated its outreach to high-risk patients for comprehensive, specialty support. Pregnant women are eligible for not simply treatment, but also for supportive programming, including housing and transportation, which can vastly improve health outcomes for mothers and infants.[47] The State has been providing up to 120 days of addiction treatment to inmates and has pioneered efforts to divert low-level drug offenders from prosecution and incarceration if they agree to treatment shortly after arrest. As of July 1, 2018, all Vermont inmates who enter the correctional system on Medication-Assisted Treatment and/or are diagnosed with opioid use disorder will continue to be provided with Medication-Assisted Treatment while incarcerated, for as long as treatment is medically necessary.[48]

39. In December 2013, the Vermont Department of Health launched an overdose reversal pilot project to distribute naloxone to people at risk for overdose, along with their family

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[45] IMS Institute for Healthcare Informatics, *Use of Opioid Recovery Medications* (September 2016), https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/use-of-opioid-recovery-medications.pdf, at 5.

[46] *Id.*

[47] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders, supra* n.39, at 7.

[48] S. 166, An act relating to the provision of medication-assisted treatment for inmates, https://legislature.vermont.gov/assets/Documents/2018/WorkGroups/House%20Corrections%20and%20Institutions/Bills/S.166/S.166~Ed%20Paquin%20~As%20Introduced,%201-31-2018~3-29-2018.pdf.

members and others most likely to be present in the event of an overdose.[49] To date, more than 17,000 kits have been distributed at 30 sites in Vermont—all free of charge to the recipients. [50]

40. In August 2016, the Vermont Commissioner of Health issued a statewide, standing order authorizing every pharmacy to dispense naloxone to anyone—without a prescription.[51]

41. Statewide rules and protocols for Emergency Medical Services (EMS) personnel were changed in 2013 to allow EMT providers at all license levels to administer nasal naloxone. Additional legislation passed in 2016 allowed VDH to provide all EMS agencies and law enforcement entities with naloxone at no charge.[52]

42. In June 2013, the Vermont Legislature passed Act 75 which, among other things, mandated every health care provider who prescribes or dispenses any Schedule II, III, or IV controlled substances to register for and use the Vermont Prescription Monitoring System (VPMS).[53] This law was amended in 2016, through Act 173, to increase the mandatory reporting frequency for dispensers from at least once per week to daily.[54] Today, when a prescription is

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[49] Vermont Department of Health, *Naloxone Pilot Project – Data Brief* (April 18, 2014), https://legislature.vermont.gov/assets/Documents/2014/WorkGroups/House%20Human%20Services/Bills/S.295/Witness%20Testimony/S.295~Barbara%20Cimaglio~Naloxone%20Pilot%20Project%20%E2%80%93%20Data%20Brief~4-24-2014.pdf.

[50] Vermont Opioid Coordination Council, *Initial Report of Recommended Strategies, supra* n.30, at 30; Naloxone Distribution and Administration in Vermont – Data Brief, updated May 2018, http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Naloxone_Data_Brief_0.pdf.

[51] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders* (March 2017), supra n.39.

[52] *Id.*

[53] Act No. 75. An act relating to strengthening Vermont's response to opioid addiction and methamphetamine abuse. (H. 522) (2013), http://www.leg.state.vt.us/docs/2014/Acts/Act075.PDF.

[54] Act. No. 173, An act relating to combating opioid abuse in Vermont. (S. 243) (2016), https://legislature.vermont.gov/assets/Documents/2016/Docs/ACTS/ACT173/ACT173%20As%20Enacted.

dispensed to a patient, information about the drug, recipient, prescriber, and pharmacy is uploaded into VPMS within 24 hours so that this data can be tracked and monitored, which improves a prescriber's ability to detect abuse and diversion. The Vermont Department of Health works to ensure compliance with data uploading and data quality.[55]

43. Act 75 also required professional licensing authorities for healthcare providers to develop evidence-based standards to guide them in the prescription of Schedule II, III, and IV controlled substances for the treatment of chronic pain, which was later supplemented by Act 173 to include development of guidelines for treatment of acute pain. Act 173 also created the Controlled Substances and Pain Management Advisory Council to advise the Department of Health on the drafting of guidelines for prescribing opioids for acute and chronic pain. Rules for responsible prescribing of opioids for chronic and acute pain were finalized in December 2016. The rules provide information to prescribers on appropriate treatment of pain and guidance on how to reduce the likelihood of drug dependence. Importantly, the rules require prescribers to consider non-opioid alternatives before prescribing opioids and to re-evaluate treatment at least every 90 days, if not more frequently.[56]

44. Finally, the State has undertaken many initiatives to increase public awareness and education about the dangers of opioids. The Vermont Department of Health launched Vermont's Most Dangerous Leftovers campaign in 2014, to increase awareness of the safe use, safe storage, and proper disposal of prescription drugs, including promoting the "Vermont 2-1-1" informational telephone line as a source to find local drug disposal sites. The Department of

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[55] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, supra n.39.

[56] Vermont Department of Health, Rule Governing the Prescribing of Opioids for Pain, July 1, 2017, R. §§ 6.2, 6.2.1, 6.2.1.1, 6.2.2.

Health also produced Public Service Announcements to promote the safe use, safe storage, and safe disposal of prescription drugs and promote naloxone to prevent overdose deaths.[57]

45. Additionally, the Vermont Department of Health launched ParentUpVT.org, which provides strategies and actions for parents and caregivers to help prevent drug use among youth. And the State is establishing educational campaigns to increase the perception of risk associated with prescription pain reliever misuse and increase awareness on the responsible use of prescription pain relievers.[58]

46. Yet, much more remains to be done. The cost and effort of remediating the opioid crisis require tremendous resources and persistence. For decades, Purdue cultivated the demand for its opioids and opioids generally, and profited from their overprescribing, misuse, and abuse. The State has filed this lawsuit to expose Purdue's misconduct and legal culpability in Vermont—because the public deserves to know how it has been deceived, and because Purdue must be held accountable so that it is required to pay its share of the extraordinary costs required to abate this crisis.

47. Purdue's success in promoting opioids is particularly astonishing in light of the efforts Vermont had made to curb the influence of drug manufacturers on prescribing. In 2009, Vermont passed a law banning gifts from manufacturers of prescription drugs and products to health care professionals and providers. *See* Vt. Stat. Ann. tit. 18 § 4631a. These prohibitions include a ban on any payment, food, entertainment, travel, subscription, service, or anything else of value with limited exceptions for things like research grants and teaching honoraria that must

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[57] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, supra n.39.

[58] *Id.*

be disclosed to the Attorney General's Office.[59] But Purdue did not rely exclusively on in-person visits and gifts to persuade doctors. Purdue used front groups disguised as independent patient advocacy organizations, paid spokespeople disguised as experts, and biased studies disguised as legitimate academic research to reach doctors and patients. All of this conduct needs to be exposed.

48. Even today, Purdue seeks to obscure its culpability for this crisis, as set forth in Section D. Purdue distances itself from its past misconduct, and attempts to portray itself as a responsible corporate citizen by falsely portraying the opioid epidemic as mainly a problem of illicit drug diversion and abuse. But the genesis of this crisis can be placed squarely on Purdue's doorstep. Purdue's efforts to change the medical consensus and public perception about the inherent dangers of opioids were tremendous in their scope, strategy, and success. Purdue has been the epitome of greed and deception for more than 20 years.

49. Purdue's unfair and deceptive conduct, which fomented and perpetuates the opioid crisis, has violated and continues to violate Vermont law. To redress and punish Purdue's conduct, the Attorney General of Vermont seeks an Order requiring Purdue to permanently cease its unlawful promotion of opioids, correct its past and current misrepresentations, abate the public nuisance its deceptive marketing has created, and pay civil penalties for its continuous, pervasive, deceptive and unfair business practices in connection with the marketing of opioids.

PARTIES

A. Plaintiffs

50. The Attorney General is authorized to represent the State in all civil matters at common law and as allowed by statute. Vt. Stat. Ann. tit. 3, § 152. The Attorney General is

[59] 18 V.S.A. § 4631a.

charged with the responsibility of enforcing the Consumer Protection Act ("CPA") and all regulations promulgated thereunder, Vt. Stat. Ann. tit. 9, § 2458.

51. The State also has standing *parens patriae* to protect the health and well-being, both physical and economic, of its residents. Opioid use and abuse have affected a substantial segment of the population of Vermont.

B. Defendants

52. Purdue Pharma L.P. is a Delaware limited partnership. Purdue Pharma Inc. is a New York corporation that is the general partner of Purdue Pharma L.P. The Purdue Frederick Company is a New York corporation. Defendants operate as an integrated enterprise with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901.

53. Purdue manufactures, promotes, sells, and distributes the opioids OxyContin, MS Contin, Dilaudid, Dilaudid HP, Butrans, and Hysingla ER in the United States and Vermont. OxyContin is Purdue's best-selling opioid. Purdue has generated sales estimated at more than $35 billion since it launched OxyContin in 1995.[60]

JURISDICTION AND VENUE

54. The Court has personal jurisdiction over Purdue because it has regularly transacted business in Vermont, purposely directed business activities into Vermont, maintained employees who operated in Vermont, and engaged in unlawful practices in Vermont against Vermont consumers.

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[60] Alex Morrell, "The OxyContin Clan: The $14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families, *Forbes* (July 1, 2015), https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#4921c27475e0; Chase Peterson-Withorn, "Fortune of Family Behind OxyContin Drops Amid Declining Prescriptions," *Forbes* (June 29, 2016), https://www.forbes.com/sites/chasewithorn/2016/06/29/fortune-of-family-behind-oxycontin-drops-amid-declining-prescriptions/#7142049f6341.

55. Defendants Purdue Pharma L.P. and Purdue Pharma Inc. are registered to do business in Vermont with Corporation Service Company as their registered agent located at 100 North Main St., Suite 2, Barre, VT, 05641.

56. Purdue has generated millions of dollars of revenue through sales of its opioid pain medications in Vermont. Until recently, Purdue also consistently maintained a sales force in the State. During the Relevant Period, at least 19 different Purdue sales representatives and sales managers have had a sales territory in or including Vermont. In that period, Purdue's Vermont sales force made more than 5,300 sales visits regarding OxyContin and other Purdue opioids to Vermont health care providers.

57. As alleged herein, Purdue has deceptively and otherwise unlawfully marketed its opioids in Vermont, through both conduct within the State and other business activities directed into the State. This conduct includes (a) directly conveying promotional messages to Vermont health care providers through the sales force, and (b) funding, developing, influencing, adopting, and/or disseminating or making available publications regarding opioids—such as promotional materials, continuing medical education, and prescribing guidelines—to Vermont health care providers and consumers.

58. Venue in this Court is proper, pursuant to Vt. Stat. Ann. tit. 9, § 2458(a), because Purdue does business in Chittenden County. Among other things, Purdue made nearly 2,000 sales visits regarding opioids to health care providers in Chittenden County during the Relevant Period.

GENERAL ALLEGATIONS COMMON TO ALL COUNTS

A. Cementing the Foundation: From the Late 1990s to 2007, Purdue Engaged in a Campaign of Deception to Create and Sustain a Market for Its Opioids

The success of Purdue's opioid enterprise was due to a bold master plan. Purdue offered a product—opioids—that had been previously viewed by the medical community and the public

as dangerous. A healthy aversion to opioid use existed. That was true until Purdue built a campaign to mainstream opioid use for long-term pain patients, co-opted the science and understanding of opioids by disseminating false and deceptive information about studies and testing, and blanketed the medical community with disinformation, incentives, and false evidence about opioids—and particularly, about its flagship product, 12-hour extended release OxyContin. This reprehensible and illegal conduct led to investigations by federal and state governments, including Vermont, forcing Purdue to enter into criminal and civil settlements in 2007 to the tune of $635 million dollars.

59. Beginning in 1996, Purdue presented OxyContin—and later its other opioids—as the solution to the problem of chronic pain. (As used in this Complaint, "chronic pain" means non-cancer pain lasting twelve weeks or longer.) Through marketing that was as pervasive as it was deceptive, Purdue convinced health care providers that the risks of long-term opioid use were overblown and also that the alleged benefits—reduced pain, improved function, and quality of life—were proven, even though Purdue had no evidence to support these assertions.[61] By the mid-2000s, Purdue had succeeded in drastically changing medical and public opinion about opioids. Purdue's marketing convinced prescribers, educators, and patients that opioids were safe and effective for long-term use and also that they were an appropriate, first-line treatment for routine chronic pain conditions.

1. Purdue Mainstreamed Opioids for Chronic Pain

60. Purdue marketed its opioids directly to health care providers and patients, nationwide and in Vermont. Purdue's sales representatives, also known as "detailers," made thousands of in-person sales calls to Vermont healthcare providers in which they misleadingly portrayed opioids as safe, effective, and appropriate for the treatment of chronic pain. In Vermont especially, Purdue targeted generalists—primary care physicians, nurse practitioners,

[61] Centers for Disease Control and Prevention, *Guideline for Prescribing Opioids for Chronic Pain* (2016), https://www.cdc.gov/drugoverdose/prescribing/guideline.html (hereafter, "CDC Guideline"), at 2, 20, 25. (confirming, based on existing research and evidence, that opioid use presents a "serious risk" of addiction, use for three months or more "substantially increases" that risk, and there never has been "good evidence that opioids improve pain or function with long-term use").

and physician assistants—as opposed to other healthcare professionals with specialized training and knowledge about the use and risks of opioids. Purdue's deceptive marketing created a cadre of primary care doctors, nurse practitioners and physicians' assistants who were "educated" by Purdue's sales representatives and marketing literature to look for pain and to treat it with opioids. This, in turn, created a patient population that came to expect and specifically request opioids.

61. Purdue misrepresented key facts about the safety of its opioids – in particular, the risk of addiction. Purdue admitted, in 2007, that its sales representatives, as a matter of course:

- falsely told health care providers that OxyContin had a less euphoric effect, and less abuse potential, than short-acting opioids;[62]
- falsely told prescribers that OxyContin—the first "extended-release," a/k/a "long-acting" ("ER/LA") opioid—had fewer "peak and trough" effects than short-acting opioids, also known as immediate release ("IR") opioids;[63]
- falsely told prescribers that patients could discontinue OxyContin therapy abruptly without experiencing withdrawal symptoms; and
- falsely told prescribers that OxyContin was more difficult to abuse intravenously than generic oxycodone.[64]

62. In addition to making deceptive claims through its sales force, Purdue also widely advertised OxyContin, including in print ads in medical journals and in videos distributed directly to prescribers. These ad campaigns deceptively underplayed the risks and overemphasized benefits of chronic opioid therapy. For example, in 1998 and 2000, Purdue

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[62] Agreed Statement of Facts, *U.S. v. The Purdue Frederick Company, Inc.*, May 9, 2007, at 6; Press Release, U.S. Attorney's Office, Western District of Virginia, The Purdue Frederick Company, Inc. and Top Executives Plead Guilty to Misbranding OxyContin, Will Pay Over $600 Million (May 10, 2007), https://media.defense.gov/2007/May/10/2001711223/-1/-1/1/purdue_frederick_1.pdf, at 3.

[63] *Id.* at 6.

[64] *Id.* at 6.

distributed to doctors thousands of copies of videos, titled "I Got My Life Back," which made the unsubstantiated claim that opioid addiction occurred in less than 1% of patients.[65] In 2003, FDA warned Purdue about advertisements Purdue paid to run in the *Journal of the American Medical Association*, expressing concern that they would lead to ill-considered prescribing of OxyContin because the body of the ad text nowhere referred to the "serious, potentially fatal risks associated with OxyContin."[66] In 2005, Purdue also paid to run an advertisement that ran in pain journals that misleadingly implied long-term improvement in patients' pain, function and quality of life, touting OxyContin as an "around-the-clock analgesic . . . for an extended period of time" and featuring a man and a boy fishing under the tagline "There Can Be Life With Relief."

63. Purdue's advertising also included the claim that OxyContin provides "Consistent Plasma Levels Over 12 Hours."[67] That claim was accompanied by a chart, shown below, that depicted plasma levels on a logarithmic scale. However, this presentation visually distorted and obscured the steep decline in OxyContin's efficacy over 12 hours, by depicting 10 milligrams in a way that it appeared to be half of 100 milligrams in the table's y-axis, falsely making the absorption rate appear more steady or consistent over 12 hours:

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[65] United States General Accounting Office Report to Congressional Requesters, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, December 2003, https://www.gao.gov/products/GAO-04-110, at 27.

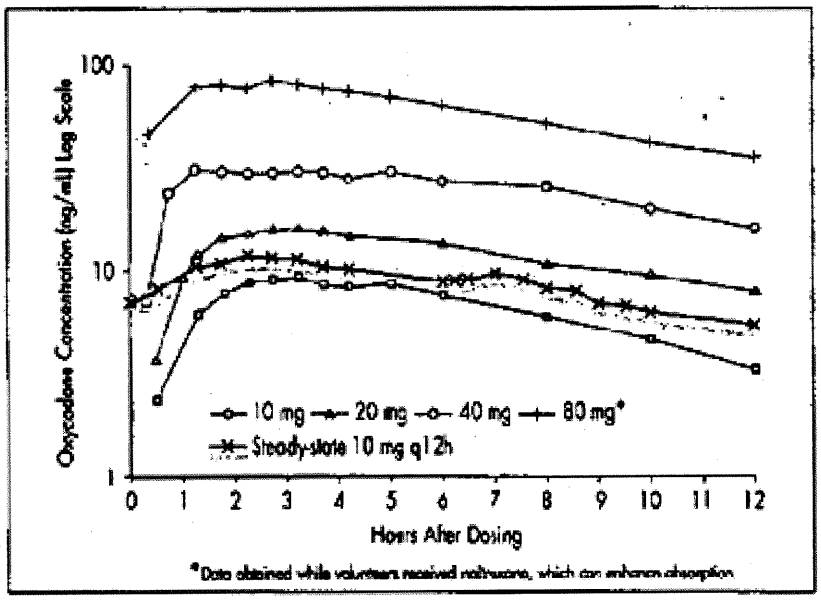
[66] Letter from Thomas Abrams, Dir. FDA Div. of Drug Mktg., Advert. and Commc'n, to Michael Friedman, Exec. Vice President and Chief Operating Officer, Purdue Pharma L.P. (Jan. 17, 2003).

[67] Jim Edwards, *How Purdue Used Misleading Charts to Hide OxyContin's Addictive Power*, CBSNews.com (Sept. 28, 2011), http://www.cbsnews.com/news/how-purdue-used-misleading-charts-to-hide-oxycontins-addictive-power/.

For moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time

Consistent Plasma Levels Over 12 Hours

Plasma concentrations (ng/mL) over time of various dosage strengths



- **OxyContin® 80 and 160 mg Tablets FOR USE ONLY IN OPIOID-TOLERANT PATIENTS requiring minimum daily oxycodone equivalent dosages of 160 mg and 320 mg, respectively. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids**

Steady state achieved within 24 to 36 hours

In fact, OxyContin works by releasing a greater proportion of oxycodone (about 40%) into the body when administered, followed by a steep decline over the subsequent hours.[68]

2. Purdue's Pervasive and Deceptive Unbranded Marketing

64. In addition to its branded marketing efforts that showcased specific Purdue opioids, Purdue also undertook or financially supported a number of "unbranded" marketing initiatives that were designed to promote opioids generally, and to convey Purdue's key messages about opioids without properly disclosing that Purdue created, funded, directed, or was in any way involved with these endeavors. Purdue intended patients and prescribers to read

[68] New Zealand Ministry of Medicine Data Sheet (http://www.medsafe.govt.nz/Profs/Datasheet/o/OxyContintab.pdf); *How Purdue Used Misleading Charts to Hide OxyContin's Addictive Power*, supra n.67.

these materials and to perceive (incorrectly) that the materials were published by neutral researchers, clinicians, and legitimate patient advocacy groups.

65. As part of its unbranded marketing scheme, Purdue recruited and paid physicians to make presentations on opioids to their peers at lunch and dinner events. It funded the biased research that formed the basis of these presentations and sponsored Continuing Medical Education programs ("CMEs") that misleadingly portrayed the risks and benefits of chronic opioid therapy. Purdue collaborated with professional associations and pain advocacy organizations, such as the American Pain Foundation, to develop and disseminate pro-opioid educational materials and guidelines for prescribing opioids.

66. Purdue had a particularly close relationship with the American Pain Foundation ("APF"), which was highly dependent on pharmaceutical company funding and produced numerous publications touting the use of opioids to treat chronic pain. Purdue was APF's second-biggest donor, with donations totaling $3.6 million between 1999 and 2012. As early as 2001, Purdue grant letters informed APF that the contributions reflected Purdue's effort to "strategically align our investments in nonprofit organizations that share our business interests," making clear that funding depended on APF continuing to support Purdue's objectives. Purdue also engaged APF as a paid consultant on various initiatives.

67. Purdue created a range of unbranded materials—from websites to glossy pamphlets—that were copyrighted by Purdue but on their face implied that the recommendations and research contained therein were the work of independent organizations with names like *Partners Against Pain*. Purdue ensured that these unbranded materials supported Purdue's branded marketing efforts to promote the use of opioids.

68. Among these tactics, all of which originated in the late 1990s and early 2000s, three stand out for their lasting influence on opioid prescribing nationwide and in Vermont: Purdue's capture, for its own ends, of healthcare providers' increased focus on pain treatment; Purdue's efforts to seed the scientific literature on chronic opioid therapy; and Purdue's corrupting influence on authoritative treatment guidelines issued by professional associations.

a. *Co-opting the Medical Community's Focus on Pain*

69. As Purdue marketed OxyContin in the late 1990s, it both capitalized on and co-opted a movement in the medical community to make pain identification and treatment a priority for all patients. Purdue provided financial support to the organizations and people leading the movement, and in turn they promoted the aggressive treatment of chronic pain, especially with opioids.

70. Purdue already had laid the groundwork for this strategy by financially supporting researchers who were willing to advocate for the expanded use of opioids without adequate scientific support. Chief among these was Dr. Russell Portenoy, who wrote a seminal 1986 paper supporting chronic opioid therapy while receiving Purdue funding and serving as Purdue's consultant. Dr. Portenoy concluded—based on a review of just 38 patients—that "opioid maintenance therapy can be a safe, salutary and more humane alternative" to not treating patients with chronic pain.[69]

71. Beginning in 1995, the American Pain Society ("APS"), of which Dr. Portenoy later would become president, launched a national campaign to make pain a "vital sign"—an indicator doctors should monitor alongside blood pressure, temperature, heartbeat, and breathing.

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[69] Russell K. Portenoy & Kathleen M. Foley, *Chronic use of opioid analgesics in non-malignant pain: report of 38 cases*, 25(2) Pain 171-86 (May 1986).

Purdue provided substantial funding to APS both to promote pain awareness generally and, on information and belief, to support the group's "Pain as the 5th Vital Sign" campaign. The Veterans Health Administration adopted this concept in its facilities nationwide in 1999, and "Pain as the 5th Vital Sign" spread from there to the private sector.

72. Coming on the heels of the APS campaign was the work of the Joint Commission on the Accreditation of Healthcare Organizations ("JCAHO"), which accredits hospitals across the United States. In 2001, JCAHO issued pain treatment standards that called for assessment of pain in all patients and in each physician-patient interaction, and made accreditation decisions contingent on institutions having policies in place to accomplish these goals. JCAHO worked closely with Purdue to promote the pain standards and licensed Purdue—exclusively—to distribute certain educational videos about how to comply with the new pain management standards.[70] Purdue also sponsored various guides for implementing the JCAHO standards, such as *Pain Assessment and Management: An Organizational Approach.* This book promoted the use of opioids, claiming that "[s]ome clinicians have inaccurate and exaggerated concerns about addiction, tolerance, respiratory depression, and other opioid side effects . . . . despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control." (Emphasis added.) JCAHO distributed the book to hospital officials and physicians nationwide at a series of Purdue-sponsored "leadership summits" on pain management.[71]

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[70] United States General Accounting Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, supra n. 65, at 23.

[71] American Pain Society Press Release, 10-May-2000, *National summit on pain management to discuss new standards for pain assessment and treatment*, https://www.eurekalert.org/pub_releases/2000-05/PN-Nsop-1005100.php; United States General Accounting Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, supra n. 65, at 23.

73. Both the APS "Pain as the 5th Vital Sign" campaign and the JCAHO pain standards have been widely integrated into medical practice. Although the JCAHO standards were developed to apply strictly in hospital settings, they influenced the entire medical profession through hospital-based residency training.

74. Vermont health care providers interviewed by the State recall learning about "Pain as the Fifth Vital Sign" and the importance of treating pain, through training and medical literature, during the 1990s and early 2000s. Many of these providers credit such initiatives with driving an increased focus on treatment of pain and increased use of opioids.

b. *Seeding the Science Regarding the Efficacy and Risks of Opioids with Flawed and Biased Research*

75. Rather than rigorously test the safety and efficacy of opioids for long-term use, Purdue created scientific support for its marketing claims by sponsoring studies that were methodologically flawed, biased, and drew inappropriate conclusions from prior evidence. These studies, once published, formed a seemingly objective, research-based foundation for liberalized opioid prescribing and were cited in subsequent studies, resulting in a body of literature on which physicians relied.

76. Some of these methodologically flawed studies claimed that the risk of psychological dependence or addiction is low in opioid use, absent a patient history of substance abuse.[72] One such study making this claim, published in the journal *Pain* in 2003 and widely referenced since (with more than 600 citations in Google Scholar),[73] ignored existing research

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[72] Seddon R. Savage *et al.*, *Definitions related to the medical use of opioids: Evolution towards universal agreement*, 26 J. Pain and Symptom Mgmt. 1:655-667 (2003); Watson, C. Peter N., *et al.*, *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy*, 105 Pain 71 (2003).

[73] C. Peter N.Watson *et al.*, *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy*, 105 Pain 71 (2003).

showing actual addiction rates between 8% and 13%,[74] and instead relied heavily on a 1980 letter to the editor—not a peer-reviewed study or in-depth article, but a letter—in the *New England Journal of Medicine*. That letter, J. Porter & H. Jick, "Addiction Rare in Patients Treated with Narcotics," 302(2) New Eng. J. Med. 123 (1980) ("Porter-Jick Letter"), is reproduced below:

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

77. The Porter-Jick Letter does not reflect any study, but simply describes a review of the charts of hospitalized patients who had received opioids. Both the authors of the letter[75] and

[74] *See, e.g.*, Lawrence Robbins, *Long-Acting Opioids for Severe Chronic Daily Headache*, 10(2) Headache Q. 135 (1999); Lawrence Robbins, *Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache*, 19 Headache Q. 305 (1999).

[75] NPR, *Doctor Who Wrote 1980 Letter on Painkillers Regrets That It Fed The Opioid Crisis* (June 16, 2017), http://www.npr.org/sections/health-shots/2017/06/16/533060031/doctor-who-wrote-1980-letter-on-painkillers-regrets-that-it-fed-the-opioid-crisis.

the *New England Journal of Medicine*[76] have repudiated the misuse of the Porter-Jick letter, but it became a mainstay in scientific literature, with more than 1,000 citations in Google Scholar.[77]

78. Purdue also sponsored flawed studies that were published in the *Journal of Rheumatology*[78] and the *Clinical Journal of Pain*[79] in 1999. Both studies concluded that long-term opioid therapy rarely resulted in addiction despite short trial periods and high drop-out rates.

c. *Funding and Influencing Professional Associations*

79. Treatment guidelines were particularly important to Purdue in securing acceptance for chronic opioid therapy. Treatment guidelines inform doctors' prescribing practices, are cited throughout the scientific literature, and are referenced by third-party payors when determining which prescriptions should be covered by insurance. Purdue financed and collaborated with three groups, in particular, on guidelines that have been, and continue to be, broadly influential in Vermont and nationwide: the American Academy of Pain Medicine (AAPM), the American Pain Society (APS), and the Federation of State Medical Boards (FSMB).

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[76] http://www.nejm.org/doi/10.1056/NEJM198001103020221.

[77] Purdue has also relied upon the Porter-Jick letter in its marketing efforts. Purdue, for example, has cited it in support of Purdue's patently false marketing claim that "less than 1%" of opioid patients become addicted, most prominently in its 1998 "I Got My Life Back" video. Yet Purdue failed to disclose both the nature of the citation (a letter, not a study) and any of its serious limitations. *See* OxyContin Promotional Video, "I got my life back," Purdue Pharma L.P. (1998), https://www.youtube.com/watch?v=Er78Dj5hyeI.

[78] Jacques R. Caldwell *et al.*, *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 26:4 Journal of Rheumatology 862-868 (1999)."

[79] Martin E. Hale *et al.*, *Efficacy and Safety of Controlled-Release Versus Immediate-Release Oxycodone: Randomized, Double-Blind Evaluation in Patients with Chronic Back Pain*, 15(3) Clinical J. Pain 179-183 (Sept. 1999).

AAPM/APS Guidelines

80. The American Academy of Pain Medicine and American Pain Soiety each received substantial funding from Purdue. From 2009 to 2012, Purdue gave APS nearly $500,000, and AAPM more than $400,000. An internal Purdue request to its CEO for approval of "2009 funds for AAPM and APS proposals" described each group as "one of our top tiered organizations."

81. In 1997, AAPM and APS issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," that endorsed using opioids to treat chronic pain and claimed that the risk of patients becoming addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was, at the time, a paid speaker for Purdue. He later became a senior executive for the company. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained, though it lingers on the Internet elsewhere.[80]

82. AAPM and APS also issued a 2001 set of recommendations, titled "Definitions Related to the Use of Opioids for the Treatment of Pain," which advanced the unsubstantiated (and since discredited) concept of "pseudoaddiction." The term, coined by Dr. Haddox in a 1989 journal article, reflects the idea that signs of addiction may actually be the manifestation of undertreated pain and will resolve once the pain is effectively treated—*i.e.*, with more or higher doses of opioids.[81] The 2001 AAPM/APS recommendations asserted that "clock-watch[ing]," "drug seeking," and "[e]ven such behaviors as illicit drug use and deception can occur in the

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[80] Available for purchase at http://journals.lww.com/clinicalpain/toc/1997/03000.

[81] David E.Weismann & J. David Haddox, *Opioid pseudoaddiction—an iatrogenic syndrome*, 36 Pain 363-366 (1989).

patient's efforts to obtain [pain] relief." The lack of evidentiary support for this definition has since been exposed and the treatment approach has been definitively discredited.[82]

83. In 2009, AAPM and APS issued comprehensive opioid prescribing guidelines ("2009 AAPM/APS Guidelines"), drafted by a 21-member panel, that promoted opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendation[s]" regarding management of chronic opioid therapy, even while acknowledging "low quality evidence," to support its positions, and it concluded that the risk of addiction is manageable for patients, even patients with a prior history of drug abuse. Six of the panel members, including Dr. Portenoy, received financial backing from Purdue, and another eight received funding from other opioid manufacturers.[83]

84. The 2009 AAPM/APS Guidelines were reprinted in the *Journal of Pain* and widely distributed nationally.[84] The guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited nearly 1,700 times in academic literature.

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[82] The CDC Guideline makes clear that the scientific literature does not support the concept of pseudoaddiction, explaining that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," (CDC Guideline, supra n.61, at 13) and that physicians should "reassess[] pain and function within 1 month" to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit" (CDC Guideline, supra n.61, at 25).

[83] *See* John Fauber, *Chronic Pain Fuels Boom in Opioids*, Milwaukee Journal Sentinel (Feb. 19, 2012), https://www.medpagetoday.com/neurology/painmanagement/31254.

[84] Roger Chou *et al.*, *Opioid Treatment Guidelines, Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, The Journal of Pain, Vol 10, No 2 (February), 2009: pp 113-130.

FSMB Guidelines

85. The Federation of State Medical Boards ("FSMB") is an association of the various state medical boards in the United States. The state boards that comprise the FSMB membership, including Vermont's, have the power to license doctors, investigate complaints, and discipline physicians. The FSMB has financed opioid- and pain-specific programs through grants from pharmaceutical manufacturers, including more than $800,000 from Purdue between 2001 and 2008.

86. In 1998, the FSMB developed its *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which the FSMB acknowledged were produced "in collaboration with" pharmaceutical companies and allied groups such as the American Pain Society (a professional society that received funding from Purdue). The FSMB Guidelines stated that opioids "may be essential" for treatment of both acute and chronic pain, but failed to mention risks of respiratory depression and overdose death; addressed addiction only to define the term as separate from physical dependence; and stated that an "inadequate understanding" of addiction can lead to "inadequate pain control."

87. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from them, *Responsible Opioid Prescribing*, repeated the 1998 version's claims. The book also stated that opioids would improve patients' function and included the now-discredited concept of pseudoaddiction, suggesting that signs of addiction may actually reflect undertreated pain that should be addressed with more opioids.

88. *Responsible Opioid Prescribing* was sponsored by Purdue, among other opioid manufacturers, and Purdue had editorial input into its contents. In particular, Purdue's David Haddox, the inventor of the term "pseudoaddiction," made edits to the book to ensure that pseudoaddiction was presented as an accepted medical concept.

89. Through at least 2015, the FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." Purdue provided an "educational grant" of $100,000 in 2007—sponsored internally by David Haddox—to support FSMB's distribution of *Responsible Opioid Prescribing* to physicians nationwide through state medical boards.

90. The FSMB Guidelines and *Responsible Opioid Prescribing* were widely distributed in Vermont. The Vermont Board of Medical Practice's first Policy for the Use of Controlled Substances for the Treatment of Pain, published in January 2006, was largely based on the 2004 FSMB model Guidelines.[85] FSMB (with the help of Purdue's grant funding) distributed *Responsible Opioid Prescribing* to 4,412 Vermont prescribers, through the Vermont Board of Medical Practice and other channels. Vermont prescribers interviewed by the State recalled receiving, reviewing, and relying upon the book into the Relevant Period.

B. Even after the 2007 Vermont Consent Judgment, Purdue's Marketing in Vermont Continued to Misrepresent the Risks and Benefits of Opioids

Notwithstanding its settlement with the federal government and Vermont, Purdue persisted in misrepresenting the risks and benefits of opioids. Rather than correcting its prior misrepresentations, Purdue built upon them. It stayed largely silent about the serious risks of opioids and continued to miseducate the medical community and public about the benefits and risks of using opioids for chronic pain.

91. In 2007, Purdue entered into consent decrees with the federal government and numerous states, including Vermont, to resolve investigations into its marketing of OxyContin. As reported by USDOJ, those investigations centered on misrepresentations that OxyContin was less addictive and had less abuse potential than IR opioids, and that patients taking OxyContin

[85] Vermont Board of Medical Practice, *Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain* (2014), http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioid_Pain_Treatment_Policy_0.pdf, at 1.

could discontinue the drug without withdrawal symptoms. Prospectively, the decrees required Purdue more generally to discontinue all deceptive marketing, including any misrepresentations regarding OxyContin's potential for abuse, addiction, or physical dependence, and to provide a fair balance of risk and benefit information as required by FDA regulations. Specifically, the Vermont Consent Judgment required that all material used in promoting OxyContin be "not inconsistent with the Package Insert, contain only information that is truthful, balanced, accurately communicated, and not minimize the risk of abuse, addiction or physical dependence associated with the use of OxyContin." The Vermont Consent Judgment also required Purdue to disseminate "written, non-branded educational information related to detecting and preventing abuse and diversion of opioid analgesics," the intended purpose of which was to enlist Purdue's considerable financial resources to set the record straight on the abuse and diversion potential of opioids. Instead, Purdue seized a new opportunity to continue deceiving the public regarding the broader risks of dependence and addiction.

92. Notwithstanding its legal commitments to the State of Vermont, Purdue failed to correct its misrepresentations or actually reform its conduct. Purdue built upon its decades-long foundation of deceptive messaging that had established chronic opioid therapy as commonplace and generated billions of dollars in profit for Purdue. Throughout the Relevant Period, Purdue continued to omit discussion of the serious risks of opioids and lack of evidence supporting long-term opioid use—thereby failing to correct its prior deceptions—and to affirmatively under-represent the serious risks and over-represent the benefits of opioids for the treatment of chronic pain.

93. Purdue accomplished much of this through its sales force: the messages they verbally conveyed to healthcare providers, and the materials they showed or distributed to

prescribers, or directed prescribers to review online. Since the launch of OxyContin, Purdue has relied heavily on its sales representatives to market its opioids directly to prescribers, and that practice continues. For example, of the $167 million Purdue spent on promoting opioids nationwide in 2016, $156 million—93.4%—was spent on detailing. By establishing personal relationships with doctors, Purdue's sales representatives were able to disseminate their misrepresentations in targeted, one-on-one settings.

94. At least 26 different Purdue sales representatives have detailed Vermont prescribers since 2006. Purdue set goals that each sales representative should make seven to eight in-person sales calls to prescribers per day. Purdue's own records indicate that its representatives detailed at least 645 Vermont prescribers (a very significant percentage of the several thousand physicians, nurse practitioners, and physician's assistants practicing in the State) between 2006 and 2017. Many of these prescribers were visited repeatedly. Indeed, in that same period, Purdue sales representatives made in excess of 11,000 unique sales visits in Vermont. Purdue assessed sales representatives' performance based on their ability to drive prescribing of its opioids; for example, one former Purdue detailer in Vermont had a sales goal of 1,100 OxyContin prescriptions per month.

95. The content of these sales calls was documented in "call notes," which Purdue expected to be detailed, thorough, and accurate. According to internal sales training documents, sales representatives were instructed to "[p]repare a concise call note that captures the key points of the dialogue between the Representative and the Customer," "ensure that call reporting clearly reflects the sales presentation," "[r]e-read every word of your call report to make sure that it is clear and accurate," "[a]lways review a call note before saving the record to ensure that it

accurately reflects the important events that took place during the call," and complete the call note shortly after the sales call to ensure accuracy.

96. Purdue developed sophisticated plans to select prescribers for sales visits based on their prescribing habits. It purchased and closely analyzed prescription sales data that allowed the company to track prescribing of its opioids and those of its competitors. According to a former Purdue employee who trained and supervised Vermont sales representatives, any prescribing of an opioid—whether Purdue's or a competitor's—could land a prescriber on a detailing target list.

97. Purdue employed the same marketing tactics and messages in Vermont as it did nationwide, using uniform marketing materials and national and regional sales training. Purdue carefully trained its sales representatives to deliver company-approved sales messages. The company exactingly directed and monitored its sales representatives—through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' "call notes" from each visit—to ensure that individual detailers actually delivered the company's desired messages. Purdue likewise required its sales representatives to deploy sales aids reviewed, approved, and supplied by the company.

C. Purdue's Material Misrepresentations and Omissions: 2010 - present

Purdue continued to build upon the foundation of deception it had laid in Vermont and nationally. Using unbranded marketing, Purdue carried on its prior deceptions by misleading Vermont prescribers and consumers about the risks and benefits of opioids for long-term pain. Purdue also pushed its sales force to target general practitioners in the State's medical community. Purdue exploited these practitioners' lack of specialized training in pain management to bias them into prescribing their drugs, by misleading them about the effectiveness of their drugs, and failing to discuss with them the dangerous risks of addiction. Purdue also pursued new targets to expand their market: patients who were not taking opioids (the opioid naïve) and the elderly. The Company aggressively marketed low dose OxyContin (10 and 15mg), including for the opioid naïve and elderly—knowing that these doses were no better than a placebo for pain management and carried serious side effects.

98. Through its sales force and deceptive promotional materials, Purdue continued to misrepresent the risks and benefits of its opioids to Vermont prescribers from the beginning of the Relevant Period until February 2018, when Purdue announced that it would stop promoting its opioid drugs to prescribers. Purdue also expanded the market for its drugs through unfair and deceptive conduct.

99. Purdue faced special challenges in Vermont during this time period, because the State passed legislation that barred pharmaceutical companies from giving gifts—including meals—to healthcare providers and required drug manufacturers to report permissible expenditures like research grants and teaching honoraria. Without the ability to give prescribers access to free meals and other goodies—and with the added requirement that any permissible expenditure would need to be disclosed annually to the Vermont Attorney General in a public report—in-person sales meetings became less reliable for Purdue.

100. In 2013, the year after the Vermont Gift Ban law took effect, Purdue detailer visits to Vermont prescribers plummeted from 1,381 to 384. And yet, Purdue benefitted nevertheless: Vermont prescribers were left to rely on Purdue's older, branded and unbranded marketing materials, which contained some of the worst and most harmful deceptions about opioid therapy for chronic pain, and unbranded websites that Purdue continued to fund and support, like *Partners Against Pain*, *In the Face of Pain*, and the sites of other advocacy and professional groups that were supported by Purdue.

101. Purdue's marketing strategy to increase opioid prescriptions during the Relevant Period focused on two distinct patient groups: keeping existing patients with "continuing" opioid prescriptions, which constituted over 80% of Purdue's sales, and identifying and gaining new patients who were not yet on opioid therapy or were new to the Purdue brand. To maintain

and expand "continuing" prescription patients, Purdue built on its prior deceptions and persisted in (1) misleading prescribers and the public about the benefits of opioids and of its specific opioid products, especially for long-term use, while (2) minimizing the serious risks associated with these drugs, including addiction and overdose. To expand its reach and generate new prescriptions, Purdue took additional steps to (3) expand the market for its opioids.

102. Overall, Purdue's marketing strategy created the impression that opioids were an ordinary and appropriate treatment for many kinds of people, that opioids generally (and OxyContin, specifically) provided meaningful benefits that justified their use, and that the risks of these drugs were minimal (and outweighed by the benefits).

1. Purdue Misled Prescribers and Consumers About the Benefits of Opioids

103. Purdue's efforts to promote the benefits of its opioid products were a critical part of Purdue's overall marketing efforts, because the risks of these drugs are so substantial—Purdue needed to persuade prescribers and consumers of the benefits, so that the risks would seem acceptable in comparison. In reality, for many Vermont consumers, Purdue's opioid products exposed them to significant risk of addiction, overdose, and other health problems, while providing no meaningful health benefits.

104. Purdue's deceptive marketing about the benefits of its products focused on (a) reinforcing the supposed benefits of long-term opioid use, in general, and (b) promoting the benefits of OxyContin's unique 12-hour dosing, which differentiated it from its competitors. These marketing messages lacked scientific support and were, in many cases, false.

a. Peddling the Benefits of Long-Term Opioid Therapy Without Evidence

105. To convince Vermont prescribers and patients that opioids should be used to treat chronic pain, despite the unavoidable risk of addiction, Purdue had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline made clear,

there was "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." (Emphasis added.) In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[86] (Emphasis added.) FDA similarly recognized the lack of scientific support for long-term opioid use, stating in 2013 that it was "not aware of adequate and well-controlled studies of opioid use longer than 12 weeks."[87] Thus, Purdue's ongoing representations, to prescribers and consumers, regarding the benefits of long-term opioid therapy have continued to be misleading and deceptive.

The Medical Consensus

106. It is well established—and has been throughout the Relevant Period—that long-term opioid use harms, rather than helps, patient health and wellbeing. Purdue's marketing scheme runs contrary to the real science on the known risks and unproven benefits of long-term opioid use.

107. The available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health. As early as 2006, numerous peer-reviewed studies conducted by independent researchers have concluded that: (1) "[f]or functional outcomes, . . . other [non-addictive] analgesics were significantly more effective than were opioids,"[88] (2) increasing

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[86] CDC Guideline, supra n. 61, at 9, 15.

[87] Letter from Janet Woodcock, M.D., Dir., FDA Ctr. for Drug Evaluation and Research, to Andrew Kolodny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013) https://www.regulations.gov/document?D=FDA-2012-P-0818-0793, at 10.

[88] Andrea D. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589-1594 (2006).

duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater healthcare utilization,[89] and (3) "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[90] Most recently, the 2016 CDC *Guideline for Prescribing Opioids for Chronic Pain—United States* ("CDC Guideline"), approved by FDA, concluded that "there is no good evidence that opioids improve pain or function with long-term use."[91] (Emphasis added.) The CDC reinforced this conclusion throughout the CDC Guideline, finding that (a) "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later";[92] (b) "[a]lthough opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy";[93] and (c) "evidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."[94] The CDC also noted that the risks of addiction and death "can

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[89] Richard A. Deyo *et al.*, *Opioids for Back Pain Patients: Primary Care Prescribing Patterns and Use of Services*, 24 J. Am. Bd. Fam. Prac. 717-27 (2011).

[90] Andrea Rubenstein, *Are we making pain patients worse?*, Sonoma Medicine (Fall 2009).

[91] CDC Guideline, supra n.61, at 20.

[92] *Id.* at 15.

[93] *Id.* at 18.

[94] *Id.* at 18-19.

cause distress and inability to fulfill major role obligations."[95] As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life spent cycling through periods of addiction, abuse, and recovery do not improve their function and quality of life.

108. Purdue long has been aware of the disconnect between the academic literature, which has never assessed efficacy beyond 12 weeks, and the prescribing reality—which Purdue was instrumental in shaping—that many patients use OxyContin and other opioids for many months or years. For example, a 2011 internal email among Purdue researchers discussed the need for "new research studies of not less than 12 months duration to determine the long-term effectiveness of opioids for chronic non-cancer pain"—an acknowledgement that such evidence did not exist.

Material Misrepresentations and Omissions Regarding Long-Term Use of Opioids

109. The FDA-approved labeling of Purdue's ER/LA opioids does not address long-term use (*i.e.*, beyond 12 weeks). Relied upon in the first OxyContin label—and still, to this day, the only clinical study Purdue has cited for OxyContin's efficacy in adults—is a two-week study of a scant 133 patients. Yet, Purdue marketed OxyContin with the expectation that health care providers—believing the drug to be appropriate for long-term use—would prescribe it to their chronic pain patients over periods of months or years. The State of Vermont did not uncover, in its review of call notes reflecting thousands of sales visits to prescribers, that detailers disclosed Purdue's lack of evidence supporting the use of opioids for more than 90 days.

110. Routine, chronic pain conditions—like osteoarthritis and lower back pain—continued to be a focus of Purdue's marketing efforts for OxyContin and Butrans. In more

[95] *Id.* at 20.

recent years, sales representatives have used "patient vignettes" or "patient profiles"—brief summaries of the background and medical needs of fictional patients—to illustrate the kinds of patients who should be identified as "good" (according to Purdue) candidates for drugs like OxyContin and Butrans. These vignettes typically featured chronic, long-term health problems as indications appropriate for opioid use. For example, the "Carol" and "Maggie" patient profiles, used to market OxyContin, featured osteoarthritis of the hip and chronic low back pain. The "Scott" and "Pam" patient profiles, used to market Butrans, both featured chronic low back pain due to osteoarthritis. Purdue provided its sales representatives with these and other patient profiles, along with training on their use, and Vermont sales representatives used them in sales calls to Vermont healthcare providers during the Relevant Period.

111. In Vermont, Purdue sales representatives positioned Purdue's opioid products—namely OxyContin and Butrans—*specifically for* long-term pain relief, to encourage healthcare providers to convert patients from short-acting opioids or other pain relievers to Purdue's extended-release opioid products. For example, sales representatives asked prescribers how long they typically wait before transitioning patients from short-acting opioids to an extended-release product, like OxyContin. During one Vermont sales call, for example, the sales representative initiated this discussion, and the prescriber agreed that "he would think about some patients who have been on an IRO [immediate release opioid] way too long."

112. Upon information and belief, sales representatives in Vermont also delivered a national "insight message" crafted by Purdue specifically for use in sales calls—that "according to IMS, a 3rd party prescription data source, 41% of IR hydrocodone/APAP combination prescriptions were associated with a length of therapy lasting 90 days or longer. Of these prescriptions lasting at least 90 days, the average number of days until a patient was converted to

an extended- release opioid was 287." This message implied that long-term use was inappropriate for short-acting opioids, but not so for extended-release opioids, and that such patients should be transitioned to an extended-release opioid like OxyContin.

113. Purdue also reinforced the appropriateness of OxyContin for long-term use through written materials it distributed in Vermont. For example, Purdue's OxyContin *Conversion and Titration Guide*, which sales representatives widely referred to during sales visits and distributed in Vermont, implied that use could continue safely for years. A 2007 version of that guide recommended that "the need for around-the-clock opioid therapy should be reassessed periodically (*e.g.*, every 6 to 12 months) as appropriate for patients on chronic therapy," but did not disclose the absence of evidence supporting safety and efficacy of use for 6 to 12 months. Later versions of this *Guide* omit the parenthetical "(*e.g.*, every 6 to 12 months)" and simply state that prescribers should "periodically reassess the continued need for opioid analgesics." However, Purdue continued to train sales representatives to tell prescribers to periodically reassess "every 6 to 12 months," when prescribing OxyContin, even after this language had been removed from the printed marketing materials, but they did not train representatives to disclose that Purdue had no studies supporting efficacy of use beyond 12 weeks.

114. Purdue and Purdue-sponsored materials distributed nationally reinforce the message that opioids offer benefits to the patient with use that lasts months or even years. The APF-published *Exit Wounds*, a book written as a personal narrative of one veteran recovering from war injuries, asserted unequivocally that "[w]hen used correctly, opioid pain medications increase [a person's] level of functioning" and that opioids "can really help improve your functioning in daily life." APF promoted this book until at least 2011.

115. Purdue also sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, a 2011 publication that falsely claimed that "multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving [d]aily function . . . [and] quality of life for people with chronic pain." *A Policymaker's Guide* cited a single study for this claim – which, upon examination, expressly noted the absence of long-term studies and actually found that "[f]or functional outcomes, . . . other analgesics were significantly more effective than were opioids."[96]

116. Purdue provided substantial funding to, and closely collaborated with, APF in creating *A Policymaker's Guide*. Purdue provided a grant for its development and distribution and kept abreast of the content of the guide as it was formulated. On information and belief, based on Purdue's close relationship with APF and the periodic reports APF provided to Purdue about the project, Purdue had editorial input into *A Policymaker's Guide*.

117. FDA has said for years that opioid manufacturers should not make claims regarding functional improvement and ability to perform daily activities, and FDA has warned Purdue competitors in public letters that such claims lacked substantial scientific evidence.[97]

118. These unsubstantiated and deceptive statements regarding the benefits of long-term opioid therapy misled prescribers and patients into believing that there were advantages to continuing opioid use over many months or even years.

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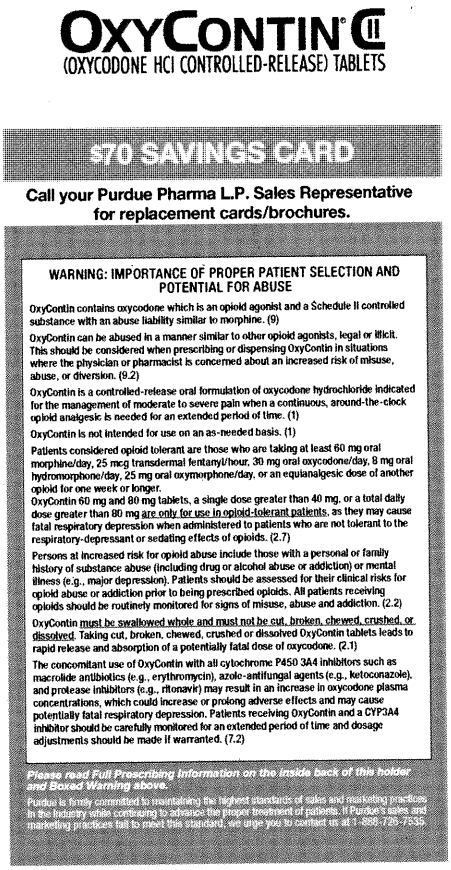
[96] Andrea D. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589-1594 (2006).

[97] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf; Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008).

Use of Savings Cards to Encourage Long-Term Use of Opioids

119. Purdue's distribution of Savings Cards for OxyContin and Butrans was part of a deliberate marketing strategy to encourage and increase long-term use of these drugs, well beyond the duration of treatment for which Purdue had scientific support.

120. Purdue promoted "Savings Cards" in Vermont to provide patients with a Purdue-funded discount on their out-of-pocket cost for OxyContin and encourage long-term use of OxyContin:



121. Purdue trained sales representatives to discuss Savings Cards on every sales call. The company also carefully tracked redemption of Savings Cards and evaluated sales representatives on the number of Savings Cards redeemed in their districts.

122. The purpose behind Purdue's emphasis on Savings Cards was to boost the "continuing prescriptions" group of patients—which constituted 80% of its OxyContin sales—beyond 90 days of use. In a 2012 sales training document, Purdue explained that "market research has shown that ~60% more patients stay on therapy >90 days if a savings card is redeemed." Purdue had no research showing the benefits of OxyContin for these longer durations of treatment.

123. Purdue also used Savings Cards to encourage initiation of new patients on its opioids, lowering the barrier of entry by making the drugs cheaper to try. In a 2012 sales training presentation, Purdue described its rationale for subsidizing a $0 (*i.e.*, free) copayment through Savings Cards for new Butrans patients: that a Savings Card was "effectively acting as a sample."

124. Sales representatives routinely distributed OxyContin Savings Cards during their sales visits to Vermont prescribers and pharmacies. Some Vermont healthcare providers declined Savings Cards, expressly referencing the prescriber's concerns about OxyContin use.

125. But Purdue continued to distribute the Savings Cards through marketing efforts in Vermont pharmacies, instructing pharmacists to inform opioid patients about available discounts for OxyContin that would bring the out-of-pocket price down significantly. In 2012, Purdue introduced what it described in internal documents as "new channels" to broaden access to Patient Savings Card Program: "Relay Health," which provided automatic rebates at pharmacies, and downloadable savings cards on PurdueHCP.com. This training document identified the Savings Cards as being downloadable by "HCP"—or healthcare providers, but Purdue sales representatives seem to have encouraged pharmacists to tell *patients* to download the cards directly, as a workaround when prescribers chose not to offer them. In one 2012 sales call to a

pharmacy, the Purdue detailer advised the pharmacy techs about how patients can go online to obtain savings cards "[s]ince the p[re]scribers in town are changing policies about cards."

126. Purdue has long been aware of the State of Vermont's concern that offering free or heavily subsidized opioids to consumers was an unfair business practice. In the 2007 Consent Judgment, Purdue expressly agreed to stop distributing samples of OxyContin in Vermont. Nonetheless, Purdue used the promotion of Savings Cards to eliminate or steeply discount patient co-payments—effectively making these drugs free to patients—as a way to drive long-term use.

b. ***Misrepresenting OxyContin's Supposed 12-Hour Dosing***

127. Purdue's key point of differentiation between OxyContin and other opioid pain relievers on the market is its extended-release formulation and "Q12"—or every 12 hour—dosing. However, Purdue consistently overstated the efficacy of this dosing interval while omitting the serious risks associated with it, compared to other alternative pain relievers.

128. Purdue sought FDA approval for OxyContin's 12-hour dosing schedule to maintain a competitive business advantage over more-frequently dosed (*e.g.*, every 8 hours, or as needed) opioids, despite knowing that OxyContin does not provide pain relief for 12 hours in many patients, a phenomenon known as "end of dose failure." Internal Purdue marketing documents indicate that 12-hour dosing was considered key to differentiating the drug from the competition—generic, short-acting opioids that require patients to wake in the middle of the night to take the next dose.[98]

[98] Memo to OxyContin Launch Team (April 4, 1995), available at http://documents.latimes.com/oxycontin-launch-1995/.

129. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. Purdue relied on labeling that it sought from FDA, and for which the company is legally responsible, directing 12-hour dosing. However, Purdue went well beyond the label's limited instructions to take OxyContin every 12 hours by affirmatively advertising that OxyContin lasts for 12 hours—and by failing to disclose that OxyContin does not provide 12 hours of pain relief to many patients.

130. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night."[99] But FDA has never approved such a marketing claim. To the contrary, FDA found in 2008, in response to a citizen petition by the Connecticut Attorney General, that a "substantial proportion" of chronic pain patients taking OxyContin experienced "end of dose failure."[100]

131. Sales representatives frequently referenced "Q12" dosing as a benefit of OxyContin during sales visits in Vermont. These misrepresentations continued into the Relevant Period in Vermont. Purdue trained its sales representatives to deliver the message of "[p]roven relief with Q12h dosing" to prescribers during sales calls.

132. Twelve-hour dosing is also featured in most OxyContin promotional pieces. A 2012 version of the *Conversion and Titration Guide*, for example, contains the tag line:

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[99] Purdue Pharma L.P., *New Hope for Millions of Americans Suffering from Persistent Pain*, PR Newswire (May 31, 1996), https://assets.documentcloud.org/documents/2815975/Pressreleaseversionone.pdf.

[100] FDA response letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation and Research, to Richard Blumenthal, Conn. Att'y Gen. (Sept. 8, 2008), http://www.purduepharma.com/wp-content/pdfs/fda_response_blumenthal_oxycontin.pdf, at 5.

"Because each patient's treatment is personal / Individualize the dose / Q12 OxyContin Tablets." And a 2014 visual aid used by sales representatives repeatedly refers not merely to OxyContin, but to *"[E]very 12-hour OxyContin"* and *"Every-12-Hour OxyContin Tablets."* None of these pieces discloses that the pain relief from each 12-hour dose will last well short of 12 hours for many patients, leaving prescribers and patients unprepared for end-of-dose failure and the craving for more opioids that the failure creates.

133. Purdue has known, since the launch of OxyContin, that the drug often wears off well short of 12 hours. According to a 2016 *Los Angeles Times* investigation, Purdue's own early studies showed many patients asking for more medication before their next scheduled dose. In one clinical trial, one-third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental short-acting opioids—"rescue medication"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once.[101] Prescribers, including prescribers in Vermont, likewise have observed and complained to Purdue sales representatives that OxyContin does not supply 12 hours of pain relief in a significant number of the prescribers' patients. And it was well-known to Purdue that OxyContin was routinely prescribed (including in Vermont) every 8 hours—rather than every 12 hours, as directed. One former Purdue employee, who trained and supervised sales representatives in Vermont, said Purdue knew providers frequently prescribed OxyContin for every 8 hours, tracked statistics on such prescribing, and sought to change it: "We talked about that in almost every meeting, how we were going to try and get people to buy [the 12-hour dosing]."

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[101] Harriet Ryan, Lisa Girion & Scott Glover, *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, Los Angeles Times (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/.

134. Purdue's solution to the end-of-dose failure experienced by many patients was to advise prescribers to maintain the 12-hour dosing schedule but to increase the dose of OxyContin. Purdue's sales representatives routinely told doctors in Vermont that, if the Q12 dose didn't last the full 12 hours, the doctor should increase—or "titrate"—the dose, rather than increasing the frequency of dosing. The OxyContin label and the *Conversion and Titration Guide* also advise prescribers that they can increase the dosage to achieve adequate pain relief "as clinical need dictates, while maintaining every 12-hour dosing." Increased opioid dosing poses greater risks, as discussed in Section C(2)(d). However, Purdue's advice to "titrate up" when a patient experienced end-of-dose failure was not accompanied by appropriate warnings regarding the increased risk of addiction associated with higher doses.

135. Purdue's misrepresentations regarding 12-hour dosing—which Purdue has made since 1996 and continued to make at least until 2018, when it stopped promotion of opioids to prescribers through sales representatives—are particularly dangerous because the inadequate dosing helps fuel addiction. End-of-dose failure causes patients to experience the early stages of psychological and physical withdrawal symptoms on a daily basis, followed by a euphoric rush when they take their next dose—leading to a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[102]

[102] Harriet Ryan, Lisa Girion & Scott Glover, *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, Los Angeles Times (May 5, 2016), http://www.latimes.com/ projects/oxycontin-partl.

2. Purdue Built on Prior Deceptions to Mislead Prescribers and Consumers about the Known, Serious Risk of Addiction

136. To convince Vermont prescribers and patients that opioids were safe, Purdue built upon its extensive and effective foundation of deceptive marketing and continued to minimize and omit discussion of the risks of long-term opioid use, particularly the risk of addiction. This strategy has been crucial to Purdue's business model, because the vast majority of Purdue's OxyContin sales are for patients who are continuing users of the drug (as opposed to new prescriptions). Deceptively minimizing the risk of addiction also was critical to Purdue's efforts to encourage new prescriptions, as prescribers and consumers have become more aware of the opioid epidemic over the last ten years.

137. Purdue trained its sales representatives to deflect questions about addiction into discussions of how to identify "appropriate patients," and to draw distinctions between "physical dependence" and "addiction" to allay prescribers' concerns about addiction risks.

138. Purdue's misrepresentations and omissions, described further below, have reinforced each other to create the dangerously misleading impressions that:

(a) Purdue's ER/LA opioids present a reduced risk of addiction, and even patients who present symptoms of addiction may simply be physically dependent on the drug or have undertreated pain that should be treated with more opioids;

(b) patients at greatest risk of addiction can be identified and vetted out, allowing doctors to confidently prescribe opioids to all other patients and even prescribe to high-risk patients, provided they are closely managed;

(c) the abuse-deterrent formulations of Purdue's opioids both prevent abuse and are inherently less addictive; and

(d) physicians can prescribe steadily higher doses of opioids without added risk.

Each of these misrepresentations has been debunked by FDA and the CDC.

139. These deceptive messages were often delivered in combination and had a cumulative impact.

a. *Perpetuating the Fiction of "Pseudoaddiction" and Trivializing Addiction Risk*

140. Purdue's sales representatives regularly omitted from their visits to Vermont prescribers any discussion of the addiction risks that are plainly associated with long-term use of opioids. Given that Purdue made admitted misrepresentations between 1996 and 2007, these material omissions were particularly damaging. Purdue did not train its sales force to correct the company's historic, deeply misleading—but highly profitable—message that patients who receive chronic opioid therapy for legitimate pain conditions face only a very small risk of becoming addicted.

141. The messages delivered in Vermont by detailers to prescribers were, as Purdue intended, passed on to patients. Patients receiving substance abuse treatment and whose addiction began with prescriptions for chronic pain often report that they were not warned of the risk they might become addicted to opioids. This is confirmed by national research: A 2015 survey of more than 1,000 opioid patients found that 40% were not told opioids were potentially addictive.[103]

"Pseudoaddiction"

142. Purdue represented to Vermont prescribers that red-flag signs of addiction may simply be indicators of medically undertreated pain that should be treated with higher doses. This concept was dubbed "pseudoaddiction" in earlier marketing, and the term persisted in marketing to Vermont prescribers until at least 2014. Even after Purdue stopped calling it "pseudoaddiction," Purdue continued to advance this unsubstantiated and misleading concept.

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[103] Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities* (Jan. 27, 2016), http://www.hazeldenbettyford.org/about-us/news-and-media/press-release/doctors-missing-questions-that-could-prevent-opioid-addiction.

Purdue consistently used this concept to suggest to prescribers that they should prescribe higher doses of opioids when presented with patients who quite clearly exhibit drug-seeking behaviors.

143. As discussed in Section A above, the concept of "pseudoaddiction" was developed by Dr. Haddox, a paid Purdue speaker in the 1990s who went on to become a high-level Purdue executive. Purdue ensured that the term and concept of "pseudoaddiction" appeared in *Responsible Opioid Prescribing*, a reference book that was distributed through the Vermont Board of Medical Practice to prescribers in Vermont. The concept has since been discredited. Nonetheless, Vermont prescribers interviewed during the State's investigation of Purdue's deceptive marketing scheme stated that they currently have in their possession, continue to reference, and rely upon copies of this book.

144. Purdue was aware of growing concerns in the regulatory and medical community that the concept of "pseudoaddiction" was misleading. In 2012, U.S. Senators Baucus and Grassley requested documents and communications about *Responsible Opioid Prescribing* as part of an investigation into whether pharmaceutical companies encouraged and funded efforts by non-profit organizations to promote misleading information about opioids. In 2014, Purdue circulated internally a news article about how *Responsible Opioid Prescribing* and its author had contributed to the rate of deaths and addictions by downplaying the risks of opioids. The notation from James Heim, Senior Director, Public Affairs, on an email accompanying this article said only: "FYI, no action required."

145. Rather than take steps to correct the fundamentally misleading information about "pseudoaddiction" in *Responsible Opioid Prescribing* – which remains in circulation and use by Vermont prescribers to this day – Purdue reinforced the message with its own marketing materials during the Relevant Period through its distribution of a pamphlet entitled "*Providing*

Relief, Preventing Abuse." This pamphlet was distributed for the purpose of fulfilling Purdue's obligation under the 2007 Vermont Consent Judgment to provide "written, non-branded educational information related to detecting and preventing abuse and diversion of opioid analgesics," and it was broadly disseminated in Vermont. But rather than provide accurate, non-deceptive information about the risk of abuse and diversion, this pamphlet reinforced the misleading message that drug-seeking behaviors—commonly understood to be symptoms of addiction—are instead signs of benign "pseudoaddiction."

146. The term "pseudoaddiction" persisted in *Providing Relief, Preventing Abuse* through several versions that were distributed in Vermont until February 2014. Subsequent editions of *Providing Relief, Preventing Abuse* omitted the term "pseudoaddiction" but continued to include a description of the phenomenon without using the word, saying "[S]ome patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate. Such behaviors may occur occasionally even with successful opioid therapy for pain; a pattern of persistent occurrences should prompt concern and further assessment."

147. Internal Purdue documents show that the company had engaged in a long-standing debate since at least 2009 about whether to include the term and concept of "pseudoaddiction" in the *Providing Relief, Preventing Abuse* pamphlet, with some senior level employees—including Purdue's Senior Manager for Medical Services—recommending its removal. Nonetheless, the term "pseudoaddiction" was not removed from the pamphlet until its 3rd Edition, distributed in February 2014, and the deceptive and scientifically-debunked concept—that drug-seeking conduct should be interpreted as untreated pain, not addiction—continued to be included in that and subsequent versions.

148. Purdue promoted the concept of "pseudoaddiction" through other extensive, unbranded marketing that it funded or controlled. *Partners Against Pain* is a Purdue marketing imprint consisting of both medical education resources, distributed to prescribers (including Vermont prescribers) by the sales force, and a now-defunct website that, before Purdue shut it down in 2016, was styled as an "advocacy community" for better pain care. *Partners Against Pain* existed since at least the early 2000s and served as a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. Through at least 2013, the *Partners Against Pain* website relied on and directed users to the 2001 Guideline from American Academy of Pain Medicine and American Pain Society, which endorsed the concept of "pseudoaddiction."

149. A *Partners Against Pain* "Pain Management Kit" that debuted in 2009 likewise advocated the "pseudoaddiction" concept, referring prescribers to the 2001 AAPM/APS "Definitions Related to the Use of Opioids for the Treatment of Pain." The kit also introduced another resource—a set of drug abuse screening tools (discussed in Section C(2)(b))—by stating that "[b]ehaviors that are suggestive of drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior." Purdue sales representatives have regularly directed Vermont prescribers to the *Partners Against Pain* website and distributed the Pain Management Kit to Vermont prescribers, and Vermont prescribers have used the *Partners Against Pain* website as a prescribing resource.

Distinction between "Physical Dependence" and Addiction

150. Purdue also attempted to assuage prescribers' concerns about its products by distinguishing between "addiction" (dependence that results in compulsive drug use despite harmful consequences) and "physical dependence" (the body's need for higher doses of the opioid over time and withdrawal symptoms if opioids are discontinued). Purdue described "physical dependence" as a normal consequence of extended opioid use, but failed to disclose

the serious risks and problems associated with physical dependence. Purdue misled prescribers when it drew a distinction between "physical dependence" and "addiction" without fully explaining the risks associated with both conditions—deliberately creating the impression that the negative consequences prescribers (and patients) were worried about would only occur in the context of "addiction."

151. Purdue's omissions about the risks of physical dependence are all the more glaring because the risks are expressly included in the label. The 2013 version of the OxyContin label describes the risk that a patient will experience withdrawal symptoms if OxyContin is discontinued or reduced in dose. The label also states that infants born to mothers physically dependent on opioids will be physically dependent and may experience withdrawal themselves.

152. This misleading and incomplete message minimizing the risks of "physical dependence" was delivered through both sales calls and in written advertising materials. Purdue sales representatives were trained to differentiate between "physical dependence" and "addiction," and sales representatives delivered this message in sales calls to prescribers. Promotional materials and other publications Purdue disseminated or made available in Vermont have included similar, mutually reinforcing messages minimizing the risk of addiction by distinguishing it from "physical dependence."

MEANINGFUL DEFINITIONS

IMPORTANT DEFINITIONS RELATED TO THE USE OF OPIOIDS FOR THE TREATMENT OF PAIN[8]

Addiction*: a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.[8]

Addiction is a disease. It is not caused by drugs; it is triggered in a susceptible individual by exposure to drugs, most commonly, though not always, through abuse. The kind of drug, the person's environment, genetic factors, including their psychological makeup, and social factors can contribute to the risk of addiction.[3]

Physical dependence*: a state of adaptation manifested by a specific drug class withdrawal syndrome produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or the administration of an antagonist.[8]

Physical dependence is a known effect of certain medications. Confusing physical dependence with addiction is a common error, caused by the fact that most people that healthcare or law enforcement professionals encounter with addiction are also physically dependent to the substance(s) they are abusing. Thus, withdrawal is frequently seen in these people, and it is easy to think that withdrawal equals addiction. The number of people who are physically dependent (i.e., at risk for withdrawal syndrome, if the medicines are abruptly stopped) on some type of medication (e.g., antihypertensives, decongestants) far exceeds the number who are addicted to drugs that induce physical dependence. Discussion of the topic is also muddled because for many years addiction was called "psychological dependence" (not to be confused with physical dependence) and thus an addict was often said to be simply "dependent" on the drug.

Tolerance*: a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.[8]

Tolerance may develop to some opioid side effects, such as respiratory depression.[9]

Tolerance to the respiratory depressant effects of opioids is what allows a patient with pain to regularly take a dose of medicine that would be fatal for someone who wasn't taking the same medicine on a regular basis. Exceeding tolerance, by taking larger than usual doses or abusing a number of drugs simultaneously, can be fatal.[9]

Other Considerations: Some patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate. Such behaviors may occur occasionally even with successful opioid therapy for pain; a pattern of persistent occurrences should prompt concern and further assessment.[8]

* As recommended by the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine.

Terminology

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153. The *Providing Relief, Preventing Abuse* pamphlet included similar deceptions. It downplayed "physical dependence" as "a known effect of certain medications," citing benign blood pressure medications and decongestants as analogous examples. It also asserted that "physical dependence" and "addiction" are commonly confused.

154. Purdue's distinction between "physical dependence" and "addiction" was especially deceptive in the context of increasing public awareness of the risks of opioid addiction, because it implied that "physical dependence" was less harmful than "addiction." These messages also implied that physical dependence on OxyContin was no more problematic

than physical dependence on blood pressure medication. *Providing Relief, Preventing Abuse* also showed graphic pictures of the stigmata of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa, to illustrate "potential signs consistent with drug abuse." In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients becoming addicted through oral use. These depictions deceptively reassured doctors that, as long as they do not observe physical signs of snorting or injecting, they need not worry that their patients are abusing or addicted to opioids.

155. Purdue's *Partners Against Pain* website likewise offered misleading and deceptively reassuring distinctions between addiction and physical dependence, presenting addiction as a neurobiological disease and physical dependence as a benign "state of adaptation."

156. In disseminating such messages, Purdue was attempting to remove the stigma of "addiction" that had become linked to its products. This failed to acknowledge the very serious reality that Vermont consumers faced: that no matter what definitions and labels are applied, patients taking opioids are at serious risk of becoming "hooked," needing ever-increasing doses to avoid withdrawal symptoms, and being unable to stop taking opioids.

Other Unbranded Marketing Minimizing the Risk of Addiction

157. Purdue disseminated or supported the dissemination of unbranded marketing materials that also minimized the risk of addiction associated with opioids generally.

158. Purdue maintained an online "interactive toolkit" for patients, caregivers, and prescribers—*In the Face of Pain* (www.inthefaceofpain.com)—that deceptively downplayed the risks of chronic opioid therapy. *In the Face of Pain*, which Purdue deactivated in October 2015 following an investigation by the New York Attorney General, was another example of "unbranded" marketing. Although it featured the Purdue copyright at the bottom of each page, the site did not refer to Purdue products in particular and cultivated the impression that it was

neutral and unbiased.[104] As of 2010, the "In the Face of Pain Toolkit" was also available on the *Partners Against Pain* website, which detailers frequently referenced during Vermont sales calls.

159. *In the Face of Pain* asserted that policies limiting access to opioids are "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. As of 2015, while a document linked from the *In the Face of Pain* website briefly mentioned opioid abuse, the site itself did not—even once—mention the risk of addiction, a risk so significant that it requires a black box warning on all opioid drug labels. At the same time, the website contained testimonials from several dozen physician "advocates" speaking positively about opioids. The website failed to disclose that, from 2008 to 2013, Purdue paid 11 of these advocates a total of $231,000.[105]

160. Purdue also continued working closely with allies, such as the American Pain Foundation—a group that, as discussed above, was heavily dependent on funding from Purdue and other pharmaceutical companies—to disseminate misleading, unbranded messages about the risks of opioids.

161. APF's *Exit Wounds* described opioids as the "'gold standard' of pain medications" and minimized the risk of addiction. It emphasized that physical dependence often is mistaken for addiction and claimed that "[l]ong experience with opioids shows that . . . people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."

162. APF's *A Policymaker's Guide to Understanding Pain & Its Management* claimed pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction" and

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[104] *In the Matter of Purdue Pharma L.P.*, Assurance No. 15-151, Assurance of Discontinuance (signed August 19, 2015).

[105] *Id.*

asserted, without basis, that "less than 1 percent of children treated with opioids become addicted." In addition to mischaracterizing the risk of addiction, *A Policymaker's Guide* perpetuated the misleading concept of pseudoaddiction, stating that "[p]seudo-addiction describes patient behaviors that may occur when pain is undertreated" and that "[p]seudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated"—*i.e.*, with more opioids.

The True Risks of Opioids

163. Purdue's claims regarding addiction are contrary to longstanding scientific evidence, and its failures to address the risk of addiction when promoting the use of these drugs are material omissions, given both the magnitude of the risk and the grave consequences of addiction. As confirmed by the CDC in its 2016 Guideline, "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])" exists. The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder." (Emphasis added.)

164. Studies have shown that at least 8-12%, and as many as 30% or even 40%, of long-term users of opioids experience problems with addiction.[106] In requiring a new black-box warning on the labels of all IR opioids in March 2016, similar to the warning already required for ER/LA opioids, FDA emphasized the known, "serious risks of misuse, abuse, [and] addiction . . .

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[106] Joseph A. Boscarino *et al.*, *Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system*, 105(10) Addiction 1776-82 (Oct. 2010); Joseph A. Boscarino *et al.*, *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM5 vs. DSM-4 Diagnostic Criteria*, 30(3) J. of Addictive Diseases 185-94 (July-Sept. 2011); Vowles, Kevin E. *et al.*, *Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis*, Pain 156.4 (2015): 569-576.

. across all prescription opioid products."[107] That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published its *Guideline for Prescribing Opioids for Chronic Pain.*[108] The CDC found that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder."[109] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[110]

b. *Overstating the Efficacy of Screening Tools*

165. Purdue deceptively promoted screening tools—such as drug testing, pill counts, and patient contracts—as reliable ways to prevent addiction and safely prescribe long-term opioids. While screening tools may help doctors identify the most susceptible patients and identify diversion, and patient contracts convey the gravity of risks and establish protocols to stop diversion, they cannot prevent dependence or addiction from occurring.[111] These misrepresentations provided false assurances to healthcare providers and patients that addiction was avoidable and largely the result of other prescribers' failure to rigorously manage and weed out problem patients who could have been easily identified with screening tools.

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[107] Food and Drug Administration, *FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death* (Mar. 22, 2016), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[108] CDC Guideline, supra n.61, at 2.

[109] CDC Guideline, supra n.61, at 2.

[110] CDC Guideline, supra n.61, at 25.

[111] The CDC Guideline confirms the lack of substantial scientific evidence to support Purdue's claims regarding the utility of screening tools and patient management strategies in managing addiction risk. There are no studies assessing the effectiveness of screening tools, patient contracts, urine drug testing, or pill counts—all which were widely promoted by Purdue and believed by doctors in Vermont—"for improving outcomes related to overdose, addiction, abuse, or misuse." CDC Guideline, supra n.61, at 11. In fact, the CDC Guideline recognizes that risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy." *Id.* at 28. (Emphasis added.)

166. Purdue conveyed these messages during in-person sales calls in Vermont. For example, when one prescriber discussed with the Purdue sales representative the increasingly aggressive behavior of his opioid patients and his fears for his staff's safety, the representative emphasized the importance of continuing to prescribe OxyContin for "appropriate patients": *e.g.*, ones who attended scheduled appointments, signed and abided by patient contracts, and complied with urine screens and pill checks.

167. Purdue also promoted the "Opioid Risk Tool" created by opioid advocate Dr. Lynn Webster, who received research funding from Purdue, as part of its *Partners Against Pain* "Pain Management Kit." This "Opioid Risk Tool" is a five-question, one-minute screening tool that relies on honest patient self-reporting (particularly unlikely given the sensitive topic and the nature of addiction) to purportedly allow doctors to manage the risk that their patients will become addicted to or abuse opioids. Sales representatives distributed the kit in CD ROM format to prescribers in Vermont, and frequently directed prescribers to the *Partners Against Pain* site throughout the Relevant Period.

168. Purdue promoted screening tools as a reliable means to manage addiction risk in CME and scientific conferences available to Vermont prescribers. In 2011, Purdue sponsored a CME taught by Dr. Lynn Webster via webinar titled "Managing Patient's Opioid Use: Balancing the Need and Risk." This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths." Purdue also funded a 2012 symposium called "Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes," which taught doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addictive behavior could be safely treated with opioids.

c. *Exaggerating the Efficacy of Abuse-Deterrent Properties*

169. Since 2010, Purdue deceptively marketed its abuse-deterrent opioids—a reformulated version of OxyContin and Hysingla ER—to Vermont prescribers in a manner that falsely implies that these abuse-deterrent drugs can curb abuse and even addiction. In truth, all these reformulations do is make it harder to crush the pill. This does nothing to protect against the most common form of abuse, which is via oral ingestion.

170. Oral abuse of prescription opioids includes not only taking the drugs without a prescription, but also taking higher or more frequent doses than prescribed. Rather than focus on the oral abuse associated with the widespread prescribing of OxyContin for chronic pain, Purdue tied abuse and addiction to less common illegal product diversion and abuse via snorting or injecting the drug. Purdue's proffered solution—introduced as an abuse-deterrent formulation in 2010—was a new pill coating and other elements to make its opioids more difficult to crush or inject (*i.e.*, making it tamper resistant). Purdue misleadingly assured prescribers that they could prescribe Purdue's opioids without contributing to the epidemic of misuse and abuse.

171. FDA approved the reformulated OxyContin in 2010.[112] In its medical review of Purdue's application, however, FDA found that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)" and that "[w]hile the reformulation is harder to crush or chew, possibly mitigating some accidental misuse, oxycodone HCI is still relatively easily extracted."[113] (Emphasis added.)

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[112] Center for Drug Evaluation and Research Approval Package for NDA 22-272, Apr. 5, 2010, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/ 022272s000Approv.pdf.

[113] Center for Drug Evaluation and Research, NDA 22-272, *Summary Review for Regulatory Action* (Dec. 30, 2009), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000MedR.pdf, at 7.

172. Purdue regularly cites its introduction of abuse-deterrent opioids as evidence of its commitment to addressing the opioid crisis, as described in Section C(2)(c). In fact, the tamper-resistant reformulation, and the change in labeling, made Purdue richer by solving an inconvenient business problem: how to keep the money flowing after April 2013, when OxyContin's patent was set to expire. Generic versions of OxyContin had become available in February 2011, threatening to erode Purdue's share of the long-acting opioid market and decrease the price Purdue could charge. However, Purdue convinced FDA in April 2013 that original OxyContin—which Purdue had designed and promoted for years—should be removed from the market as unsafe because it lacked abuse-deterrent properties. The impact was that generic equivalents of the old formulation could not be sold, once again securing brand exclusivity for OxyContin and Purdue through at least 2017.

173. Purdue also uses the abuse-deterrent properties of its opioids as a primary selling point to differentiate its products from its competitors, including generic short-acting opioids. As recently as 2015, internal sales training documents characterize the "abuse-deterrence labeling" as one of four "Strategic Pillars" for achieving OxyContin sales goals, directing Purdue employees to "[e]levate the importance of abuse deterrence as a key driver for [extended-release opioid] prescribing."

174. However, Purdue knew or should have known that its abuse-deterrent drugs still are regularly tampered with and abused. In online forums such as bluelight.org and Reddit, drug abusers discuss a variety of ways to tamper with OxyContin and Hysingla ER, including by grinding the pills, microwaving then freezing them, or dissolving them in soda or lemon juice. Indeed, a citizen petition submitted by another pharmaceutical firm in 2016 challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily process OxyContin for snorting or

injection.[114] And a 2015 study by researchers at Washington University in St. Louis found that many addicts continued to abuse reformulated OxyContin. Of the survey respondents who continued to abuse the drug, most either continued with or switched to oral abuse, while roughly one-third found various methods to continue snorting or injecting it.[115]

175. There remains no substantial scientific evidence that Purdue's abuse-deterrent opioids actually reduce opioid abuse. As the CDC Guideline states, "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," and the technologies—even when they work—"do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."

176. Because of their questionable benefits, any discussion of abuse-deterrent technologies has a high potential to mislead practitioners and patients and create a false sense of security about prescribing opioids, particularly for long-term use. In a 2014 survey of 1,000 primary care physicians, nearly 50% reported that they believed abuse-deterrent formulations of opioids are inherently less addictive.[116] One-third of the doctors in that same study had the mistaken impression that most prescription pill abuse is by means other than swallowing the pills.

177. Purdue's deceptive marketing of the benefits of its abuse-deterrent formulations was particularly dangerous because it persuaded doctors—who might otherwise have curtailed

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[114] Citizen Petition to FDA by Pharmaceutical Manufacturing Research Services, Inc., Feb. 19, 2016, Docket No. FDA-2016-P-0645.

[115] Theodore J. Cicero & Matthew J. Ellis, *Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States: Lessons Learned from OxyContin*, 72(5) JAMA Psychiatry 424-430 (May 2015).

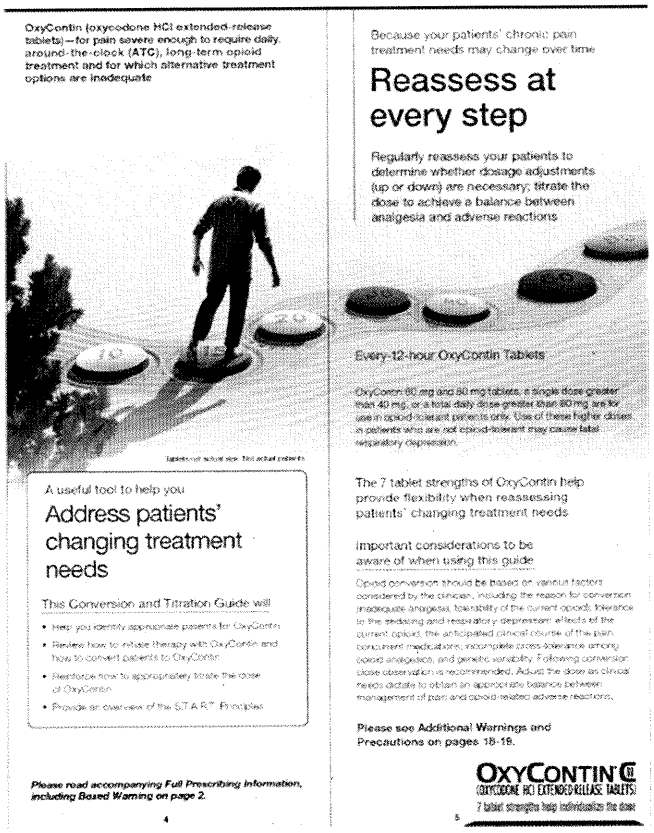
[116] Catherine S. Hwang *et al.*, *Primary Care Physicians' Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion*, 32(4) Clinical J. Pain 279-284 (Apr. 2016).

their opioid prescribing—to continue prescribing Purdue's opioids based on misleading assurances and deceptive implications that they are safer. It also allows prescribers and patients to discount evidence of opioid addiction and attribute it to other opioids that don't have tamper-resistant properties—*i.e.*, to believe that while patients might abuse or overdose on non-abuse-deterrent opioids, Purdue's opioids do not carry that risk.

d. *Failing to Disclose the Increased Risk of Higher Doses*

178. Purdue also misled Vermont prescribers and consumers by stating that opioids can be taken at ever-increasing doses for better pain relief without any maximum dosage cap, without disclosing that higher doses carry greater risk of addiction and overdose. Further, as described in more detail in Section C(1)(b), Purdue encouraged physicians to increase the dose of OxyContin rather than prescribe it more than 2x daily, despite knowing that higher doses posed greater risks and that OxyContin often did not provide 12 hours of pain relief.

179. The ability to escalate doses ("titrating up") was critical to Purdue's efforts to market opioids for long-term use to treat chronic pain. Unless doctors felt comfortable prescribing increasingly higher doses of opioids to counter tolerance to the drugs' effects, they may not have chosen to initiate opioid therapy at all. Numerous Purdue marketing materials depict the seven OxyContin tablet strengths—in a line or even a series of steps—and instruct prescribers that they can titrate, *i.e.*, increase the dose, "as clinical need dictates." Purdue's *Conversion and Titration Guide*—frequently distributed to prescribers in Vermont during the Relevant Period—reiterated the message that there was "no defined maximum daily dose" for OxyContin.



180. Through at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a doctor did not prescribe, in the patient's opinion, a sufficiently high dose of opioids, the patient should find another doctor who would.

181. *A Policymaker's Guide* asserted that dose escalations—even when unlimited—are "sometimes necessary." The publication did not disclose the risks from high doses of opioids.

182. Purdue also was deceptive in the way it compared the risks of opioids to the risks of other pain relievers, like non-steroidal anti-inflammatory drugs ("NSAIDs" like Advil) and acetaminophen (Tylenol). The company sponsored a 2013 CME titled "Overview of Management Options" that highlighted the evidence of adverse effects from high doses of NSAIDs but did not discuss the increased risk from using high doses of opioids. The CME was edited by Dr. Russell Portenoy, who received research support, honoraria, and consulting fees from Purdue. Issued by the American Medical Association in 2013, the CME remains available

from the American Medical Association ("AMA") online.[117] Purdue also sponsored a pain pamphlet for physician assistants that similarly emphasized the risk of liver damage from acetaminophen at higher doses, while omitting any comparable discussion of the risks of opioids at high doses.

183. Even where Purdue marketing materials acknowledged that certain risks rose with the dose, they failed to disclose the increased risk of addiction. For example, the *Conversion and Titration Guide* stated that "the ceiling to analgesic effectiveness is imposed only by side effects, the more serious of which may include somnolence and respiratory depression."

184. There is no substantial scientific evidence that doses of opioids can be continuously titrated upward without significant added risk. On the contrary, the risk of addiction, overdose, and death are increased when patients are prescribed higher doses of prescription opioids.[118] Patients receiving high doses of opioids as part of long-term opioid therapy are 3x to 9x more likely to suffer overdose than those on low doses.[119] For example, in 2015 in Vermont, over 80% of individuals with opioid prescription histories who suffered opioid-related accidental fatalities had received high dose (at least 90 MME) analgesics in the five years prior to death.[120]

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[117] American Medical Association, *Pain Management – Overview of Management Options*, https://cme.ama-assn.org/activity/1296783/detail.aspx (last visited 8/3/18).

[118] National Institute on Drug Abuse, *Improving Opioid Prescribing*, last updated March 2017, https://www.drugabuse.gov/publications/improving-opioid-prescribing/improving-opioid-prescribing; Centers for Disease Control and Prevention, *Calculating Total Daily Dose of Opioids for Safer Dosage*, last visited Aug. 6, 2018, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.

[119] Kate M. Dunn *et al.*, *Opioid prescriptions for chronic pain and overdose: a cohort study*, 152(2) Annals of Internal Med. 85-92 (Jan. 19, 2010). Most overdoses were medically serious and 12% were fatal.

[120] *Opioids in Vermont: Prevalence, Risk, and Impact*, supra n.4, at 31.

185. As compared to non-opioid pain remedies, patients develop a tolerance to opioids' analgesic effects more quickly than they develop a tolerance to opioids' depressive effects on respiration. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to accidental overdose even where opioids are taken as recommended.[121]

186. As confirmed by the CDC in its Guideline, research published over the past decade has consistently found that the "[b]enefits of high-dose opioids for chronic pain are not established," while the risks for serious harms are clear and dose-dependent. More specifically, the CDC explains—citing research dating back to 2010—that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid doses." The CDC also states that there are "increased risks for opioid use disorder, respiratory depression, and death at higher dosages."

187. The CDC Guideline reinforces earlier findings announced by FDA. In 2013, FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." [122]

188. Because of these risks, the CDC Guideline advises doctors to "avoid increasing doses" above 90 morphine milligram equivalents (MME) per day. Yet, many patients continue to receive dangerously high doses of opioids, and every dosage of OxyContin available on the market imposes increased risks (compared to lower-dose analgesics) on patients. Of the seven

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[121] *See* Laxmaiah Manchikanti *et al.*, *Opioid Epidemic in the United States*, supra n.1 (60% of opioid overdoses prescribed were within guidelines).

[122] Letter from Janet Woodcock, M.D., Dir., FDA Ctr. for Drug Evaluation and Research, to Andrew Kolodny, M.D., President, Physicians for Responsible Opioid Prescribing, supra n.87.

available OxyContin tablet strengths, the three strongest all exceed the CDC guideline limit when taken (as directed) twice daily: 40-mg (120 MME per day), 60-mg (180 MME per day), and 80-mg (240 MME per day). Patients on the twice-daily 80-mg dose receive nearly 3x the recommended ceiling of 90 MME. Even patients taking 30-mg of OxyContin twice daily reach the CDC daily maximum of 90 MME. Moreover, the CDC has made it clear that even much lower daily doses—exceeding just 20 MME per day—put patients at increased risk.[123] The lowest strength of OxyContin—the 10-mg tablet strength—exceeds this amount when taken twice daily as prescribed.[124] However, despite the known and growing body of research on the risks of these high-dose opioids during the Relevant Period, Purdue marketed OxyContin, and advocated for doctors to prescribe higher and higher doses to patients, without providing adequate disclosures of the risks these drugs posed.

3. Purdue Expanded the Market for its Opioids through Unfair and Deceptive Practices

189. As discussed above, a key component of Purdue's marketing efforts during the Relevant Period focused on expanding the market for its opioid drugs—specifically, OxyContin and Butrans—to generate new prescriptions. Purdue used a variety of strategies to increase the pool of potential customers: (a) focusing the in-person marketing efforts of its sales force on medical generalists, the highest prescribers of opioids in Vermont during the Relevant Period; (b) deceptively marketing OxyContin at low (and ineffective) doses, to overcome barriers to prescribing; (c) targeting elderly and opioid-naïve (not previously treated with opioids) patients; and (d) targeting unbranded marketing at the general public, to stoke demand.

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[123] Centers for Disease Control and Prevention, *Calculating Total Daily Dose of Opioids for Safer Dosage*, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.

[124] *Id.*

a. *Focusing Its Sales Team on High Prescribing Medical Generalists*

190. The overwhelming majority of Purdue's marketing efforts in Vermont focused on prescribers who were generalists—primary care physicians and internists, physician assistants, and nurse practitioners—with less specialized background and experience with opioid therapy and long-term pain management:

Purdue's VT Detailer Visits, by Specialty (2010-2015):

Specialty	# of Detailer Visits	Percentage of Total Visits
GENERAL PRACTICE & FAMILY MEDICINE	1,243	34.71%
INTERNAL MEDICINE	984	27.48%
NURSE PRACTITIONER	364	10.16%
PAIN MEDICINE	31	0.87%
PHYSICIAN ASSISTANT	520	14.52%
OTHER SPECIALTIES	439	12.26%
Total	3,581	

Purdue's emphasis on generalists was based on—and also likely drove—the large percentage of OxyContin being prescribed by generalists in the State. The overwhelming majority of OxyContin prescriptions during the same time period were written by the same types of prescribers:

OxyContin Prescriptions in VT, by Specialty:

Specialty	# of Prescriptions	Percentage of Total
GENERAL PRACTICE & FAMILY MEDICINE	31,049	41.75%
INTERNAL MEDICINE	19,081	25.66%
NURSE PRACTITIONER	7,109	9.56%
PAIN MEDICINE	8	0.01%
PHYSICIAN ASSISTANT	7,678	10.33%
OTHER SPECIALTIES	9,438	12.69%
Total	74,363	

191. Vermont prescribing data are consistent with national prescribing data that Purdue tracked and analyzed. For example, in an internal 2015-2016 "Brand Strategy" presentation for OxyContin, Purdue highlighted the fact that primary care prescribers (including nurse practitioners and physician assistants) write 82% of all OxyContin prescriptions.

192. Internal Purdue documents show that this focus on generalists was not coincidence: it was a deliberate marketing strategy. Internal documents show that part of that strategy was to overcome prescriber concerns about their lack of experience treating chronic pain.

193. When primary care physicians began prescribing less OxyContin, Purdue shifted its marketing focus to nurse practitioners and physician assistants. A Purdue Annual Marketing Plan from 2013, for example, states that "[w]hile [primary care physicians] remain the largest group of prescribers of OxyContin, they are also one of the fastest-declining groups. The only specialties still growing are [nurse practitioners] and [physician assistants], which make up the fastest-growing group in both the [extended-release opioid] market and the industry in general." Purdue also believed that nurse practitioners and physician assistants were particularly susceptible to marketing messages, saying "NPs and PAs desperately seek information, typically from sales representatives." Purdue also sought to influence nurse practitioners and physician assistants through their peers, outlining a strategy in 2012 to "[s]trengthen relations with NP & PA thought leaders" as part of an overall effort to enhance Purdue's reach with Key Opinion Leaders.

194. Purdue's marketing to nurse practitioners and physician assistants over the Relevant Period was effective. The percentage of OxyContin prescriptions in Vermont written

by nurse practitioners doubled between 2010 and 2015. The percentage of OxyContin prescriptions in Vermont written by physician assistants nearly tripled over the same time period.

195. Purdue's purposeful targeting of generalists with its deceptive marketing messages was particularly insidious, because of the asymmetry between Purdue's resources and knowledge and those of a practicing doctor. Purdue is an expert in pharmacology, employing numerous scientists and doctors who work full-time on developing, studying, and understanding its pharmaceutical products. Moreover, Purdue operates in a heavily regulated field, in which misrepresenting the benefits and risks of its drugs is illegal. Prescribers generally do not have extensive specialized training in pharmacology. They relied on Purdue to tell the truth when it provided them with information about Purdue's drugs.

b. *Pitching OxyContin at (Ineffective) Low Doses*

196. Purdue has also deceptively marketed OxyContin at the lower doses—10- and 15-mg—for which the Company has offered no evidence of efficacy. The apparent purpose of these efforts was to overcome barriers to prescribing, such as doctors' and patients' well-founded concerns about the health and addiction risks of the drug.

197. Despite the fact that Purdue built a multi-billion dollar empire based largely on the sale of OxyContin, the actual label for the drug lists only one study showing its efficacy in adults. The results of this study, as printed on the label, state that, "OxyContin 20 mg, but not 10 mg, was statistically significant in pain reduction compared with placebo."[125] (Emphasis added.) Yet, Purdue aggressively marketed OxyContin in both the 10- and 15-mg doses, without informing prescribers of the lack of evidence to support these prescriptions.

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[125] OxyContin ER Full Prescribing Information (last revised 12/2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf.

198. Even Purdue's own study showed the 10-mg dose to be no better than placebo for reducing pain. Moreover, 10-mg of OxyContin is—overall—indisputably more harmful than a placebo because of its potential for diversion, its dangerous side effects, and its ability to cause physical dependence—information that Purdue has known since at least 2000. Most patients taking these low and ineffective doses of OxyContin inevitably need to "titrate up" to a higher dose of OxyContin to attain adequate pain relief, as discussed in Section C(2)(d) above.

199. Call notes show that Vermont sales representatives regularly promoted the 10- and 15-mg doses of OxyContin, encouraged their prescription, and worked with prescribers to identify candidates for starting OxyContin on these doses. Purdue trained sales representatives to promote these doses, particularly when they encountered a reluctant prescriber. Purdue specifically evaluated its sales representatives on their ability to increase the number of 10- and 15-mg doses of OxyContin prescribed in their territory. One nurse practitioner interviewed during the State's investigation described the marketing messages about these low doses as prompting a "paradigm shift" in her mind regarding OxyContin prescribing.

200. In its sales training materials, Purdue specifically identified "chronic moderate to severe pain patients" who were opioid-naïve as "appropriate" candidates for the 10-mg dose. These sales messages presumed that the dose would need to be increased over time for these patients, telling sales representatives to "probe to reinforce individualized titration." However, nowhere in these sales messages did Purdue acknowledge that its own research found the 10-mg dose to be no better than placebo at controlling pain.

201. Sales training materials included affirmative misrepresentations about the 10- and 15-mg doses, which detailers across the country—including in Vermont—were instructed to repeat to healthcare providers. A Training Bulletin titled "New to Brand 'The New OxyContin

Patient'" lays out a strategy for marketing lower-dose OxyContin to prescribers who had already prescribed higher doses to some patients. This document instructs sales representatives to "fram[e] the call" by saying "Doctor, I would like to talk to you about your persistent moderate to severe pain patient whose pain can no longer be controlled solely with NSAIDs, and whose pain is now progressing beyond propoxyphene or codeine." It also provides the following "Positioning Benefit Statements" to be used on sales calls with doctors:

> "Doctor, do you realize (or are you aware) that initiating 10 mg of OxyContin q12h is comparable to initiating 5 mg hydrocodone/oxycodone q6h, while also giving the patient all the benefits of less frequent dosing and the fact that OxyContin is a single-entity opioid, containing only oxycodone.
>
> You will be providing a more convenient q12h dosing regimen. Doctor, since these are established opioid patients with persistent ATC moderate to severe pain, doesn't this make sense?

This training document expressly positioned the 10-mg dose of OxyContin as superior to alternatives, even though nothing in this document acknowledges (or instructs sales representatives to explain) that Purdue's own studies show the 10-mg dose to be no more effective than a placebo.

202. In interviews conducted as part of the State's investigation into Purdue's deceptive marketing scheme, Vermont prescribers affirmed that they had not been aware that Purdue lacked evidence to support the efficacy of OxyContin at the 10- and 15-mg doses.

203. Purdue knew this marketing of low-dose OxyContin was deceptive. In 2000, FDA warned Purdue that an advertisement showing the 10-mg OxyContin pill under statements about the drug's efficacy misleadingly implied that the drug was effective at this dose:

> You present the headline, "IN A STUDY OF 133 PATIENTS WITH MODERATE TO SEVERE OSTEOARTHRITIS PAIN*," followed by bulleted claims about this study. This presentation is followed by the product logo for OxyContin along with various doses of OxyContin that are available. This presentation suggests that any dose of OxyContin can be used for the treatment of

> moderate to severe osteoarthritis pain. However, the study only demonstrated OxyContin 20mg given twice daily to be significantly more effective than placebo at day 7 and 14. In fact, Oxycontin 10mg given twice daily was no better than placebo in reducing pain intensity. Therefore, your suggestion that any dose of OxyContin can be used in the treatment of moderate to severe osteoarthritis pain is unsubstantiated, and consequently misleading.[126]

204. Despite this FDA warning, Purdue made similar misrepresentations during the Relevant Period as to the efficacy of the 10- and 15-mg doses for the treatment of pain. Purdue made these representations directly to prescribers, through a visual aid used by detailers during in-office visits that was specifically labeled as "retained" and "not for distribution." This visual aid was sent by Purdue to sales representatives in Vermont during the Relevant Period. These designations ("retained" and "not for distribution") were clearly intended to prevent documents from circulating. On information and belief, the State alleges that Purdue did not want these documents to come to the attention of regulators.

[126] Letter from Food and Drug Administration to Beth Connelly, R.N., Senior Associate Regulatory Affairs, Purdue Pharma (May 11, 2000), available at https://wayback.archive-it.org/7993/20161023000825/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM166015.pdf.

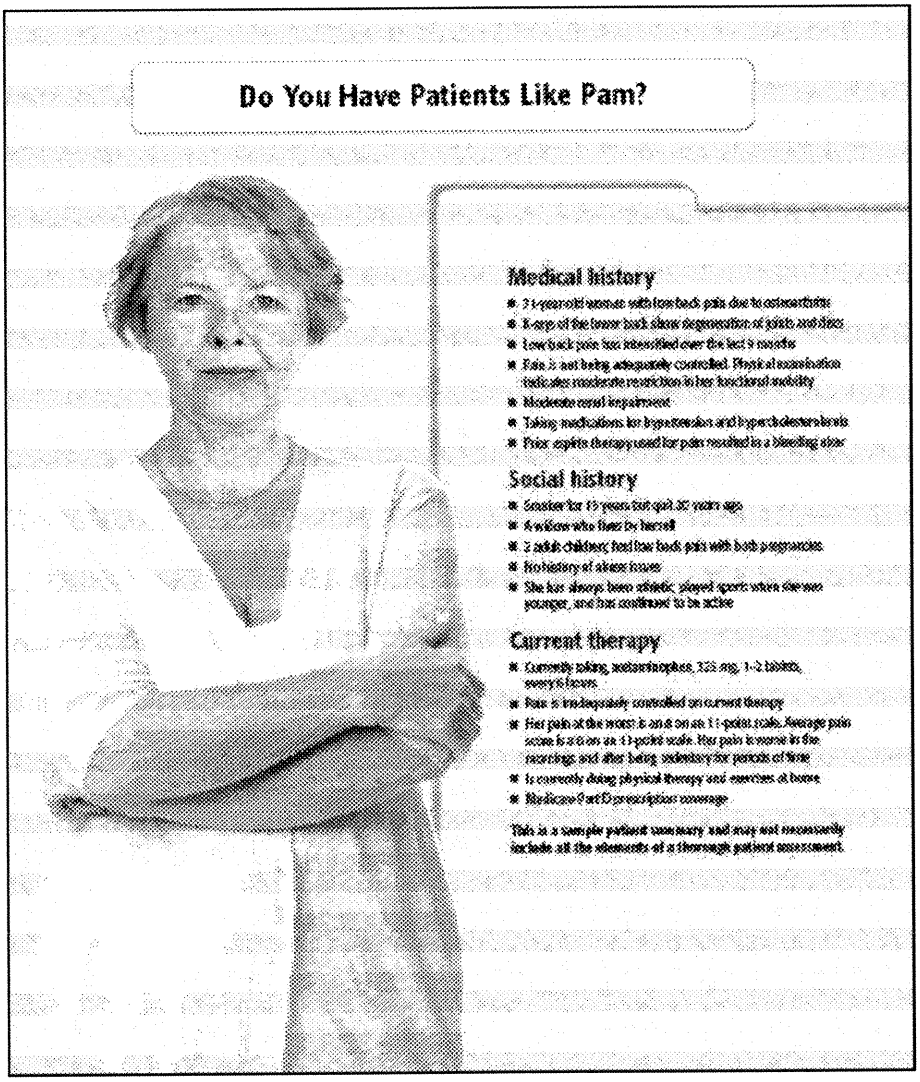
c. *Targeting Elderly and Opioid-Naïve Patients*

205. Part of Purdue's strategy to continue expanding its market share, and hence its revenue, has been to target two overlapping markets in particular: the elderly, a demographic that has seen an explosion in opioid prescribing in recent years, and opioid-naïve patients—those who had not previously taken opioids.

206. Training materials, reviews of sales representatives, and Vermont detailer call notes include multiple references to Purdue's efforts to persuade doctors to start prescribing its ER/LA opioids to elderly patients.

207. Purdue also used its "patient vignettes" or "patient profiles" to subtly persuade doctors that OxyContin and Butrans were appropriate for their elderly patients, by featuring

fictional patients who were older and/or who suffered from conditions like osteoarthritis that are common in older patients.



208. Purdue's unbranded marketing efforts also targeted elderly patients. For example, *In the Face of Pain*'s publication "The Handbook for People with Pain: A Resource Guide (5th Edition"), available through *In the Face of Pain*'s website, included a section entitled "Special Considerations for Seniors." This section identified "pain in the absence of disease" as a major problem affecting seniors—"experienced daily by a majority of older adults in the United States." It goes on to list problems associated with pain, including "decreased mobility" and

"increased risk for falls and weight loss." It highlights the fact that "most pain can improve with treatment," instructing seniors to speak to their healthcare providers and develop a treatment plan. These unbranded marketing materials were intended to drive demand among elderly consumers for pharmacological pain treatment, including opioid therapy. However, they omit any reference to the risks and side effects of such treatments.

209. Purdue focused heavily on marketing its opioids in Vermont as medications that were covered by insurance plans, with a focus on educating physicians about Medicare Part D (prescription benefit) coverage for opioids, including OxyContin in particular. Sales representatives frequently wrote in call notes that they talked to prescribers about Medicare Part D coverage for OxyContin.

210. Purdue managers and sales representatives also focused detailing efforts on the nursing home market. For example, a call note from a visit to a Vermont pharmacy in May 2010 reflects the pharmacist's suggestion that the sales representative bring copies of the *Conversion and Titration Guide* to area nursing homes. In response text from the sales representative's supervisor, the supervisor stated "Good Call...you were given the names of two homes to focus on, lets [sic] talk about plans for these on our next work session." Other Vermont call notes from 2011 and 2012 discuss sales representatives' efforts to identify and gain access to providers at nursing homes and senior/assisted living facilities.

211. Purdue has targeted seniors for a reason: they have been an important growth sector for the opioid industry. In 2016, one-third of all enrollees in Medicare Part D—over 14.5 million beneficiaries, nationwide—received at least one opioid prescription.[127] And more than

[127] U.S. Department of Health & Human Services Office of the Inspector General, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing*, HHS OIG Issue Brief (July 2017), https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf, at 1.

500,000 enrollees nationwide were on a high dose of at least 120 MME—well above the CDC's recommended maximum dosage of 90 MME.[128] These high doses underscore the eventuality that elderly patients will not simply remain on OxyContin 10-mg but will require escalating amounts—which come with escalating dangers and side effects that are particularly acute in the elderly.

212. Purdue's targeting of elderly patients overlapped with Purdue's broad marketing push to persuade doctors to prescribe OxyContin to opioid-naïve patients—even when faced with reluctant practitioners.

213. Sales representatives regularly suggested 10- and 15-mg OxyContin for elderly and opioid-naïve patients, without disclosing that Purdue had no evidence of efficacy at those doses. For example, during one sales call in April 2010, a sales representative wrote that she "[r]eviewed [OxyContin] newer strengths and IR to ER conversion guide, explained 10mg q12h is indicated for op[i]oid naive pts and well covered on part d. He will consider for his elderly." Another sales representative wrote in call notes in 2013 that he would ask providers about initiating opioid-naïve patients at the 10-mg dose: "Would it surprise you to know that an opioid naïve patient could be started on OxyContin 10 mg Q 12.?" None of these call notes indicate that sales representatives disclosed that OxyContin was no more effective than placebo at that dose.

214. Purdue's decisions to target the elderly and opioid-naïve patients reflect a business strategy that placed little value on the well-being and safety of consumers. For patients in these populations, opioid treatment generally—and especially OxyContin treatment—imposes significant risks and should be undertaken only if less-risky analgesics prove ineffective. .

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[128] *Id.*

215. Elderly patients taking opioids are at greater risk for fracture and hospitalization, and they have increased vulnerability to adverse drug effects such as respiratory depression, which Purdue acknowledges in its opioids' labels (but not in its marketing).[129] Elderly patients who use opioids also have a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs.[130] The severity of these risks is increased with OxyContin treatment—which involves a higher opioid dose than as-needed opioids or opioid combination drugs—because the risks associated with opioids are dose-dependent. (*See* Section C(2)(d).)

216. Purdue's specific focus on opioid-naïve patients was likewise unwarranted, in light of the steady stream of information over the past decade emphasizing (as the CDC summarized in 2016), that "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[131] Such risks are simply not warranted for most opioid-naïve patients. Other, less-risky analgesics are available on the market for opioid-naïve patients needing pain relief, including non-opioid pain relievers.

217. Nonetheless, through its marketing efforts, Purdue sought to capture elderly and opioid-naïve patients as a critical customer base that would grow Purdue's profits by continuing to require opioids as they became dependent on and/or addicted to these dangerous drugs.

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[129] OxyContin ER Full Prescribing Information (last revised 12/2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf; OxyContin & Hysingla labels; Hysingla ER Full Prescribing Information (revised 12/2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206627s004lbl.pdf; Kathleen W. Saunders, *et al.*, *Relationship of opioid use and dosage levels to fractures in older chronic pain patients*, J Gen Intern Med 2010; 25:310-5 (April 2010).

[130] *Relationship of opioid use and dosage levels to fractures in older chronic pain patients*, supra n.129.

[131] Thomas R. Frieden & Debra Howry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501, 1503 (Apr. 21, 2016).

d. *Marketing Directly to the General Public, to Drive Demand*

218. Through the *Partners Against Pain* website, Purdue spoke directly to patients and caregivers, encouraging patients to demand effective pain treatment and telling caregivers that they have a responsibility to advocate for "access to appropriate and effective pain care."

219. Purdue re-launched *Partners Against Pain* in 2010, with a re-designed website and celebrity spokesperson campaigns. These campaigns were effective in driving traffic to the website: the number of visitors doubled between October and November 2010, with the addition of content from country music star Naomi Judd and writer Lee Woodruff, the wife of an injured war correspondent. In 2011, after the "Hands On Approach to Pain Management" campaign with *Dirty Dancing* actress Jennifer Grey, site visits went up 542%. Through these campaigns, interviews with Judd, Woodruff, and Grey were widely reported in the news media, including the *Huffington Post*, *Woman's Day*, and *Parade*.

220. The re-designed Purdue's *Partners Against Pain* website provided numerous resources that Purdue positioned as helping consumers talk to their doctor about their pain and treatment options. Purdue suggested that consumers review and even complete the pain assessment tools that their doctor will use to evaluate their pain. Purdue also directed consumers to maintain a daily pain log to take to their doctor, providing numerous samples for patients to

download. In a brochure available on the *Partners Against Pain* website, Purdue provided a list of model questions for patients to ask their doctor, including questions about the proper storage and disposal of their medication, side effects of the medication, and drug interactions. But any discussion of the risks of opioids, in particular the risk of addiction, was conspicuously missing from the suggested list of questions patients should ask their doctors.

221. Elsewhere on the *Partners Against Pain* website, Purdue instructed patients to talk to their doctors if their current medication was not working and "adjust [their] pain management plan accordingly." Purdue omitted any mention of the serious risks associated with increasing the dosage level of opioids.

222. By designing the *Partners Against Pain* site for consumers, and communicating directly to consumers on the website, Purdue stoked consumer demand for its opioids—which it knew to be highly addictive—by creating an atmosphere of broad entitlement to pain medication. Purdue also used this website to coach consumers on how to ask for—and document the need for—pain medications like opioids. However, this website presented only part of the story to consumers, because it did not advise them of the serious risks of these drugs.

D. Purdue Deliberately Continued its Misinformation Campaign, While Concealing its Deceptive Conduct from Regulators

Despite agreeing in a 2007 settlement to stop deceptively marketing its opioids, Purdue continued its misconduct during the Relevant Period—fueling the opioid epidemic in Vermont—even though the Company knew it had no evidence about the benefits and effectiveness of opioids for indefinite use in the treatment of chronic pain and that they carried serious risks of abuse and addiction. In the face of growing scrutiny and regulatory efforts, Purdue concealed its ongoing misconduct from regulators.

223. Purdue made, promoted, and profited from its misrepresentations about the risks and benefits of opioids for chronic pain during the Relevant Period, even though it knew that its marketing was false and misleading. Purdue also actively concealed its unfair and deceptive conduct from regulators and others who were working to curb the growing opioid epidemic.

224. The medical profession's historic understanding of the risks that opioids pose, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of serious adverse outcomes. FDA and other regulators warned Purdue of this, and Purdue entered into settlements in the hundreds of millions of dollars with the United States and numerous states (including Vermont) in 2007 to address similar misconduct. Purdue had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers.

225. Notwithstanding this knowledge, at all times relevant to this Complaint, Purdue took steps to avoid detection of and to conceal its deceptive and unlawful conduct, and also to conceal or minimize questions or concerns raised by prescribers about addiction.

226. In Purdue's 2007 settlement with Vermont committed that it would not make written or oral claims about OxyContin that were deceptive, and that it would not market OxyContin in a way that was inconsistent with the "Indication and Usage" section of the Package Insert. Purdue also promised to provide "fair balance" statements in its marketing of OxyContin, including statements regarding OxyContin's potential for abuse, addiction, or physical dependence, and that it would not make misrepresentations about OxyContin's potential for abuse, addiction, or physical dependence.

227. However, unbeknownst to the State, Purdue continued its deceptive and misleading marketing. As alleged in greater detail above, Purdue sales representatives rarely discussed the risks of addiction during sales calls, and instead were trained to distinguish it from physical dependence (while omitting key information about the risks of physical dependence)

and "appropriate patient selection" (implying that the risks of dependence and addiction can be avoided through prescriber vigilance). These deflections misleadingly reassured doctors that they could safely prescribe Purdue's opioids long-term for chronic pain without fear of addiction.

228. In fact, only once Purdue was being investigated a second time by the State, did it make an attempt to educate prescribers about the risk of addiction posed by its drugs. There are zero references in the call note records to any addiction materials or handouts provided by Purdue sales representatives to Vermont prescribers prior to October 26, 2016. Yet, suddenly, in the fourteen-month period between October 26, 2016 and December 6, 2017 (the last date for which the State received call note records from Purdue), there are 62 references to a "Risk of Addiction" handout provided to prescribers (the handout was provided in approximately 47% of the 131 Vermont detailer visits that occurred between October 26, 2016 and December 6, 2017).

229. Purdue also disguised its own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third-party advocates, and professional associations. Purdue purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Purdue's false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue masked or never disclosed its role in shaping, editing, and approving the content of this information. Purdue also distorted the meaning or import of studies it cited and offered them as evidence for propositions the studies did not support.

230. Purdue's public stance long has been that opioid misuse and diversion to illicit secondary channels are to blame for widespread addiction and abuse. But Purdue has consistently failed to address the problems caused by over-prescribing opioids. Instead, Purdue funded various drug abuse prevention programs nationwide and introduced abuse-deterrent

opioids reformulated to make non-oral ingestion more difficult. Purdue also generated papers for presentation at conferences of addiction prevention professionals that stressed the importance of patient selection and touted the efficacy of its "abuse deterrent" opioids. Depicting the opioid crisis as a problem of misuse and diversion, and promoting its pills as solutions, allowed Purdue to present itself as a responsible corporate citizen while continuing to profit from the commonplace prescribing of its drugs, even at high doses for long-term use.

231. At the heart of Purdue's public outreach has been its claim that the Company works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation features in virtually all of Purdue's recent pronouncements in response to public scrutiny of opioid abuse: "[W]e are acutely aware of the public health risks these powerful medications create . . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ."[132]

232. Purdue's statement on "Opioids Corporate Responsibility" likewise stated, until recently, that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government." But Purdue has failed to accurately and diligently report to authorities illicit or suspicious prescribing of its opioids, even as it publicly and repeatedly touted its "constructive role in the fight against opioid abuse" and "strong record of coordination with law enforcement." In responding to criticism of its failure to report suspicious prescribing to government regulatory and enforcement authorities,

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[132] Purdue Pharma L.P., *Opioids With Abuse-Deterrent Properties*, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/ (last visited Aug. 6, 2018).

Purdue's website similarly proclaimed that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."

233. These public pronouncements created the misimpression that Purdue is proactively working with law enforcement and government authorities, nationwide and in Vermont, to root out drug diversion, including the illicit prescribing that can lead to diversion. They aimed to distance Purdue from its past, publicly-admonished conduct in deceptively marketing opioids, which gave rise to 2007 criminal pleas, and to make its current marketing seem more trustworthy and truthful. In fact, Purdue has consistently failed to report suspicious prescribing to authorities, despite having all the necessary tools—detailed prescribing data and the eyes and ears of its sales force—to observe such practices.

234. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. According to Purdue, physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing volume. Purdue has said publicly that "[o]ur procedures help ensure that whenever we observe potential abuse or diversion activity, we discontinue our company's interaction with the prescriber or pharmacist and initiate an investigation." According to Purdue, it prohibits the detailing of health care providers added to the database, and sales representatives receive no compensation tied to these providers' prescriptions.

235. Yet, according to a 2016 investigation by the *Los Angeles Times*, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. In an interview with the *Los Angeles Times*, Purdue's

former senior compliance officer acknowledged that, in five years of investigating suspicious pharmacies, Purdue consistently failed to report suspicious dispensing or to stop supplies to the pharmacy, even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers. Despite its knowledge of illicit prescribing, Purdue did not report its suspicions, for example, until years after law enforcement shut down a Los Angeles clinic that Purdue's district manager described internally as "an organized drug ring" and that had prescribed more than 1.1 million OxyContin tablets.[133] The New York Attorney General's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing.

236. Purdue thus successfully concealed from the medical community, patients, and the State facts sufficient to arouse suspicion of the claims that the State now asserts. The State was unaware of the existence or scope of Purdue's unlawful conduct and reasonable diligence would not have revealed this information at the time it was occurring. Only by conducting a second investigation of Purdue's marketing conduct, beginning in 2016, was the State able to gain access to information about Purdue's continued deceptive and misleading marketing conduct during the Relevant Period.

CAUSES OF ACTION

Purdue deliberately and, for over two decades, perpetuated a disinformation campaign and fraud on the medical community and the public—in the United States generally and in Vermont specifically. Purdue engaged in this deception for its own profit. And Purdue indeed profited—at a high cost to Vermont and its people. Accordingly, the State of Vermont seeks recourse from Purdue for its unlawful conduct.

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[133] Harriet Ryan *et al.*, *More than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/

COUNT ONE
DECEPTIVE ACTS AND PRACTICES
VIOLATIONS OF THE VERMONT CONSUMER PROTECTION ACT

237. The State realleges and incorporates by reference each of the allegations contained in all paragraphs of this Complaint as though fully set forth herein.

238. Defendants engaged in unfair and deceptive trade practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), by making material misrepresentations and omissions regarding the risks and benefits of its opioid products, including by:

(a) making and disseminating false or misleading statements about the use of opioids to treat chronic pain [Purdue's affirmative misrepresentations];

(b) causing false or misleading statements about opioids to be made or disseminated [funding, influencing, and distributing misrepresentations made by third parties];

(c) making statements to promote the use of opioids to treat chronic pain that omitted or concealed material facts [Purdue's material omissions]; and

(d) failing to correct prior misrepresentations and omissions about the risks and benefits of opioids [continuing to market opioids without correcting past misrepresentations].

239. Purdue's statements about the use of opioids to treat chronic pain were not supported by or were contrary to substantial scientific evidence, as confirmed by recent pronouncements of the CDC and FDA based on that evidence. Further, Purdue's material omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading because they were materially incomplete. At the time it made or disseminated its false and misleading statements or caused these statements to be made or disseminated, Purdue failed to include material facts about the risks and benefits of long-term opioid use and intended that the recipients of its marketing messages would rely upon those omissions.

240. At all times relevant to this Complaint, Purdue violated 9 V.S.A. § 2453(a) by engaging in deceptive acts or practices, including, but not limited to, the following:

(a) Misrepresenting the benefits and/or efficacy of long-term opioid use;

(b) Mischaracterizing OxyContin's onset of action and duration of efficacy to imply that the drug provides a full 12 hours of pain relief, when Purdue knew it does not.

(c) Mischaracterizing the risk of opioid addiction and abuse;

(d) Claiming or implying that addiction can be avoided or successfully managed through the use of screening and other tools;

(e) Promoting the misleading concept of pseudoaddiction and drawing distinctions between "physical dependence" and "addiction," for the purpose of concealing the true risk of dependence and addiction and minimizing the risks of dependence;

(f) Claiming or implying that increasing the dose of opioids (titrating up) poses no significant additional risk;

(g) Misrepresenting the efficacy of 10- and 15-mg OxyContin doses;

(h) Targeting deceptive, unbranded marketing at the general public and medical community; and

(i) Exaggerating the efficacy of abuse-deterrent formulations of its drugs.

241. These misrepresentations and omissions were likely to mislead prescribers and consumers, affecting their decisions regarding the prescribing and use of opioids. The meaning Plaintiff ascribes to Defendants' misrepresentations herein is reasonable, given the nature thereof.

242. Purdue also engaged in unfair and deceptive trade practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), because Purdue's affirmative statements were not substantiated by competent and reliable scientific evidence.

COUNT TWO
UNFAIR ACTS AND PRACTICES
VIOLATIONS OF THE VERMONT CONSUMER PROTECTION ACT

243. The State realleges and incorporates by reference each of the allegations contained in all paragraphs of this Complaint as though fully alleged herein.

244. Defendants engaged in unfair acts or practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), by:

(a) Engaging in deceptive, marketing that was unsupported by substantial scientific evidence to support its product claims in violation of 21 C.F.R. § 202.1(e);

(b) Engaging in a marketing campaign that failed, despite the known, serious risks of addiction and adverse effects posed by opioids, to present a fair balance of benefit and risk information in its promotion of opioids, in violation of FDA regulations, including 21 C.F.R. § 202.1(e);

(c) Promoting high doses for extended periods of time, in contravention of longstanding public policy to avoid and minimize the risk of addiction and abuse of controlled substances;

(d) Targeting a vulnerable population—the elderly—for promotion of opioids to treat chronic pain in the face of the known, heightened risks of opioid use to that population, including risks of addiction, adverse effects, hospitalization, and death;

(e) Targeting opioid naïve patients and patients using IR or weaker (Schedule III) opioids for conversion to Purdue's ER/LA opioid products;

(f) Promoting the initiation of opioid use and/or continuation of opioid use beyond 90 days by providing Savings Cards to reduce patients' out-of-pocket expense for these drugs; and

(g) Using unbranded marketing, front groups, and key opinion leaders to evade FDA oversight and rules prohibiting deceptive marketing and to deceive prescribers and consumers regarding the impartiality of the information conveyed.

245. These acts or practices may be deemed unfair in that they offend public policy reflected in (a) the CPA, which protects consumers and competitors from deceptive marketing and to ensure an honest marketplace, and (b) federal law, which requires the truthful and balanced marketing of prescription drugs, 21 C.F.R. § 202.1(e).

246. These acts or practices were unfair because they unethically deprived prescribers of the information they needed to appropriately prescribe—or not prescribe—these dangerous drugs. Patients who use opioids can quickly become dependent and addicted, such that neither the patient nor the prescriber can avoid injury by simply stopping or choosing an alternate treatment.

247. By reason of Purdue's conduct, Vermont consumers have suffered substantial injury by reason of the health risks associated with opioid use, including the pain, and suffering associated with opioid addiction, injury, disability, overdose, and death, as well as the associated financial costs.

COUNT THREE
PUBLIC NUISANCE

248. Purdue, through the actions described in the Complaint, has created—or was a substantial factor in creating— a public nuisance by unreasonably interfering with a right that is common to the general public and that harms the health, safety, peace, comfort, or convenience of the general community.

249. The State and its citizens have a public right to be free from the substantial injury to public health, safety, peace, comfort, and convenience that has resulted from Purdue's illegal and deceptive marketing of opioids for the treatment of chronic pain.

250. This injury to the public includes, but is not limited to (a) widespread dissemination of false and misleading information regarding the risks and benefits of opioids to treat chronic pain; (b) a distortion of the medical standard of care for treating chronic pain, resulting in pervasive overprescribing of opioids and the failure to provide more appropriate pain treatment; (c) high rates of opioid abuse, injury, overdose, and death, and their impact on Vermont families and communities; (d) increased health care costs for individuals, families,

employers, and the State; (e) lost employee productivity resulting from the cumulative effects of long-term opioid use, addiction, and death; (f) the creation and maintenance of a secondary, criminal market for opioids; and (g) greater demand for emergency services and law enforcement paid for by the State at the ultimate cost of taxpayers.

251. At all times relevant to the Complaint, Purdue's marketing substantially and unreasonably interfered in the enjoyment of this public right by the State and its citizens. Purdue engaged in a pattern of conduct that (a) overstated the benefits of chronic opioid therapy, including by misrepresenting OxyContin's duration of efficacy and by failing to disclose the lack of evidence supporting long-term use of opioids; and (b) obscured or omitted the serious risk of addiction arising from such use. This conduct effected and maintained a shift in health care providers' willingness to prescribe opioids for chronic pain, resulting in a dramatic increase in opioid prescribing and the injuries described above.

252. At all times relevant to the Complaint, Purdue exercised control over the instrumentalities constituting the nuisance—*i.e.*, its marketing as conveyed through sales representatives, other speakers, and publications, and its program to identify suspicious prescribing. As alleged herein, Purdue created, or was a substantial factor in creating, the nuisance through multiple vehicles, including (a) making in-person sales calls that contained false or misleading statements or material omissions; (b) disseminating deceptive advertisements and publications; (c) sponsoring and creating flawed and biased scientific research and prescribing guidelines; and (d) sponsoring and collaborating with third parties to disseminate false and misleading messages about opioids. To the extent Purdue worked through third parties, it adopted their statements as its own by disseminating their publications, and/or exercised control over them by financing, reviewing, editing, and approving their materials.

253. Purdue's actions were a substantial factor in creating the public nuisance by deceiving prescribers and patients about the risks and benefits of opioids and distorting the medical standard of care for treating chronic pain. Without Purdue's actions, opioid use would not have become so widespread, and the opioid epidemic that now exists in Vermont would have been averted or would be much less severe.

254. The public nuisance was foreseeable to Purdue. As alleged herein, Purdue engaged in widespread promotion of opioids in which it misrepresented the risks and benefits of opioids to treat chronic pain. Purdue knew that there was no evidence showing a long-term benefit of opioids on pain and function, and that opioids carried serious risks of addiction, injury overdose, and death. Purdue was positioned to foresee not only a vastly expanded market for chronic opioid therapy as the likely result of Purdue's conduct, but also the widespread problems of opioid addiction and abuse that have, in fact, materialized. Purdue was on notice and aware of signs that the broader use of opioids was causing just the kinds of injuries described in this Complaint.

255. This public nuisance can be abated—in part—through health care provider and consumer education on appropriate prescribing, honest marketing of the risks and benefits of long-term opioid use, addiction treatment, disposal of unused opioids, and other means.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff State of Vermont respectfully requests the Court enter judgment in its favor and the following relief:

(a) A judgment in its favor and against Purdue on each cause of action asserted in the Complaint;

(b) With respect to Counts 1 and 2, a permanent injunction prohibiting Purdue from engaging in the unfair and deceptive acts and practices described in the Complaint;

(c) With respect to Counts 1 and 2, a judgment requiring Purdue to disgorge all funds acquired and/or retained as a result of any acts or practices found to be unlawful;

(d) With respect to Counts 1 and 2, statutory civil penalties of $10,000 for each violation of the Vermont Consumer Protection Act;

(e) With respect to Count 3, an order providing for abatement of the nuisance that Purdue created or was a substantial factor in creating, enjoining Purdue from further conduct contributing to the nuisance, and damages as compensation for funds the State has already used to abate the nuisance;

(f) The award of investigative and litigation costs and fees to the State of Vermont; and

(g) Such other, further, and different relief as this Court may deem appropriate.

JURY TRIAL DEMANDED

The State demands a trial by jury.

Dated: October 26, 2018

Respectfully submitted,

THOMAS J. DONOVAN JR.
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STATE OF VERMONT

SUPERIOR COURT
CHITTENDEN UNIT

CIVIL DIVISION
DOCKET NO. _____

STATE OF VERMONT,

Plaintiff,

vs.

CARDINAL HEALTH, INC. and
MCKESSON CORPORATION,

Defendants.

COMPLAINT

TABLE OF CONTENTS

The Vermont Attorney General brings this suit against Cardinal Health, Inc. and McKesson Corporation for violations of the Vermont Consumer Protection Act, negligence, and creating a public nuisance. The Attorney General seeks civil penalties, injunctive relief, disgorgement, fees and costs, and other appropriate relief.

PRELIMINARY STATEMENT

1. Over the past two decades, a public health crisis caused by prescription opioids has spread across Vermont and the entire country.

2. In Vermont, drug-related fatalities involving opioids nearly tripled between 2010 and 2018.[1]

3. Vermont ranks as the 8th-highest state in the nation for drug dependence,[2] despite other favorable health indicators like better access to health care and insurance coverage as compared to other states.[3]

4. Serious consequences radiate from every case of overdose and addiction, including harm to individuals and families and strain on the State's healthcare and social services systems. In a small state like Vermont, no case of addiction or overdose is anonymous.

5. Just the presence of prescription opioids in the State represents a risk that must be managed. Prescription opioids—including fentanyl, oxycodone, hydrocodone, and combination drugs—are controlled substances. They have a high potential for abuse and misuse; can cause serious injury, including severe psychological or physical dependence; and, therefore, are highly regulated. Equally significant, prescription opioids are subject to diversion away from legitimate

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[1] Vermont Department of Health, *Opioid-Related Fatalities Among Vermonters* (updated February 2019), http://www healthvermont.gov/sites/default/files/documents/pdf/ADAP_Data_Brief_Opioid_Related_Fatalities.pdf.
[2] amfAR Opioid & Health Indicators Database, Percent of people 12+ Reporting Drug Dependence, http://opioid.amfar.org/indicator/drugdep.
[3] *See* State Health Assessment Plan - Healthy Vermonters 2020 (December 2012), http://www healthvermont.gov/sites/default/files/documents/2016/11/Healthy%20Vermonters%202020%20Report.pdf, at 13, 5, 27.

medical, research, and scientific channels to unauthorized use and illegal sales. An inflated volume of opioids invariably leads to increased diversion and abuse. Indeed, there is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[4] Prescription opioids are diverted away from legitimate medical channels in a variety of ways, but the vast majority of people who misuse prescription opioids obtain their drugs (1) from friends or family members, or (2) through their own prescriptions. This means that, for most people who misuse opioids, the source of their drugs can typically be found in the excess supply of drugs in the community, beyond what is needed for legitimate medical purposes.

6. Because of the risks inherent in the distribution of prescription opioids, each of the participants in their supply chain has important legal responsibilities intended to protect against misuse and diversion of these dangerous drugs. The legal distribution of prescription opioids involves three key participants: (1) manufacturers that make the opioids; (2) distributors that supply the opioids to pharmacies; and (3) pharmacies that dispense the opioids to consumers.

7. By law, distributors—who are the gatekeepers in the prescription opioid supply chain—have strict obligations to monitor and control the sales of prescription opioids to prevent diversion.[5] The federal Drug Enforcement Administration ("DEA") recognized: "[D]istributors handle such large volumes of controlled substances and are the **first major line of defense** in the movement of legal pharmaceutical controlled substances ... from legitimate channels into the

[4] Dart, Richard C., *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).
[5] 21 U.S.C. § 823(b) (Controlled Substances Act, discussing diversion).

illicit market ...." Therefore, "it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances."[6]

8. The State brings this lawsuit against two major distributors for failing to fulfill their most fundamental legal duties in violation of Vermont statutory and common law. Cardinal Health, Inc. ("Cardinal") and McKesson Corporation ("McKesson") (collectively, Defendants) have a commanding share of the Vermont market: together they are responsible for about [redacted] of the prescription opioids distributed in the State.

9. Cardinal and McKesson violated their duties to prevent diversion by selling ever-increasing quantities of prescription opioids in Vermont and ignoring the mounting evidence that opioid sales—nationally, and within the State—were far out-pacing legitimate need. Indeed, through their willingness to uncritically supply whatever quantities of opioids pharmacies ordered, Defendants normalized overprescribing and caused widespread proliferation and availability of these dangerous drugs throughout Vermont communities. This over-supply of opioids flowed into Vermont through two primary channels. First, prescription opioids flowed unchecked into the State from Cardinal's and McKesson's excessive sales to Vermont pharmacies—far beyond what was needed for legitimate medical needs. Second, over-supply came to Vermont through illegal channels from other states, including those where "pill mills" stocked with opioids supplied by Cardinal and McKesson poured millions of prescription opioids into the black market.

10. Ultimately, Cardinal's and McKesson's inadequate systems to monitor, detect, and prevent diversion enabled the excessive sales of opioids to Vermont pharmacies. The

[6] Declaration of Joseph Rannazzisi (Deputy Administrator, DEA) at ¶ 10, *Cardinal Health, Inc. v. Holder* (D.D.C.) (No. 12-185 RBW), ECF No. 14-2, 2012 WL 11747342.

systems that Cardinal and McKesson designed were not only flawed; Defendants failed to adhere to their own flawed systems.

11. Cardinal and McKesson relied on sales-volume-based "thresholds" to detect suspicious orders (i.e., orders of unusual size, deviating substantially from a normal pattern, or of unusual frequency). These thresholds were caps set for each pharmacy's monthly opioid orders based on certain factors. If a pharmacy's order exceeded its threshold, that was an indication of potential diversion, and the Defendants were supposed to flag, stop, and investigate the order. These thresholds should have served as an important tool in detecting and preventing illegal orders. However, those thresholds were flawed in their design and implementation: not only did Defendants set them at improperly high levels, but they were also inadequately enforced.

12. Specifically, Cardinal and McKesson set the baseline thresholds far too high—permitting pharmacies to order truly excessive amounts of opioids with little or no functional safety check to catch suspicious orders. And Cardinal and McKesson routinely **increased** the thresholds or found other ways to ship the orders without conducting an appropriate investigation, canceling the order, or reporting the pharmacy to the DEA, as required by law.

13. Additionally, Cardinal and McKesson designed and implemented anti-diversion systems that were wholly inadequate and failed to satisfy their core legal duties as distributors of controlled substances. Defendants not only understaffed their anti-diversion compliance programs, but they provided inadequate training to those they employed. Moreover, Defendants inappropriately relied on front-line sales personnel to implement and enforce their anti-diversion programs. These sales personnel had a conflict of interest because their compensation structure **rewarded** increased sales. There was no compliance incentive for sales personnel to report their own pharmacy customers for placing excessive orders of opioids.

14. As a result of Cardinal's and McKesson's flawed systems, Defendants systematically failed to notify regulators about the increasing indications of widespread diversion that should have been apparent from their own distribution and sales data, as well as additional data they acquired from third-party databanks. Rather than utilizing the wealth of data they possessed to prevent and curtail the diversion of opioids, Defendants used the data to target potential customers and strategize ways to increase their market share, allowing them to profit from the rising tide of opioid misuse and abuse.

15. Cardinal's and McKesson's systematic failures to report suspicious volumes and patterns of prescription opioid sales—as they were required to do under Vermont and federal law—allowed the opioid epidemic to grow, unchecked, for years.

16. Compounding Defendants' failures to identify and prevent diversion, both companies actively engaged in marketing designed to increase the sale of opioids. Cardinal and McKesson promoted opioids to prescribers, pharmacies, and even consumers—working alongside opioid manufacturers to affirmatively **drive** the demand for prescription opioids.

17. Defendants' promotion and marketing of prescription opioids—particularly when viewed in the context of their obligations (and failures) to prevent and control diversion—constituted an unfair business practice. Through these marketing activities, Defendants echoed and reinforced the unfair and deceptive prescription opioid marketing that the drug manufacturers were disseminating through many different channels nationwide, and in Vermont. Further, some of Cardinal's and McKesson's marketing materials misrepresented the benefits of opioids or omitted the serious risks posed by opioid use. These marketing activities, together with the overwhelmingly deceptive branded and unbranded marketing that drug manufacturers disseminated through other channels, encouraged and normalized over-prescribing of

prescription opioids and effectively shifted the medical consensus regarding opioid prescribing and dispensing, nationally and in Vermont, in ways that will take years to undo.

18. Cardinal and McKesson also [redacted] the opioid manufacturers' prescription savings card programs to increase opioid sales by eliminating cost barriers otherwise associated with the initiation of brand-name opioid use. These discount programs subsidized or eliminated the out-of-pocket cost of these drugs, making them more accessible to Vermont consumers and effectively providing free or inexpensive samples of highly addictive substances. These programs also encouraged long-term use of prescription opioids—indeed, many of the savings cards had **no limit** to the number of times they could be used by the same patient—despite the fact that no good evidence existed to support long-term use of opioids.[7]

19. Cardinal and McKesson actively concealed their misconduct in failing to identify and prevent diversion and in promoting and marketing opioids. In sworn testimony, on their own websites, and in other public statements, Defendants vowed to the State and the public that their anti-diversion programs were thorough, effective, and vigorously enforced. And Defendants vowed that they had no role in influencing the prescribing or dispensing of prescription opioids and did not promote and market any pharmaceuticals—including opioids—directly to consumers. These were all false statements. The State has learned from its investigation, after reviewing documents only recently made available, that Defendants' systems to identify and report suspicious orders were seriously inadequate; that Defendants continue to misrepresent the

[7] *See* Centers for Disease Control and Prevention, Guideline for Prescribing Opioids for Chronic Pain (2016), https://www.cdc.gov/drugoverdose/prescribing/guideline.html (hereafter, "CDC Guideline"), at 2, 20, 25. (confirming, based on existing research and evidence, that opioid use presents a "serious risk" of addiction, use for three months or more "substantially increases" that risk, and there never has been "good evidence that opioids improve pain or function with long-term use").

quality, purpose, and key components of their programs; and that Defendants unfairly and deceptively marketed prescription opioids.

20. Defendants have continuously and routinely violated Vermont law, taking advantage of the dramatic rise in opioid prescribing and profiting heavily from the sale of prescription opioids that they knew, or should have known, were being diverted from the legitimate and necessary uses. The consequences have devastated the lives of many Vermonters and will reverberate in Vermont for years to come.

21. The effects of the opioid epidemic in Vermont have been profound: increased health care costs; premature death and disability; lost productivity during prime work years; increases in drug-related crime and incarceration; and the consequential devastation of households and extended families. These predictable outcomes have created a full-blown public health crisis.

22. The State now asks the Court to hold Cardinal and McKesson accountable for their conduct for the damage they have caused, the costs they have imposed on the State, and the burdens they have placed on Vermont's citizens.

PARTIES

23. Plaintiff the State of Vermont brings this action, by and through its Attorney General, Thomas J. Donovan Jr., who is authorized to represent the State in all civil matters at common law and as allowed by statute. 3 V.S.A. § 152. The Attorney General is charged with the responsibility of enforcing the Consumer Protection Act and all regulations promulgated thereunder. 9 V.S.A. § 2458.

24. The State also has standing *parens patriae* to protect the health and well-being, both physical and economic, of its residents. Opioid use and abuse have substantially affected a significant segment of the population of Vermont.

25. Defendant Cardinal Health, Inc. is an Ohio corporation with its principal place of business in Dublin, Ohio.

26. Cardinal, including its subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes pharmaceuticals, including prescription opioids, throughout the country and in Vermont. Cardinal operates 18 wholesale drug outlets that are currently licensed to conduct business in Vermont. Cardinal distributed opioids to Vermont pharmacies that were, in turn, purchased by Vermont consumers and governmental agencies. In addition to distributing opioids, Cardinal marketed and promoted opioids—including, on information and belief, in Vermont.

27. Defendant McKesson Corporation is a Delaware corporation with its principal place of business in San Francisco, California.

28. McKesson, including its subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes pharmaceuticals, including prescription opioids, throughout the country and in Vermont. McKesson operates 30 wholesale drug outlets that are currently licensed to conduct business in Vermont. McKesson distributed opioids to Vermont pharmacies that were, in turn, purchased by Vermont consumers and governmental agencies. In addition to distributing opioids, McKesson marketed and promoted opioids—including, on information and belief, in Vermont.

JURISDICTION AND VENUE

29. The State brings this action exclusively under Vermont law. The State does not assert any claims arising under federal law.

30. The Court has personal jurisdiction over Cardinal and McKesson because they regularly transacted business in Vermont, including by distributing opioids to pharmacies throughout the State; purposely directed business activities, including, on information and belief, marketing activities, into Vermont; had employees who operated in Vermont; and engaged in unlawful practices in Vermont.

31. McKesson is registered to do business in Vermont, with Corporation Service Company as its registered agent, located at 100 North Main Street, Suite 2, Barre, VT 05641. Several Cardinal affiliates and/or subsidiaries also are registered to do business in Vermont, with either Corporation Service Company, located at 100 North Main Street, Suite 2, Barre, VT 05641, or CT Corporation System, located at 17 G W Tatro Dr., Jeffersonville, VT 05464, as their registered agent.

32. Venue is proper in this Court, pursuant to 9 V.S.A. § 2458(a), because Defendants do business in Chittenden County, including distributing opioids within the county.

FACTUAL ALLEGATIONS

I. Vermont Law Imposes on Defendants a Duty to Prevent the Misuse, Abuse, and Diversion of Controlled Substances.

33. Cardinal and McKesson are licensed to distribute prescription drugs in Vermont, including prescription opioids, which are designated as controlled substances due to their high potential for abuse. A license to distribute controlled substances is valuable—it allows Defendants to participate in a tightly controlled, national market valued at more than $7 billion annually for opioids alone.

34. Distribution of controlled substances comes with a substantial duty. Distributors are obligated to take steps to provide effective controls and procedures to guard against theft and diversion of controlled substances, as a critical part of a regulatory system designed to combat drug abuse. These obligations are a crucial component of the State's efforts to protect the public health, welfare, and safety by regulating access to potentially dangerous controlled substances.

35. Vermont's common law imposes a general duty to exercise the degree of care that a reasonably prudent person / entity would exercise under similar circumstances. The scope of this duty of care is determined by the foreseeability of the consequences of the acts or omissions. It is foreseeable that distributing vast amounts of highly addictive prescription opioids into the State, while simultaneously promoting higher sales of these drugs and failing to take reasonable steps to minimize their illegitimate use, could result in widespread misuse, abuse, diversion, and serious injury.

36. Defendants acknowledge that their status as wholesale distributors of controlled substances subjects them to common law duties of care. For example, Defendants' professional lobbying association, the Healthcare Distribution Alliance ("HDA") acknowledges that distributors' responsibilities to detect and prevent diversion of controlled substances arise from the obligations that attach to "responsible members of society."[8]

37. The duty of care imposed under Vermont common law is reasonably informed by Vermont's statutes and regulations, which impose a variety of legal obligations on wholesale distributors that are designed "to promote, preserve, and protect the public health, safety, and welfare."[9]

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[8] Brief for Healthcare Distribution Alliance and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017) (No. 15-1335), ECF No. 1607110, 2016 WL 1321983 at *3.

[9] 26 V.S.A. § 2021.

38. Vermont law requires wholesale distributors to be licensed by the Vermont Board of Pharmacy (the "Board"). The Board's administrative rules impose a host of duties on wholesale distributors that are designed to protect public health and safety. To receive a license, a distributor must attest to the Board that it has implemented and will maintain a range of requirements. In particular, licensed wholesale distributors in Vermont must:

- "employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs," 20-4 Vt. Code R. § 1400:17.5;
- equip their facilities with security systems suitable to protect against diversion, 20-4 Vt. Code R. § 1400:17.8; and
- adopt, maintain, and adhere to written security policies, 20-4 Vt. Code R. § 1400:17.20.

39. Vermont law also imposes duties of care on controlled substance distributors that are co-extensive with those imposed under the federal Controlled Substances Act (21 U.S.C. § 801 *et seq.*) and its implementing regulations, but that are independently enforceable under state law. Vermont law requires: (1) that distributors maintain operations "in compliance with all federal requirements applicable to wholesale drug distribution;" 26 V.S.A. § 2068(9); (2) that distributors comply with all "applicable federal, state, and local laws and rules," 20-4 Vt. Code R. § 1400:17.23; and (3) that distributors dealing in controlled substances "register with the [DEA], and .... comply with all applicable state, local, and DEA requirements," 20-4 Vt. Code R. § 1400:17.25.

40. Congress designed the federal Controlled Substances Act ("CSA") "to deal in a comprehensive fashion with the growing menace of drug abuse in the United States."[10] The CSA carries out this goal by creating a "closed system" of distribution in which every entity that

[10] 1 H.R. Rep. No. 91–1444 (1970), *as reprinted in* 1970 U.S.C.C.A.N. 4566, 4567.

handles controlled substances—including manufacturers, distributors, and dispensers—does so pursuant to a registration with the DEA.[11]

41. The distributors' role is central to the efficacy of the CSA's regulatory system. As the DEA has explained, "[b]ecause distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances ... from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system created by the CSA collapses."[12]

42. Under the CSA, a registered distributor must "provide effective controls and procedures to guard against theft and diversion of controlled substances."[13] Diversion occurs when controlled substances move out of legitimate medical, scientific, and industrial channels.[14] In Vermont, "legitimate medical channel" is narrowly defined as the possession and use by a patient of a narcotic (opioid) prescription drug in accordance with the directions of the patient's licensed health care provider, whose prescription has been dispensed by a licensed pharmacist. Any other type of dispensing,[15] possession, or use is prohibited by Vermont law[16] and thus outside a legitimate medical channel.

43. In particular, distributors must "design and operate a system to disclose to the registrant suspicious orders of controlled substances," and must report to the DEA the discovery

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[11] 21 U.S.C. §§ 821-823.
[12] Declaration of Joseph Rannazzisi (Deputy Administrator, DEA) at ¶ 10, *Cardinal Health, Inc. v. Holder* (D.D.C.) (No. 12-185 RBW), ECF No. 14-2, 2012 WL 11747342.
[13] 21 C.F.R. § 1301.71.
[14] 21 U.S.C. § 823(b).
[15] "Dispense" is defined to include "leave with" and "give away." 18 V.S.A. § 4201(7).
[16] Any possession, administering, or dispensing not specifically authorized under Chapter 84 (the Vermont controlled substances act) is prohibited by 18 V.S.A. § 4205. *See also* 18 V.S.A. § 4216.

of any suspicious orders.[17] The duty to monitor, identify, and report suspicious orders is referred to as the "Reporting Requirement."

44. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, or orders of unusual frequency.[18] This list is not exhaustive,[19] and the DEA has provided extensive guidance on the identification and reporting of suspicious orders.

45. The DEA has advised distributors that:

- they must "consider the totality of the circumstances when evaluating an order for controlled substances";[20]
- monitoring only the volume of controlled substance orders is insufficient to guard against diversion because if an order "deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious";[21] and
- signs that might be indicative that a pharmacy is engaged in diverting controlled substances, include "[o]rdering excessive quantities of a limited variety of controlled substances . . . while ordering few, if any, other drugs," and ordering controlled drugs "in quantities disproportionate to the quantity of non-controlled medications ordered."[22]

46. Defendants were aware of DEA's guidance.

47. In addition to requiring a distributor to monitor, identify, and report suspicious orders, Vermont law also requires a distributor to prevent the shipment of suspicious orders to customer pharmacies, a duty referred as the "Shipping Requirement."[23]

48. The DEA has explained the scope of the Shipping Requirement to distributors on multiple occasions.[24] Before shipping an order that has raised a suspicion, a distributor must

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[17] 21 C.F.R. § 1301.74(b).
[18] 21 C.F.R. § 1301.74(b).
[19] *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 221 (D.C. Cir. 2017).
[20] Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health, Inc. (Sept. 26, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-51).
[21] Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health, Inc. (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-8).
[22] Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health, Inc. (Sept. 26, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-51).
[23] *Masters*, 861 F.3d at 222.

"conduct an independent analysis ... to determine whether the controlled substances are likely to be diverted from legitimate channels."[25] That independent analysis must be thorough and must include certain steps, including: (1) requesting information from the pharmacy that placed the order; (2) documenting the pharmacy's explanation for the order; and (3) engaging in any additional follow-up necessary to determine the legitimacy of the order.[26] The independent investigation must be sufficient to dispel all of the red flags that gave rise to the suspicion.[27]

49. Even the HDA, Defendants' lobbying organization, expressly acknowledged the Shipping Requirement in 2008, where it advised distributors that they "should not ship to the customer any units" of a potentially suspicious order without conducting a "fully documented" investigation to determine whether the order is legitimate.[28]

II. Defendants Violated Their Obligations to Prevent the Misuse, Abuse, and Diversion of Prescription Opioids.

50. Despite their duty to prevent the diversion of opioid drugs, neither Cardinal nor McKesson attempted to create formal anti-diversion programs to fulfill their duty until 2007. And even then, the programs they designed failed to meet their legal obligations to detect, prevent, and report diversion. Defendants also failed to fully implement these anti-diversion programs, rendering them both deficient on their face and unenforced in practice.

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[24] *See, e.g.*, *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01, 36,500 (DEA July 3, 2007) (holding that a distributor violated its duty by shipping suspicious orders without first conducting a due diligence investigation); Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health, Inc. (Sept. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-51) (providing that a distributor must "exercise due care in confirming the legitimacy of all orders prior to filling").

[25] Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-8).

[26] *Masters Pharm., Inc.*, 861 F.3d at 212-13.

[27] *Masters Pharm., Inc.*, 861 F.3d at 212-13.

[28] *HDA Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, available as Attachment 1 to "Prescription Drug Diversion: Combatting the Scourge," Hearing before the Subcommittee on Commerce, Manufacturing & Trade of the U.S. House of Representatives Committee on Energy and Commerce (112th Cong., 2d Session) (March 1, 2012) at 216, 227, 230 (hereinafter "HDMA Industry Compliance Guidelines"), available at https://archive.org/details/gov.gpo.fdsys.CHRG-112hhrg80861.

51. Cardinal and McKesson each designed anti-diversion programs that allowed them to continue shipping ever-increasing and excessive quantities of opioids into Vermont without conducting the required due diligence into their pharmacy customers or notifying law enforcement of ordering volumes and patterns that were indicative of diversion.

52. Both Defendants' anti-diversion programs relied on monthly, volume-based order "thresholds" for each pharmacy customer as the purported trigger for identifying potentially suspicious orders. Their systems failed to identify all orders of unusual size, frequency, and pattern, in violation of Defendants' duties to identify, report, and prevent shipment of all suspicious orders.

53. Cardinal and McKesson each designed and implemented their anti-diversion programs in a way that manipulated and reduced the likelihood of "threshold events," which in turn allowed them to avoid conducting appropriate investigations of their pharmacy customers. Defendants were motivated to minimize threshold events because they wanted to avoid losing customers.

54. Cardinal and McKesson pumped unwarranted volumes of prescription opioids into Vermont, disregarding the obvious signs that diversion was occurring and that a serious health crisis was developing. Based on information currently available to the State, McKesson shipped [redacted] of opioids into Vermont from [redacted] That is equivalent to more than [redacted] prescription opioid pills for every man, woman, and child in the State. Based on the same data, Cardinal shipped [redacted] of opioids into Vermont during the same time frame, equivalent to about [redacted] opioid pills for every man, woman, and child in the State.

55. Defendants' failure to create and implement effective anti-diversion programs, in violation of their duty under Vermont law, resulted in the distribution of excessive quantities of dangerous and addictive prescription opioids into Vermont, facilitating an epidemic of opioid abuse, misuse, and diversion that was both foreseeable and inevitable.

A. Cardinal designed a monitoring system that failed to monitor, identify, report, and prevent the fulfillment of suspicious orders.

56. Following a series of investigations in 2006 and 2007 by state and federal law enforcement into Cardinal's anti-diversion monitoring practices, *see infra* at Part V.A, Cardinal created an anti-diversion program that purported to monitor, identify, report, and prevent the shipment of suspicious controlled substance orders. The main components of Cardinal's program purported to include:

- conducting a due diligence review before onboarding new pharmacy customers;
- setting thresholds, or order limits, to restrict the number / volume of opioids a pharmacy could order each month;
- utilizing an electronic system to hold orders that exceeded thresholds, termed "threshold events," pending further review by Cardinal's anti-diversion staff; and
- conducting regular site visits of existing customers to uncover evidence of suspicious activity.

57. In actuality, Cardinal's four-pronged system was designed to ensure that its pharmacy customers would receive a steady stream of opioids and that anti-diversion duties would never interfere with the Cardinal's bottom line.

1. Cardinal's due diligence policies for onboarding new pharmacy customers were facially inadequate.

58. Cardinal's anti-diversion policy required review of potential new pharmacy customers before onboarding them to ensure that customers purchasing opioids from Cardinal were not engaged in diversion. However, Cardinal's customer onboarding policies were

inadequate because they did not allow Cardinal to independently assess a pharmacy's risk of diversion.

59. From approximately December 2007 through 2012, Cardinal's process for approving new pharmacy customers seeking to order opioids was limited to (1) receiving a customer survey with basic information about the pharmacy's business; (2) receiving an agreement signed by the pharmacy pledging compliance with DEA regulations; and (3) confirming that the pharmacy and its employees were registered with the DEA and relevant state regulatory entities.

60. As written, Cardinal's policies were insufficient to determine whether new pharmacy customers were involved in diversion. Those policies provided Cardinal's sales representatives—[redacted]—with responsibility for collecting relevant documents and completing the survey for the customer. Cardinal did not require an independent inquiry into whether other distributors were providing controlled substances to the pharmacy, nor did it require the pharmacy to provide [redacted] preventing Cardinal from [redacted] Cardinal also did not require site visits at a new pharmacy customer before beginning to ship opioid drugs to it, further evidence of Cardinal's failure to fulfill its broader duty to guard against diversion.

61. To this day, Cardinal's new customer approval review policy relies [redacted] Cardinal still does not [redacted]

[redacted] These inadequacies prevent Cardinal from ensuring the legitimacy of controlled substance purchases by new pharmacy customers.

2. Unreasonably high "thresholds" made it possible for Cardinal to avoid identifying and reporting suspicious orders.

62. Cardinal's suspicious order monitoring system relied on thresholds to identify opioid orders that required review. But Cardinal relied on unreasonably high thresholds, which minimized the number of flagged orders, and allowed Cardinal to avoid investigating or reporting its pharmacy customers when they placed ever-increasing or otherwise suspicious orders for opioids.

63. Cardinal designed its system so that, if an opioid order exceeded a pharmacy's pre-set monthly threshold limit, the order would be held pending review. Moreover, under Cardinal's system, subsequent orders of opioids in the same drug family (i.e., opioids sharing the same narcotic ingredient) also were supposed to be held pending review, interrupting the pharmacy's supply of all opioids in that drug family.[29]

64. However, Cardinal systematically set thresholds at inappropriately high levels to minimize the number of threshold events, to avoid order delays, and to prevent disruption of Cardinal's revenue stream and pharmacy customer satisfaction. Cardinal (1) used unreasonably high sales figures to set thresholds, (2) allowed chain pharmacies with their own anti-diversion programs to have even *higher* thresholds; and (3) set thresholds without accounting for critical factors that the DEA had explained it was required to consider and that would have allowed Cardinal to detect diversion.

65. Fearing that any [redacted] Cardinal set its thresholds at unreasonably high levels from approximately December 2007 through 2012.

[29] For example, OxyContin and Percocet are in the same drug family with generic oxycodone, while hydrocodone is a different drug family.

66. Cardinal categorized pharmacy customers based on order volume (small, medium, and large) and business class (e.g., retail pharmacies, hospitals, and long-term care facilities). Cardinal then averaged the monthly quantity of each opioid drug family [redacted] for a given pharmacy size and type, and then **tripled** the monthly average to create the threshold amount. Cardinal's thresholds thus allowed its pharmacy customers to order **three times** the average volume of opioid drugs ordered by pharmacies of similar size and type before triggering any suspicious order review.

67. Moreover, the averages on which Cardinal relied were inflated even before Cardinal tripled them to set the final thresholds. As the baseline for its thresholds, [redacted]—a time period during which opioid sales, and diversion of opioids to non-medical use, were already at dangerously excessive levels. In 2007, for example, pharmacies dispensed 228.43 million opioid prescriptions nationwide—at the time, the highest number ever recorded—equivalent to 75.9 prescriptions per 100 persons and a 243% percent increase compared to opioid prescription levels in 1996, the year OxyContin ER, an extended release formulation of oxycodone, was launched with an aggressive marketing campaign. In 2008, opioid prescribing increased further, reaching 78.2 prescriptions per 100 persons.

68. From approximately December 2007 through 2012, Cardinal's system granted even higher thresholds to pharmacies that maintained their own anti-diversion or loss-prevention programs. Cardinal permitted these higher thresholds based on the flawed premise [redacted][30] which ignores and abdicates Cardinal's own independent duty to identify and report suspicious orders and guard against diversion.

[30] CAH_MDL2804_02953792 at 3–4.

69. [redacted] Cardinal's oxycodone thresholds for [redacted] Cardinal justified the disproportionate thresholds at these pharmacies on the theory that the hospitals or other institutions they serve [redacted][31] Yet Cardinal acknowledged that [redacted]. Through these inflated thresholds, Cardinal ensured that Vermont pharmacies would not trigger a threshold event, even if they ordered significantly greater-than-usual volumes of opioids.

70. Only when confronted with enforcement actions by the DEA and DOJ in 2012, *see infra* at Part V.A, [redacted], making clear just how inflated Cardinal's threshold formulas had been previously. For example, [redacted] in Chittenden County, Vermont [redacted]

[31] CAH_MDL2804_01891921 at 4, 8.

[redacted]

71. Additionally, Cardinal's threshold calculations failed to incorporate critical factors necessary to make the thresholds a meaningful tool for monitoring suspicious orders. Despite the DEA's guidance that a suspicious order monitoring system should account for factors including the geographic location of its pharmacy customers, Cardinal's thresholds have never accounted for the size or demographics of the population served by a pharmacy, nor the total number of pharmacies within the same service area.

72. From approximately December 2007 through 2012, Cardinal's thresholds also did not account for the possibility that pharmacies were receiving opioids from multiple distributors. Cardinal also sometimes set its thresholds without considering pharmacies' actual prescription volumes. If a retail independent pharmacy did not provide Cardinal with its dispensing data, Cardinal automatically provided the pharmacy with generic "mid-level" threshold limits rather than demand the information or conduct an investigation. Cardinal did this to [redacted]

73. Cardinal's thresholds for chain pharmacies—retail pharmacies owned by a common parent company and operating under the same name with multiple locations—were based on a standard threshold for the entire chain. Thus, a pharmacy serving a small community in Vermont, or that had a minimal opioid portfolio, could nevertheless be permitted to order unnecessarily large quantities of opioids merely because that pharmacy was part of a retail pharmacy chain. In one instance, [redacted]

[redacted] Windham County, Vermont [redacted]

[redacted]

74. Throughout the entire period from approximately December 2007 to the present, Cardinal's thresholds have failed to account for the quantity of opioids distributed and dispensed in a given geographic region. Despite easily accessible state and regional (1) distribution data, (2) prescribing data, (3) market share data, and (4) population data, some of which is also available at the county- and census tract-level, and all of which [redacted] [redacted] see *infra* Section IV.B, Cardinal's thresholds did not account for opioid distribution, opioid prescribing, its own market share, or the population of a given geographic area. Cardinal failed to [redacted]

75. Because of these fundamental design flaws and Cardinal's exclusive reliance on volume-based thresholds to trigger investigation of orders, Cardinal's threshold-based system has been ineffective at identifying suspicious orders. From approximately December 2007 to the present, Cardinal's system has relied exclusively on these thresholds to trigger investigation of pharmacy orders. Cardinal's monitoring system was originally "primarily focused on volume," and even after Cardinal began considering additional factors in 2011—pharmacy ordering patterns and frequency—Cardinal only reviewed those factors when an investigation of an order was "triggered" by exceedance of the volume-based threshold. By design, this system is too simplistic for Cardinal to reliably identify orders that are potentially suspicious for other reasons, such as unusual frequency or pattern.

76. Because of the flaws in Cardinal's design of—and exclusive reliance on—these improperly high volume-based thresholds, Cardinal's suspicious order monitoring system was and is insufficient to identify, review, and report suspicious orders as Cardinal is required to do under applicable law.

3. Cardinal manipulated its policies to help pharmacies prevent threshold events.

77. Cardinal has been aware of [redacted] From approximately December 2007 through 2012, Cardinal's official policy was to not disclose specific threshold levels to pharmacies. However, Cardinal also wanted to prevent threshold events from occurring.

78. Thus, without disclosing a specific threshold to a pharmacy, Cardinal would: (1) alert pharmacies when they were approaching their thresholds, thereby allowing the pharmacies to request a preemptive threshold increase; (2) coach pharmacies on how to avoid triggering review of their orders; and (3) raise thresholds without conducting any investigation into the pharmacy's operations.

79. While in the earliest stages of [redacted] To meet this need, from approximately December 2008 through 2012, Cardinal tracked pharmacies' proximity to their thresholds—their "threshold accrual"—and used an "early dialogue" process, in which sales representatives were required to [redacted] a pharmacy when the pharmacy's controlled substance orders reached a certain percentage of its threshold. [redacted]

[redacted][32] this process directly subverted the very purpose of the thresholds—alerting Cardinal to potentially suspicious orders. Instead, Cardinal warned pharmacies when they were approaching a potential threshold event so that the pharmacy could request—and Cardinal could grant—a preemptive increase. Cardinal was extremely successful in shielding itself and its pharmacy customers from threshold events: from 2010 to 2011—the first year of the early dialogue intervention program—threshold events dropped by 37%.

80. After 2012, Cardinal became even more aggressive about helping pharmacies to avoid threshold events and evade review. From approximately [redacted] to [redacted][33] Sales representatives had multiple tools available to review a pharmacy customer's thresholds and accruals, [redacted][34]

81. Further undermining the threshold system, Cardinal's [redacted]

[32] CAH_MDL2804_02246162 at -197.
[33] CAH_MDL2804_02011099.
[34] Deposition of Todd Cameron, Sept. 26, 2018, CAH_MDL2804_02953369, at 295:5–22.

[redacted][35] Pharmacies selected [redacted] However, instead of [redacted] Cardinal's anti-diversion investigator [redacted]

82. [redacted]

83. Even after Cardinal finally did implement [redacted] it continued to [redacted] For example, the policy [redacted]

[35] CAH_MDL2804_00035120 at 1.

[redacted] Cardinal's policy also allows [redacted]

4. Cardinal avoided adequately investigating, blocking, and reporting orders triggered by threshold events.

84. Cardinal designed its suspicious order monitoring system so that when a pharmacy did place an order exceeding a threshold—indicating that the order was potentially suspicious and required further review—Cardinal could resume normal shipments to that pharmacy as quickly as possible. To that end, Cardinal (1) gave pharmacies [redacted] [redacted] (2) required minimal due diligence before fulfilling held orders; (3) allowed pharmacies that exceeded a threshold for one opioid drug family to continue ordering opioids from other drug families; and (4) used a monthly accrual period, [redacted] [redacted] Finally, even when Cardinal determined that an order was "unreasonable" and should not be shipped, Cardinal (5) failed to report all such orders to the DEA, as required by law.

85. From approximately 2013 to the present, [redacted]

[redacted]

86. When Cardinal did hold a pharmacy's order pending review, Cardinal failed to conduct adequate due diligence to determine whether to cancel the order and report it as suspicious or to release and ship the order. From approximately December 2007 through 2012, Cardinal's diligence review was limited to an online survey completed by the pharmacy responsible for the potentially suspicious order; a "customer profile" that included only basic information about the pharmacy and its opioid drug purchases; and the held order itself. Cardinal did not require a site investigation before releasing an order that exceeded a threshold, [redacted]

87. From approximately 2013 to the present, [redacted]

88. Cardinal's suspicious order monitoring system also failed to ensure adequate investigation of orders flagged as potentially suspicious by Cardinal's distribution center employees. Cardinal labeled these potentially suspicious orders as "orders of interest." From approximately December 2007 through 2012, Cardinal allowed distribution center supervisors, "based upon [their] knowledge and experience," to release these orders of interest without any

further review, oversight, or documentation.[36] Only if the supervisor, in his or her sole discretion, decided to hold the order would the order be subject to review by Cardinal's anti-diversion department.

89. Cardinal also designed its thresholds so that "threshold events"—and any resulting hold and investigation of a pharmacy's order—would have as little impact as possible on the pharmacy's ability to continue ordering opioids. From approximately December 2007 to [redacted], Cardinal has set separate thresholds for each drug family, and following a threshold event, only holds orders for drugs in the specific drug family with the threshold exceedance. The logical result of this policy is that a threshold event in one drug family does not impact or interrupt a shipment of opioids belonging to another drug family, despite the indication that the pharmacy could be a source of opioid diversion. [redacted]

90. From approximately December 2007 to [redacted], Cardinal's monthly threshold levels reset with each new monthly accrual period—without accounting for suspicious ordering activity that occurred in the preceding accrual period. This means that pharmacies [redacted]

91. From approximately December 2007 through 2012, Cardinal also failed to appropriately report suspicious orders to the DEA. Under Cardinal's policy, an employee reviewing a threshold event had the authority to decide whether the excessive order was

[36] Investigation Report of the Special Demand Committee, Board of Directors of Cardinal Health (Apr. 12, 2013) at 15, https://www.cardinalhealth.com/content/dam/corp/web/documents/Report/CH-Report-of-Special-Demand-Committee-April-12-2013-Redacted.pdf

"reasonable" or "unreasonable." Cardinal's policy gave little guidance as to what orders were "reasonable," specifying only that a reviewer should use "applied reasoning" and offering several general factors for consideration, including "seasonal events, natural events, [and] regional prescribing habits." Even though an excessive and unreasonable order would certainly meet the definition of "suspicious" under the controlling regulations, Cardinal would still not report those orders to the DEA unless a Cardinal reviewer also designated those orders as suspicious at the reviewer's own discretion. By building this discretionary process into its anti-diversion system, Cardinal allowed its personnel to limit the number of "suspicious orders" they reported to the DEA, even when those orders were flagged by Cardinal's system because they bore all the hallmarks of a "suspicious order."

5. Cardinal's sales representatives conducted the majority of site visits, and Cardinal's investigators deferred to the pharmacies they were investigating.

92. Many indicators of diversion, including those listed in Cardinal's policies governing on-site investigations of its pharmacy customers, cannot be identified through electronic order monitoring alone. Thus, a critical component of Cardinal's duty was to conduct regular due diligence reviews of its pharmacy customers, including regular on-site visits, to monitor for and guard against diversion. Despite this, Cardinal relied on threshold events to trigger most site visits. Moreover, Cardinal (1) placed most of the responsibility for conducting site visits on its sales force; and (2) required that its investigators defer to the pharmacies supposedly under investigation.

93. Cardinal's anti-diversion program relies heavily on its sales force—rather than compliance personnel—to investigate the sales employees' own pharmacy customers. The

Cardinal sales force is treated as the company's [redacted]

94. Cardinal's sales employees look for the more extreme indicators of diversion including long lines, minimal front-end merchandise, and out-of-state license plates in the parking lot. But, from at least June 2009 to March 2013, sales employees only were required to report pharmacy customers that exhibited "two or more" of these indicators, thus allowing Cardinal to continue selling opioids to pharmacies that exhibited suspicious activity without further investigation.

95. From approximately December 2008 through May 2013, Cardinal's sales force monitored pharmacy customers using monthly "Highlight Reports" that identified pharmacies based on increases in their opioid drugs orders. [redacted][37]—rather than as a way to identify customers placing potentially suspicious orders. Where pharmacies had extreme increases in opioid sales—over 15 percent per month—sales employees visited the pharmacies to assess the pharmacy for visible signs of diversion. But where pharmacies had increases in their opioid sales of between 10 and 15 percent, sales employees merely were required to call the pharmacy "to understand the reason for the increased ordering."[38] Unless the pharmacy requested a threshold increase or the salesperson reported outward signs of diversion, no further action was taken. [redacted]

[37] *See* CAH_MDL2804_02954214 at 4; Deposition of Jennifer R. Norris, Aug. 7, 2018, CAH_MULTISTATE_0014000, at 269:8–22; CAH_MDL2804_02954268 at 3.

[38] Investigation Report of the Special Demand Committee, Board of Directors of Cardinal Health (Apr. 12, 2013) at 13, https://www.cardinalhealth.com/content/dam/corp/web/documents/Report/CH-Report-of-Special-Demand-Committee-April-12-2013-Redacted.pdf.

96. Cardinal's sales employees' anti-diversion duties conflicted with their compensation incentives. Cardinal expected its sales employees to [redacted][39] Reporting a pharmacy as a diversion risk could damage a sales representative's relationship with the pharmacy customer, potentially reducing the sales representative's ability to increase sales to that pharmacy. Cardinal also gave sales representatives [redacted], leaving little doubt as to where sales representatives were incentivized to direct their focus and time.

97. When Cardinal did conduct full site visits using anti-diversion investigators, those visits [redacted][40] [redacted]

B. Cardinal failed to adhere to the terms of its own anti-diversion program.

98. Not only did Cardinal design a seriously deficient anti-diversion program, it also failed to adhere to it. The company consistently has understaffed its anti-diversion department, raised pharmacy thresholds without enough scrutiny of factors relevant to potential diversion, and failed to report or otherwise diligently investigate all orders that exceeded a set threshold. Cardinal also allowed large chain pharmacies to operate independently, under their own set of rules—often by allowing chain pharmacies to carry out their own investigations of suspicious orders with no oversight from Cardinal. In each of these ways, Cardinal undermined its already-

[39] CAH_MDL2804_00618377 at 5, 9.
[40] CAH_MDL2804_02904365, at -380.

ineffective anti-diversion program, violating its legal duties and resulting in increasing and undetected diversion of opioids.

1. Cardinal understaffed its anti-diversion department.

99. Wholesale distributors of controlled substances have a duty under Vermont common law, statutes, and regulations to "employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs." 20-4 Vt. Code R. § 1400:17.5. Cardinal breached that duty by failing to staff enough well-trained individuals on its anti-diversion team.

100. Despite having [redacted] distinct pharmacy customers that order controlled substances nationwide—[redacted] of which order opioid drugs—Cardinal employed only **two people** devoted to anti-diversion prior to 2007. Following the DEA's 2007 enforcement action against Cardinal, it increased the anti-diversion group, initially hiring 24 compliance officers. These compliance officers, however, were not responsible for analyzing threshold events or investigating pharmacies, but instead were tasked with "various compliance measures" that applied specifically to distribution centers, [redacted] By 2014, there were only around [redacted] employees responsible for these compliance functions.

101. Cardinal's failure to staff a sufficient number of properly trained investigators prevented it from conducting necessary investigations of its pharmacy customers. [redacted]

[redacted]

102. [redacted]

103. These staffing failures have had real-world consequences in Vermont. Cardinal's internal documents confirm that, [redacted] Vermont retail pharmacy customers [redacted] in Chittenden County, Vermont and [redacted] in Franklin County, [redacted] Vermont [redacted]

2. Cardinal raised thresholds, failed to report flagged orders, and shipped orders, without conducting a diligent investigation.

104. Cardinal has admitted that it did not report all suspicious orders of controlled substances to the DEA. For example, from approximately December 2007 through 2012, Cardinal only reported orders that were so egregious that they led Cardinal to terminate a pharmacy's ability to order controlled substances altogether. Under this system, Cardinal's Massachusetts distribution center, which services Vermont, [redacted]

[redacted] Cardinal filled more than [redacted] opioid orders in Vermont, [redacted] In fiscal year 2011, Cardinal reported just 47 total suspicious orders to the DEA from its 24 distribution centers **nationwide**. That same year, Vermont's opioid-related overdose death rate reached 9.1 deaths per 100,000 persons, nearly triple the rate it had been in 2000; that rate has since doubled again, rising to 18.4 deaths per 100,000 persons in 2016, the most recent year for which data are available.[41]

105. On several occasions, Cardinal shipped suspicious opioid orders to Vermont pharmacies without conducting any investigation and without reporting the suspicious orders to the DEA in direct violation of its duty under Vermont law. For example, [redacted] Lamoille County, Vermont, [redacted] In violation of Cardinal's duty, this notation provides no indication of whether Cardinal visited or otherwise contacted the pharmacy to inquire about these orders; whether the pharmacy provided any response that would justify the threshold events; or whether Cardinal engaged in any form of investigation whatsoever to ensure the legitimacy of these orders.

106. [redacted] Franklin County, Vermont [redacted]

[41] NIDA, Vermont Opioid Summary (Revised March 2018), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/vermont-opioid-summary (Filesite # 2471068)

[redacted][42][redacted][43][redacted] The cursory notations contained in these files similarly provide no indication that Cardinal ever conducted any form of investigation to determine the legitimacy of the orders, as required under Vermont law.

107. In some cases, Cardinal responded to an order that exceeded a threshold by improperly and [redacted]

108. For example, in [redacted], Cardinal's monitoring system [redacted] Chittenden County, Vermont [redacted]

[42] CAH_MULTISTATE_0008706.
[43] CAH_MDL2804_00539890

[redacted]

[redacted][44] These notations are conclusory; they provide no indication of whether Cardinal contacted the pharmacy, received a response, or engaged in any other manner of investigation to ensure the legitimacy of the order or the need for a threshold increase, in violation of Cardinal's duty under the law.

109. In other instances, when an order would have exceeded a threshold, [redacted]

110. For example, [redacted] Rutland County, Vermont [redacted]

[44] CAH_MULTISTATE_0008706.

[redacted]

111. Cardinal's failure to report or sufficiently investigate these orders is particularly egregious considering this pharmacy's pattern of placing suspicious orders for controlled substances. [redacted]

112. [redacted][45] [redacted]

[45] CAH_MDL2804_00551310.

[redacted]

113. In some instances, Cardinal's failure to report suspicious orders resulted from [redacted] Vermon [redacted][46]

114. In all, an initial review of data derived from Cardinal's suspicious order monitoring system indicates that, [redacted]

3. Cardinal filled pharmacy orders for opioids after it had already identified related orders as suspicious.

115. On several occasions, Cardinal violated its duty under Vermont law by cancelling (also referred to as "cutting") an order that exceeded a threshold and allowing the pharmacy to place a subsequent, often smaller order for the same drug family (that would not trigger a threshold event). [redacted]

[46] CAH_MDL2804_02101802.

[redacted]

116. [redacted]

117. Cardinal engaged in this practice in Vermont. For example, [redacted] in Rutland County, Vermont [redacted]

4. Cardinal applied a different, even looser, set of rules to its chain pharmacy customers.

118. Cardinal did not independently investigate potentially suspicious orders by "chain pharmacies"—retail pharmacies owned by a common parent company and operating under the same name with multiple locations. Instead, when a chain pharmacy hit a threshold, Cardinal merely asked the chain pharmacy's corporate headquarters for an explanation. Cardinal relied

entirely on the corporate office's response, conducted no investigation of its own, and did not even make contact with the individual pharmacy in the chain that placed the potentially suspicious order.

119. Cardinal cannot abdicate its anti-diversion duties by delegating them to another player in the opioid distribution chain. To the contrary, Cardinal's duty to prevent diversion exists regardless of whether its customers are small, independent pharmacies or part of a large chain. As early as 2009, the DEA specifically admonished Cardinal for treating chain pharmacies differently from independent pharmacies. During a DEA review of Cardinal's Massachusetts distribution center, which ships prescription opioids into Vermont, Cardinal was unable to produce any diligence files for its chain pharmacy customers. When the DEA pressed Cardinal for the reason no diligence files existed for these pharmacies, Cardinal admitted that it was because the investigation of suspicious orders was delegated to the chain pharmacy's corporate headquarters and that Cardinal did not undertake any independent investigation of the conduct. The DEA told them at the time that "due diligence investigations must be performed on all customers, chain pharmacies included," and that those due diligence responsibilities included site visits.[47]

120. Since at least 2009 through approximately 2012, Cardinal continued to exempt its chain pharmacy customers from Cardinal's monitoring programs and instead relied on them to investigate and report their own suspicious activity. In doing so, Cardinal abdicated one of its core legal duties, and improperly relied on chain pharmacies to investigate and report their own suspicious activity—something that creates an obvious conflict and is improper on its face.

[47] Decl. of Joseph Rannazzisi, Deputy Administrator, DEA ¶ 59 (Feb. 10, 2012), filed in *Cardinal Health v. Holder*, 12-cv-00185-RBW (D.D.C.) (Dkt. No. 14-2).

121. In instances where a chain pharmacy placed an order that resulted in a threshold event, Cardinal's policy was **not** to conduct a site visit and **not** to contact the specific pharmacy that had placed the potentially-suspicious order. Instead, Cardinal's protocol was to contact only the corporate headquarters of the pharmacy chain and then permit the chain's headquarters to supply information about the held order without Cardinal taking steps to independently verify the information provided by the pharmacy's corporate headquarters.

122. Cardinal's internal policies even permitted **permanent threshold increases** for a specific pharmacy based solely on the explanation proffered provided by the pharmacy's corporate headquarters. Prior to May 14, 2012, Cardinal failed to conduct **any** site visits at any of its large chain pharmacy customers.

123. Cardinal's differential treatment of its chain pharmacy customers also extended to its new customer on-boarding process. Cardinal's on-boarding process for new, independent pharmacies included collecting a variety of "know your customer" data, including whether the pharmacy filled prescriptions for out-of-state patients, the pharmacy's expected usage for certain products, and whether there were local pain clinics in proximity to the pharmacy. In contrast, for new chain pharmacy customers, Cardinal collected only information about the chain's number of stores, anticipated drug usages, and internal diversion programs. Cardinal's failure to gather and maintain this know-your-customer data prevented it from being able to determine accurately whether orders placed at specific chain pharmacies might be suspicious or otherwise prone to diversion.

124. By employing a less rigorous onboarding process for chain pharmacies and by allowing its chain pharmacy customers to conduct their own suspicious order investigations,

Cardinal was able to appease its largest customers and continue shipping excessive quantities of opioids into Vermont without interruption.

C. McKesson designed a monitoring system that failed to monitor, identify, report, and prevent the fulfillment of suspicious orders.

125. As first referenced in Section II, McKesson failed to design an anti-diversion program to fulfill its obligations under Vermont law to detect, prevent, and report diversion. McKesson's anti-diversion program did not require adequate due diligence of new pharmacy customers; set artificially high thresholds based on poor data and metrics; proactively informed pharmacy customers of their thresholds to avoid investigations; and permitted threshold manipulation to support increased opioid sales.

126. In addition to its poor design, McKesson failed to even fully implement the inadequate components of its program, as discussed in Section D below. Consequently, McKesson's anti-diversion program, like Cardinal's, was both poorly designed and unenforced in practice.

1. Overview of McKesson's Controlled Substance Monitoring Program

127. In response to a 2008 settlement agreement with the DEA and DOJ, McKesson created an anti-diversion program called the Controlled Substance Monitoring Program ("CSMP"). McKesson's CSMP was supposed to implement the following components: (1) due diligence procedures for onboarding new pharmacy customers and monitoring existing customers; (2) maximum monthly threshold limits, or order limits, on the amount of prescription opioids available to pharmacy customers; (3) and a three-tiered investigatory and reporting process to identify and report suspicious orders of prescription opioids that exceeded these thresholds.

128. The CSMP's three-tiered investigatory procedures were supposed to be triggered by an order that exceeded a threshold. During the initial investigation of an excessive order, termed a Level 1 review, McKesson was supposed to contact the pharmacy customer to determine the reason for the excessive order, and conduct additional analysis and investigation, such as reviewing the pharmacy customer's sales patterns. If the Level 1 review indicated that the opioid order was "reasonable," the pharmacy could obtain approval for a threshold increase. If the Level 1 review was not "conclusive," the CSMP required two more levels of investigation by various McKesson personnel before deeming the order suspicious and reporting it to the DEA. **It was only after a Level 3 review that the order was deemed "suspicious" and was supposed to be reported to the DEA.**

129. To administer and oversee the CSMP in 2008, McKesson appointed one Director of Regulatory Affairs ("DRAs") for [redacted] The DRAs' duties included approving new pharmacy customers, approving threshold increase requests, and overseeing and conducting investigations of existing pharmacy customers.

130. Sales personnel and Distribution Center Managers were also charged with core anti-diversion responsibilities, including gathering information, conducting diligence investigations, and reporting suspicious activity, [redacted]

2. Due diligence policies for onboarding new pharmacy customers were facially inadequate.

131. Under the first component of the CSMP, McKesson was supposed to investigate new pharmacy customers before supplying them with prescription opioids. However, the design

of McKesson's customer onboarding procedures under the CSMP were inadequate to determine whether a pharmacy presented a risk of diversion.

132. First, McKesson's sales representatives, who had a financial incentive to [redacted] However, the questionnaire used by these sales representatives contains no [redacted] In addition, McKesson improperly [redacted]

133. McKesson also routinely failed to adhere to these procedures. For example, a [redacted]

134. McKesson's onboarding policies were even more lax for its largest chain pharmacy customers. In fact, the CSMP only requires an [redacted]

3. Unreasonably high threshold levels shielded McKesson from identifying and reporting suspicious orders.

135. The intended purpose of McKesson's threshold system, the second component of the CSMP, was to provide an "automatic block" to prevent pharmacy customers from obtaining opioids in an amount that exceeded their monthly limit. An order that exceeded the limit, and that was subsequently blocked, was sometimes termed a threshold event, [redacted] or "incursion" by McKesson. Under the CSMP, a pharmacy customer's order could be unblocked after it exceeded a threshold only if: (1) [redacted] (2) [redacted] or (3) [redacted] thereby allowing the pharmacy to once again start from zero and purchase up to the threshold limit.

136. Although thresholds were the cornerstone of the CSMP, from 2008 through 2013 McKesson routinely used improper metrics and set thresholds at artificially high levels. To assign thresholds in 2008, McKesson first calculated [redacted] Yet as discussed above, 2007 and 2008 were years that set records for opioid overprescribing. During the same time frame—in 2008—McKesson entered into an agreement with the DEA and DOJ to settle claims based on its failure to monitor and report suspicious orders across the country. Nevertheless, [redacted] On top of these inflated amounts, McKesson's threshold-setting procedures also [redacted]

Further, McKesson retained discretion to [redacted]

137. In addition, from at least [redacted] through [redacted], McKesson's thresholds did not [redacted]

138. These artificially high thresholds thwarted the CSMP's ability to monitor and identify suspicious orders in Vermont. For example, in [redacted] From [redacted] through [redacted] By consistently setting thresholds well above a pharmacy's typical monthly ordering quantity, pharmacies did not exceed their thresholds unless they ordered many multiples of prescription opioids over their monthly averages, and McKesson's pharmacy customers were able to place unusually large and suspicious orders without triggering any investigation or review.

139. Only after significant pressure from the DEA and DOJ in 2014 did McKesson begin implementing [redacted] demonstrating how inflated those pharmacies' previous thresholds had been. For example, [redacted]

[redacted]

140. Even after 2014, McKesson suggested that it continue using certain previous threshold metrics for its largest chain pharmacy customers. For example, in [redacted] [48]

4. McKesson's CSMP permitted advance warnings and inappropriate disclosures to pharmacy customers that they were approaching their monthly thresholds.

141. Although McKesson's CSMP mandated that [redacted] As one employee explained in designing this loophole, [redacted]

142. Similarly, McKesson wanted to provide assurances to pharmacy customers that the threshold system would not get in the way of sales. For example, McKesson employees discussed their concern about [redacted]

[48] MCK-AGMS-032-0003426.
[49] MCK-AGMS-035-0001696.

[redacted][50]

143. Unsurprisingly, this loophole was written directly into the CSMP manual, which noted that [redacted] The CSMP manual also stated [redacted][51]

144. McKesson permitted pharmacies to request a permanent or temporary increase in their thresholds to avoid a threshold event. This, combined with threshold warnings, enabled pharmacies to avoid having their orders blocked and allowed McKesson to evade investigatory and reporting requirements mandated by Vermont law.

145. McKesson even went so far as to [redacted]"[52] Such alerts were sometimes provided by [redacted][53]

146. In 2014, under pressure from renewed DEA and DOJ investigations, McKesson [redacted] To this day, however, [redacted]

[50] MCK-AGMS-041-0066750.
[51] MCK-AGMS-001-0000195.
[52] MCK-AGMS-032-0004671.
[53] MCK-AGMS-032-0004685.

[redacted] despite having made representations [redacted]

[redacted]

5. McKesson manipulated thresholds to support increased opioid sales.

147. When the CSMP was created, requests for threshold changes by pharmacy customers were supposed to be [redacted] However, in the face of ever-increasing prescription opioid sales, and as the opioid crisis ballooned, McKesson actively [redacted].

148. In order for a pharmacy to obtain a threshold increase, the CSMP required submission of a Threshold Change Request ("TCR") form. Threshold increases could be permanent or temporary. The completed TCR form was supposed to include a documented justification for the increase based on information gathered by McKesson sales personnel or Distribution Center Managers, [redacted]

149. However, the DRA responsible for Vermont and the Northeast region has admitted under oath that [redacted].[54] Another McKesson anti-diversion employee testified that [redacted]

[54] Deposition of Michael Oriente, July 19, 2018, MCK-AGMS-032-0003732, at 520-522.

[redacted][55]

150. The conflict of interest between sales and regulatory duties comes as no surprise, because [redacted][56] If McKesson blocked suspicious orders or stopped doing business with a pharmacy, sales employees would [redacted][57] [redacted]

151. Given this conflict of interest, thresholds were routinely and improperly [redacted] For example, McKesson's DRAs [redacted] In some instances, if a pharmacy called in to request a threshold increase after receiving [redacted]

[55] Deposition of Michael Bishop, January 9, 2019, MCK-AMGS-084-0000001, at 29.
[56] [redacted], MCK-AGMS-032-004738.
[57] Deposition of Michael Oriente, July 19, 2018, MCK-AGMS-032-0003732, at 158-160.

[redacted]

152. Information to justify threshold change requests was often merely collected [redacted]

153. McKesson also increased thresholds without appropriate justification and without adequate investigation. These problems were systemic. For example, from [redacted] through [redacted]

154. Although a particular pharmacy's [redacted] was not in and of itself a sufficient justification to increase thresholds in most cases, in one region [redacted] At one of the pharmacies for which [redacted]

[redacted][58]

155. Mirroring these systemic and nationwide problems, diligence records for pharmacies in Vermont [redacted] in Rutland County, Vermont [redacted][59] [redacted] Orleans County, Vermont [redacted][60]

156. McKesson personnel even took it upon themselves to initiate threshold increases without waiting for pharmacies to make the request—and then failed to file any documentation at all. In one alarming example, [redacted]

157. In another example, [redacted]

[58] [redacted] MCK-AGMS-019-0005802.
[59] MCK-AGMS-066-0000177.
[60] MCK-AGMS-066-0000226.

[redacted][61]

158. Notably, preemptive threshold increases were often granted [redacted]

159. In yet another example, [redacted]. In justifying this broad increase, one McKesson employee suggested that McKesson [redacted]. In response, McKesson employees improperly [redacted]

160. McKesson personnel also improperly [redacted]

161. The result of McKesson's poorly designed threshold change system was evident in Vermont. A sample of pharmacies investigated by the State shows [redacted]

[61] MCK-AGMS-032-0003383 at 12.

162. These practices should have stopped in [redacted]

163. The threshold system, touted as the cornerstone of McKesson's 2008 CSMP, thus, never served its purpose. McKesson did not "set" and then "maintain" thresholds. The thresholds did not meaningfully restrict McKesson's customers from obtaining opioid drugs, but instead were used to accommodate whatever pharmacy customers wanted to purchase, or they were set so high that they never triggered any review.

164. The result was a consistent pattern of excessive opioid sales in Vermont. For example, [redacted], McKesson shipped approximately [redacted] opioid pills to a pharmacy in [redacted] Similarly, McKesson shipped [redacted] opioid pills to another pharmacy in [redacted] In 2011 McKesson shipped approximately [redacted] opioid pills to [redacted]

D. McKesson failed to adhere to the terms of its anti-diversion program.

165. In addition to its failure to design an effective anti-diversion program, McKesson also systemically failed to implement the flawed components of the CSMP in Vermont and

nationwide. McKesson consistently understaffed its anti-diversion department, inhibiting its ability to carry out diligent investigations of its opioid drug pharmacy customers; failed to report or otherwise diligently investigate all orders that exceeded a set threshold; and allowed large chain pharmacies to conduct their own diligence investigations and police themselves with little to no oversight by McKesson.

1. McKesson understaffed and undertrained its anti-diversion department.

166. DRAs were the only [redacted] responsible for [redacted] In one region, a DRA was responsible for [redacted] Given that volume, the DRA [redacted] At this rate, it would take [redacted] years to complete a single visit to each of the pharmacies for which the DRA was responsible. This understaffing occurred despite the fact that McKesson knew or should have known that the [redacted]

167. In addition to this understaffing, neither full-time anti-diversion personnel nor front-line sales employees [redacted] One sales employee [redacted] Similarly, a former McKesson employee stated that even after [redacted] of working in the Regulatory Affairs Department he did not have [redacted]

[redacted][62] did not recall [redacted], did not understand the [redacted], and stated [redacted][63]

168. While McKesson incentivized sales personnel to increase sales, little or no effort was focused on [redacted]

2. McKesson failed to conduct investigations of suspicious orders to detect and prevent diversion.

169. As discussed in Section II.C.1., the CSMP implemented a three-tiered investigatory process that was supposed to identify orders that were suspicious and facilitate reporting to the DEA but consistently failed to do so. In practice, however, McKesson conducted some investigations into orders that exceeded threshold limits, termed Level 1 reviews, in name only and failed to follow even the low bar required by the CSMP. Instead, McKesson often used threshold events as an opportunity to [redacted].

170. Critically, Level 1 Reviews did not [redacted] In the North East region, which included Vermont, [redacted] In other

[62] Deposition of Michael Bishop, January 9, 2019, MCK-AMGS-084-0000001, at 18-20.
[63] Deposition of Michael Bishop, January 9, 2019, MCK-AMGS-084-0000001, at 21; 62; 109.

instances, [redacted]

For example, when a threshold event triggered a Level 1 review for a pharmacy [redacted]

[redacted].[64]

171. McKesson's employees were also left to [redacted] McKesson also failed to standardize the interview questions for pharmacy site visits and interviews. One DRA noted that he created his own [redacted] Despite directing employees to consider various red flags, McKesson had no standard policy or practice for evaluating red flags. And deciding whether to stop supplying a pharmacy with opioid drugs, or to escalate a review to Level 2 or 3, was largely left to the discretion of [redacted]

172. An internal McKesson audit from [redacted] confirmed [redacted] The audit also found [redacted] In

[64] MCK-AGMS-032-0004751.

many cases, [redacted]

173. These were not isolated incidents, but rather part of a systemic and nationwide problem. [redacted][65]

174. In a [redacted][66]

175. A pharmacy in rural [redacted], Vermont, provides yet another example of McKesson's failure to conduct investigations in response to orders that exceeded thresholds. McKesson documents indicate that this pharmacy had a remarkable history of [redacted] While this deluge of threshold events in and of itself should have triggered a careful investigation of the pharmacy's business practices, there is no [redacted] In fact, there are no [redacted]

[65] MCK-AGMS-076-0000319.
[66] MCK-AGMS-035-0001600 at 2.

[redacted]

176. In some instances, the [redacted] In response, McKesson personnel [redacted] For these instances, McKesson's sample regulatory files contain no indication that McKesson [redacted]

177. As a result of its systematic failure to conduct diligent investigations of threshold events, and in violation of its duty, McKesson failed [redacted] Despite all this, McKesson continued [redacted]

3. McKesson failed to report flagged orders and shipped orders without conducting a diligent investigation.

178. McKesson already has admitted that it failed to report all the suspicious orders that it should have to the DEA. For example, in its 2017 settlement agreement with the DEA and DOJ, McKesson acknowledged that suspicious orders did not get flagged in the system and it did not identify and report all the suspicious orders it should have between 2008 and 2014.

179. McKesson also failed to report and block orders in Vermont. During a similar time period, from [redacted] despite profiting from and shipping approximately [redacted] prescription opioid pills into Vermont during that period. For example, [redacted]

[redacted] Franklin County, Vermont [redacted]

180. Three months later, [redacted] Vermont pharmacy [redacted] Vermont [redacted].

181. Such practices were not limited to Vermont—they were a symptom of McKesson's systemic anti-diversion failures. Often McKesson failed to report any suspicious orders until [redacted]. Only after the DEA [redacted]

182. In [redacted]

[redacted]

[redacted] clear red flags for the presence of diversion. Although it had never previously reported a suspicious order from the [redacted] McKesson claimed [redacted] it failed to [redacted]

183. Further demonstrating its systemic problems, McKesson also failed to [redacted] In addition to the exponential threshold increases [redacted] The owner of this pharmacy and dozens of other participants were later convicted on charges related to a drug trafficking conspiracy.

184. McKesson failed to block or report orders that represented significant multiples of the average monthly orders [redacted]

185. Overall, between [redacted] and [redacted] McKesson failed to [redacted] Because of McKesson's poor implementation of its already inadequately-designed CSMP, McKesson failed to identify, report, and prevent shipment of suspicious orders, as required under Vermont law.

4. McKesson applied a different, even looser, set of rules to its chain pharmacy customers.

186. McKesson wholly abdicated its responsibility to investigate threshold events triggered by orders from its large chain pharmacy customers, in violation of its duties under Vermont law. McKesson's pharmacy customers were typically divided into ISM (independent/small/medium size) and larger chains identified as "RNAs" (Retail National Accounts). When an ISM pharmacy exceeded a threshold, [redacted] However, if a Retail National Account pharmacy did the same, McKesson [redacted]

187. McKesson relied on the corporate offices of the Retail National Accounts to conduct their own due diligence, despite a pattern that the pharmacy chains were violating their duties under federal law. For example, McKesson engaged in this conduct for one Retail National Account that was one of the largest chains serviced by McKesson in Vermont and had a significant history of settlements related to alleged violations of the Controlled Substance Act (CSA) settlements. In 2009, this chain agreed to pay $5 million in civil penalties to settle allegations of violations of the CSA, violations alleged to have occurred in several states from New York to California. This chain entered into another settlement in 2017, agreeing to pay

$834,200 to resolve allegations arising from an investigation in Los Angeles, California. And in late 2018, the chain entered into yet another settlement, agreeing to pay a $300,000 penalty for filling prescriptions at Rhode Island pharmacies over the maximum allowed under state law.

188. This chain has a significant foothold in the Vermont retail pharmacy marketplace: at least 51 individual DEA registration numbers associated with its pharmacies in Vermont with more than 145,000 transactions with these pharmacies from 2014-2018 alone. McKesson's abandonment of its duty allowed McKesson to both maintain profitable business relationships with large chain customers and continue shipping massive quantities of prescription opioids into Vermont without interruption.

189. McKesson's uniform policy of special treatment for chain pharmacies was also evident [redacted][67] McKesson also approved permanent bulk threshold change requests to chains without appropriate reasons or documentation. A permanent threshold increase was provided to [redacted][68] In yet another example, McKesson [redacted]

[67] MCK-AGMS-041-0066748.
[68] MCK-AGMS-032-0004722.

III. Cardinal and McKesson Unfairly and Deceptively Promoted Opioids by Spreading Opioid Manufacturers' Misleading Marketing to Pharmacies and Consumers.

190. Cardinal's and McKesson's contributions to the opioid epidemic are not limited to their escalating sales and failure to design and implement policies that effectively prevented diversion. Defendants' internal documents confirm that they actively marketed prescription opioids to prescribers and pharmacists. Through these marketing activities, they built upon, reinforced, and profited from the drug manufacturers' campaign to deceive healthcare providers about the risks and benefits of prescription opioid use—a campaign that encouraged and normalized over-prescribing and over-dispensing of prescription opioids.

191. Cardinal's and McKesson's promotion and marketing of prescription opioids constitutes an unfair business practice, in the context of their legal duties as licensed distributors of controlled substances and their failure to implement adequate systems to detect, prevent, and report diversion. Their marketing of prescription opioids ranged from [redacted]—to [redacted], disseminated through marketing channels over which they had unique control, as well as promotion and/or administration of prescription savings card programs designed to encourage initiation and long-term use of branded prescription opioids. Through these marketing activities, Cardinal and McKesson built upon and reinforced the opioid manufacturers' deceptive, misleading, and highly successful marketing campaign to promote prescription opioid use.

192. Cardinal's and McKesson's roles in marketing prescription opioids were at odds with their core responsibilities as licensed distributors of controlled substances. These marketing efforts were intended to increase opioid sales, which would thereby increase the supply of

opioids in the community and increase abuse and diversion, further undermining Defendants' already insufficient diversion prevention systems.

193. Cardinal and McKesson profited in two ways from their marketing activities: (1) they were paid by the drug manufacturers to promote their prescription opioids, and/or (2) they were paid from increases in pharmacy drug sales that resulted from these marketing efforts.

194. Defendants focused their marketing efforts on pharmacists because they knew—as did the opioid manufacturers—that pharmacists, as the last healthcare professionals to see patients before medication is dispensed, occupy a unique position of influence over both prescribers and consumers. Particularly over the last few decades, the typical pharmacist's role has evolved from rote dispensing of prescriptions to actively advising on drug therapies.[69]

195. In a 2010 survey by the National Community Pharmacists Association ("NCPA"), pharmacists reported interacting with other health care professionals regarding patients' drug therapy an average of 7.1 times per day. Eighty-one percent of the surveyed pharmacists reported recommending changes to patients' drug regimens, with physicians accepting 73% of those recommendations. Nearly all (93%) of the surveyed pharmacists reported, for example, recommending changes from branded to generic drugs, with physicians accepting 80% of those recommendations.[70]

196. Cardinal expressly acknowledged [redacted]. One Cardinal marketing proposal emphasized to an opioid manufacturer client that [redacted]

[69] https://www.pharmacytimes.com/publications/issue/2015/october2015/the-pharmacists-expanded-role
[70] https://www.pharmacytimes.com/publications/issue/2012/january2012/strong-pharmacy-entrepreneurs-make-for-a-strong-profession

[redacted] Cardinal's proposal advised the drug company that "[redacted][71]

197. Opioid manufacturers that used Defendants' marketing services also knew that pharmacists are key to ensuring that prescriptions are converted to sales. Purdue, for example, asserted in a [redacted][72] In 2015, when Purdue launched its extended-release hydrocodone product, Hysingla, it [redacted][73] Purdue also noted that [redacted][74]

198. Purdue and other manufacturers worked hand-in-glove with Defendants to promote their products—through the distributors—to pharmacies and pharmacists. For example, [redacted]

199. The targeting of pharmacists by Cardinal and McKesson in their marketing activities was particularly problematic because of Cardinal's and McKesson's existing and often long-term business relationships with pharmacies—with whom Defendants shared a legal responsibility to prevent diversion. Opioid distributors, like Defendants, were in a unique and trusted position in the controlled substances supply chain from which they could have spoken

[71] CAH_MDL2804_02879120.
[72] PWG00062629.
[73] PWG000362181.
[74] PWG000362181.

truthfully to their pharmacy customers about the serious risks posed by opioids (including the risk of diversion). They could have remained silent about the benefits and risks of opioids, and simply filled orders and shipped drugs. Instead, Cardinal and McKesson abused their unique position for profit, by contributing to the chorus of deception surrounding opioids.

200. To engage in the promotion of controlled substances at all, under the circumstances detailed in this Complaint, was a dereliction of Defendants' duties to prevent opioid diversion. Through these marketing activities, Defendants contributed to and reinforced the deceptive and misleading marketing messages that healthcare providers received about opioids through other channels. Moreover, much of the Defendants' marketing content was deceptive, because it either affirmatively misrepresented the benefits and risks of prescription opioids, or it omitted important information about the risks of prescription opioids. Both Cardinal and McKesson knew or should have known that these marketing messages—particularly those that misrepresented or omitted material information about the potential for diversion or risks of addiction associated with prescription opioids—were deceptive. Through their unfair and deceptive conduct, Defendants put Vermont consumers at increased risk of harm from the escalating and largely unchecked distribution and sale of prescription opioids, increased availability and diversion of opioids to non-medical use in Vermont, and increased misuse and addiction that has created an epidemic of health problems, overdose, and death in Vermont.

A. Cardinal unfairly and deceptively marketed opioids.

201. Cardinal has actively sought to increase the sale of opioids in Vermont by marketing these dangerous and addictive drugs to pharmacists and prescribers, and even directly to consumers, contrary to its public claim that it merely serves as a secure delivery service for transporting medications from warehouse to pharmacy. Cardinal not only offers marketing

services to its drug manufacturer clients, it incentivizes and encourages manufacturers to use these marketing channels as a way of building their business and increasing sales of prescription opioids.

202. Increased drug sales benefit Cardinal. [redacted]

203. Through Cardinal's marketing programs, it disseminated the drug manufacturers' promotional messages about opioids nationally and, upon information and belief, into Vermont. These marketing activities constituted an unfair business practice, under the circumstances detailed in this Complaint.

204. Cardinal offers a range of marketing services to its drug manufacturer clients. [redacted] For many manufacturers, the cost of Cardinal's marketing services is [redacted][75] [redacted]

[75] CAH_MDL2804_002893641.

[redacted]

205. [redacted]

[redacted]

206. [redacted]

[redacted] A year later, Purdue and three of its current and former executives pled guilty to federal criminal charges connected to their misleading marketing of OxyContin, paying $600 million in fines and other payments. [redacted]

207. As another example, [redacted]

[redacted] By late 2013, INSYS had publicly announced that it was under federal investigation and had received a subpoena from the U.S. Department of Health and Human Services inquiring into INSYS's sales and marketing practices relating to SUBSYS. [redacted]

208. From at least 2010 to 2017, Cardinal's marketing team routinely [redacted]

209. Cardinal did not simply [redacted], it also [redacted]

210. Cardinal's marketing programs were not [redacted]

1. Cardinal engaged in an unfair business practice by marketing prescription opioids through a variety of marketing programs.

211. Cardinal worked to increase sales of opioids through a range of in-house marketing platforms directed at prescribers, pharmacists, and consumers, implemented nationally

and, on information and belief, in Vermont. These marketing activities constituted an unfair business practice, under the circumstances detailed in this Complaint.

212. ***Direct-to-Consumer Marketing.*** Cardinal markets drugs directly to consumers through [redacted] Cardinal describes this program, [redacted][76]

213. There is ample evidence that this type of marketing is effective. A 2014 audience-research study conducted by Nielsen found 74% of PHN viewers indicated advertisements are more believable when viewed in a pharmacy; 49% of viewers surveyed indicated that they felt encouraged to discuss a product or brand they had seen on the network with their pharmacist; 48% indicated that after seeing advertisements on PHN, they felt motivated to discuss those products or brands with their physicians; and 13% of consumers who have seen advertisements on PHN have purchased those products or brands.[77]

214. As John Disher, Cardinal's Senior Manager for Marketing and Business Development, said in 2014: "This study again confirms that consumers consider advertising messages on Pharmacy Health Network to be informative and highly credible, and that ads on our network drive action, by encouraging consumers to talk with their pharmacists and physicians about products they see on our network … As our network continues to receive a

[76] CAH_MULTISTATE_0013372.
[77] *Nielson Study Confirms Ads on Cardinal Health's Retail Pharmacy Digital Advertising Network Motivate Consumers to Discuss, Purchase Products* (March 17, 2014), https://digitalsignagefederation.wildapricot.org/widget/memberpress/1520048.

positive response from advertisers and consumers alike, we look forward to expanding the number of stores and advertisers that participate in the program.[78]

215. In fact, additional studies show that, as of November 2015, Cardinal's PHN was proven to increase sales of advertised products.[79]

216. Although it is currently unknown to the State whether opioid advertisements were run [redacted][80] [redacted][81]

217. ***Direct Mail Marketing.*** Cardinal utilizes [redacted]

218. Cardinal charges [redacted]

219. ***Email Marketing.*** Cardinal also [redacted]

[78] *Id.* (emphasis added).
[79] Respario, *Case Study: Cardinal Health Engages Retail Pharmacy Customers Through Digital Signage Network* (November 2015), http://respario.com/wp-content/uploads/2015/11/respario-case-study-cardinalhealth.pdf.
[80] CAH_MDL2804_01296417.
[81] CAH_MDL2804_00134274.

220. [redacted]

221. Cardinal claims that through [redacted] Cardinal specifically promotes its ability to [redacted] In its own words, Cardinal advertises that its "commercial team helps to position [a manufacturer's] product for success by identifying physicians who treat unique patient populations, understanding prescriber behavior and driving engagement."

222. From 2010 through at least 2015, Cardinal used [redacted] [82]

223. From at least 2012 through 2017, Cardinal frequently used [redacted] [83]

[82] [redacted]

[85] [redacted]

224. ***Marketing in Customer Newsletters.*** Cardinal also offers opioid marketing through [redacted]

225. [redacted]

226. Drug manufacturers can purchase [redacted]

227. Cardinal used [redacted] including pharmacists in Vermont, from at least 2009 through 2017.[84]

228. ***Telemarketing.*** Cardinal offers its manufacturer clients the option of purchasing [redacted]

[redacted]

[84] [redacted]

229. One telemarketing script [redacted][86]

230. ***Advertisements on Ordering Platform.*** Cardinal also runs drug advertisements on [redacted]

231. Cardinal offers drug manufacturers the options of [redacted]

[85] Controlled substances—including opioids—are divided into Schedules, depending on their potential for abuse. Schedule III drugs have a potential for abuse that is lower than drugs in Schedules I and II, and abuse of these drugs may lead to moderate or low physical dependence or high psychological dependence.

[86] [redacted]

[redacted]

232. [redacted][87] [redacted]

[redacted][88]

233. ***Pharmacy Rebates.*** Cardinal further encourages purchases of opioids through its [redacted]

234. [redacted]

[redacted][89]

[87] CAH_MDL2804_00134788.

[88] [redacted]

[89] [redacted]

235. ***Auto-Shipments.*** Through its "[redacted]" program, Cardinal [redacted]

236. [redacted]

2. Cardinal deceptively marketed opioids.

237. In addition to being an unfair business practice, some of Cardinal's marketing content was also deceptive. These marketing messages—like other opioid marketing messages disseminated in the medical community by opioid manufacturers—contained deceptive statements about the benefits of particular opioids or misleading omissions about the serious risks associated with them.

238. Cardinal's deceptive and misleading marketing of opioids contributed to—and built upon—the deceptions that drug manufacturers were disseminating through other channels.

239. Cardinal disseminated certain opioid advertisements that contained deceptive statements regarding the risk of addiction, abuse, and diversion posed by these drugs. For example, [redacted][91] This

[redacted]

[90] Schedule II controlled substances are so-categorized because they have a high potential for abuse, which may lead to severe psychological and physical dependence.
[91] CAH_MDL2804_02957392.

advertisement was sent to [redacted][92]

240. Moreover, many of Cardinal's opioid advertisements failed to disclose the serious risks associated with opioids or to provide "fair balance" in their representation of the risks and benefits of the drugs. For example, [redacted][93] [redacted] Likewise, Cardinal disseminated advertisements promoting opioids without mentioning any of the drugs' risks—providing, at most, [redacted] These advertisements failed to provide "fair balance" and had material omissions, which rendered them misleading to their intended recipients, in violation of the Consumer Protection Act.

241. Cardinal disseminated advertisements that were not clearly labeled as paid advertising content and would reasonably have been mistaken by Cardinal's pharmacy customers as neutral informational content provided by Cardinal.

[92] CAH_MDL2804_02955823.
[93] CAH_MDL2804_02955979.

242. Through these and other advertisements, Cardinal took advantage of its unique position of trust as a distributor of controlled substances to promote opioids in deceptive and misleading ways. Cardinal knew or should have known that these advertisements—particularly those that misrepresented the risk of diversion for, or addictive potential of, prescription opioids—were deceptive, because of its own heightened duties, as a distributor, when handling controlled substances. Moreover, when engaging in pharmaceutical marketing, Cardinal knew or should have known about the attendant legal obligations, including the obligation to provide "fair balance" and adequately disclose the risks associated with the drugs it was promoting.

B. McKesson unfairly and deceptively marketed opioids nationally and in Vermont.

243. McKesson actively sought to increase the sale of opioids by assisting manufacturers in marketing these dangerous, addictive, and misuse- and abuse-prone drugs.

1. McKesson engaged in an unfair business practice by marketing prescription opioids.

244. McKesson's marketing programs disseminated drug manufacturers' promotional messages about opioids nationally and, upon information and belief, into Vermont. These marketing activities constituted an unfair business practice, under the circumstances detailed in this Complaint.

245. McKesson claims to have had a policy of not [redacted] Despite that policy, [redacted], McKesson's marketing team identified [redacted]

246. [redacted]

[redacted][94]

247. ***Auto-Shipments.*** Specifically, McKesson promoted prescription opioids through its [redacted] program. This marketing program identified [redacted]

248. McKesson described [redacted]

(emphasis in the original).[95]

249. The prescription opioids McKesson promoted and auto-shipped (including to Vermont pharmacies) through [redacted] include the following:

Opioid	Manufacturer	Approximate Date[96]
[redacted]	[redacted]	[redacted]

250. McKesson charged manufacturers $[redacted] program. McKesson eventually [redacted]

[94] MCKAGMS-069-0000020.
[95] MCK-AGMS-019-0008109, -8171; MCK-AGMS-038-0000040.
[96] All dates in this table reflect implementation dates.

[redacted]

[redacted][97] [redacted], McKesson lamented that it would [redacted] and would need to [redacted][98]

251. ***Email Marketing.*** McKesson also promoted opioids through the [redacted] program, which sent [redacted] McKesson described [redacted] McKesson promoted [redacted][99]

252. The prescription opioids that McKesson marketed through [redacted] include the following:

Opioid	Manufacturer	Approximate Date[100]
[redacted]	[redacted]	[redacted]

253. McKesson charged manufacturers between $[redacted] $[redacted] [redacted]

254. ***Fax Marketing.*** McKesson promoted opioids through its [redacted] program, which sent [redacted] McKesson described [redacted] as having the ability to distribute [redacted]

255. The prescription opioids that McKesson promoted through [redacted] include the following:

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[97] MCK-AGMS-069-0002800.
[98] MCK-AGMS-069-0002796.
[99] MCK-AGMS-019-0008143; MCK-AGMS-019-0008201.
[100] The dates in this table reflect the implementation date or, if unavailable, the date the marketing agreement was executed.

Opioid	Manufacturer	Approximate Date[101]
[redacted]	[redacted]	[redacted]

256. McKesson charged manufacturers between $[redacted] $[redacted] campaign.

257. ***Advertisements on Ordering Platform.*** McKesson [redacted] McKesson touted [redacted] McKesson boasted that more than [redacted] of its pharmacy customers accessed [redacted] and [redacted] of its independent pharmacy customers accessed the portal [redacted]

258. The prescription opioids that McKesson promoted through [redacted] include the following:

Opioid	Manufacturer	Approximate Date[102]
[redacted]	[redacted]	[redacted]

259. McKesson charged between $[redacted] $[redacted] per [redacted] on [redacted].

260. ***Direct Mail Marketing.*** Lastly, McKesson used its [redacted] program to promote opioids [redacted] McKesson promoted [redacted]

[101] All dates in this table reflect implementation dates.
[102] The dates in this table reflect the implementation date or, if unavailable, the date the marketing agreement was executed.

[redacted]

261. McKesson used the [redacted] program to promote opioids. For example, in January 2012, McKesson [redacted] nationally. According to the agreement between McKesson and [redacted], the estimated cost for [redacted].

262. [redacted] Calling it a [redacted] McKesson offered its [redacted] to provide a way for pharmacists to [redacted][103] [redacted] [redacted][104]

263. Through the program, [redacted]

264. As part of the program, [redacted][105] [redacted] [redacted][106]

[103] MCK-AGMS-069-0003449.
[104] MCK-AGMS-069-0000108.
[105] MCK-AGMS-028-0080256.
[106] MCK-AGMS-028-0083903.

265. McKesson touted the [redacted] as a proven way to [redacted] [107]

266. [redacted] [108]

2. McKesson deceptively marketed opioids.

267. In addition to being an unfair business practice, some of McKesson's marketing content was also deceptive. The opioid advertisements that McKesson disseminated were deceptive and misleading because they failed to disclose the serious risks of addiction, abuse, and diversion associated with opioids. The advertisements failed to provide fair balance of the risks and benefits of opioid use.

268. McKesson's deceptive and misleading marketing of opioids contributed to—and built upon—the deceptions that drug manufacturers were disseminating through other channels.

269. For example, McKesson distributed a [redacted] advertisement to [redacted] The advertisement emphasized that [redacted]

[107] MCK-AGMS-028-0073543.
[108] PVT0001185.

[redacted] (emphasis in original).[109] Yet nowhere does the advertisement mention the risk for addiction and dependence from the opioid ingredient in the drug.

270. McKesson disseminated other advertisements [redacted]

271. Finally, in [redacted] Purdue's now-defunct website, TeamAgainstOpioidAbuse.com. [redacted] a Purdue website that is known to have spread misleading information regarding the effectiveness of abuse-deterrent properties of certain opioid formulations.

272. Through these and other advertisements, McKesson took advantage of its unique position of trust, as a distributor of controlled substances, to promote opioids in deceptive ways. McKesson knew or should have known that these advertisements—particularly those that misrepresented the risk of diversion for, or addictive potential of, prescription opioids—were deceptive, because of its own heightened duties, as a distributor, when handling controlled substances. Moreover, when engaging in pharmaceutical marketing, McKesson knew or should have known about the attendant legal obligations, including the obligation to provide "fair balance" and adequately disclose the risks associated with the drugs it was promoting.

C. Cardinal and McKesson helped to initiate and facilitate long-term opioid use by disseminating prescription savings cards for these drugs.

273. Cardinal and McKesson also engaged in an unfair business practice by promoting—and in McKesson's case, administering—prescription savings card programs, which encouraged and supported both initiation and long-term use of prescription opioids.

[109] MCK-AGMS-038-0000008; *see also* MCK-AMGS-038-0000006, -7.

274. Opioid manufacturers drive initiation and long-term use of their drugs through the distribution of promotional prescription "savings cards" (a/k/a prescription "discount cards") to consumers. Savings cards reduce or eliminate the out-of-pocket cost of these drugs, thus reducing or eliminating any financial obstacles to initiating or continuing long-term treatment with expensive, brand-name drugs—including brand-name opioids.

275. Cardinal promoted and disseminated savings cards through [redacted] for opioids [redacted]:

Opioid	Manufacturer	Savings Card Offer	Approx. Year
[redacted]	[redacted]	[redacted]	[redacted]

276. McKesson administers [redacted] McKesson runs [redacted] A patient may redeem the discount at the point of sale (i.e., a pharmacy) and receive the manufacturer's pre-determined discount off the purchase price of the medication. The

pharmacy submits claims to McKesson for the difference; McKesson reimburses the pharmacy; and then McKesson submits those claims to the drug manufacturer for reimbursement.

277. An affiliate of McKesson, [redacted], also administers a similar program, [redacted], eliminating the need for patients and pharmacists to submit claims to or through McKesson for reimbursement.

278. In promoting its [redacted][110]

279. The opioids that McKesson promoted through savings-card programs include the following:

Opioid	Manufacturer	Savings Card Offer	Approx. Year
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

280. The savings cards that Defendants promoted and disseminated were intended to—and did—encourage patients to initiate and stay on long-term opioid therapy by making it easier

[110] MCK-AGMS-069-0000091 to -107.

and cheaper to access prescription opioids, even though there are **no studies demonstrating the safety or efficacy of long-term opioid use beyond 12 weeks**. In other words, Defendants' savings cards facilitated long-term use of the drugs, well beyond the duration of treatment for which there was scientific support.

IV. The Foreseeable Consequences of Defendants' Conduct Include Increased Opioid Misuse, Addiction, Diversion, Overdose, and Death in Vermont Communities.

281. Vermont—like many other states—saw an explosion in opioid prescribing between 1996 and 2008 that has fueled an escalating public health crisis of opioid overuse, misuse, and abuse over the last decade. The effects of this crisis are reverberating through Vermont to this day and are expected to continue for decades. One recently-published analysis concluded that, under the status quo, the number of opioid overdose deaths nationwide is projected to increase from 33,100 per year in 2015 to 81,700 deaths per year by 2025.[111]

282. Despite increased public awareness surrounding the dangers of opioid use and Vermont's own extensive and nationally recognized efforts to reduce overprescribing and to prevent and treat opioid abuse and addiction, opioid sales only began to meaningfully decline in the State very recently, after nearly two decades of unacceptably and unnecessarily high prescribing levels. In 2010, for example, 482,572 opioid prescriptions were dispensed in Vermont, a state with a population of just over 625,000.[112] In 2015, the number of opioid

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[111] Chen, Qiushi, *et al., Prevention of Prescription Opioid Misuse and Projected Overdose Deaths in the United States*, JAMA Network Open, Feb. 1, 2019.

[112] Anne VanDonsel, Shayla Livingston, and John Searles (Vermont Department of Health), *Opioids in Vermont: Prevalence, Risk, and Impact* (October 27, 2016), http://www healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Prevalence_Risk_Impact.pdf, at 30 ("Number of Prescriptions by Drug Type and Year"); Vermont Department of Health, *Special Report: Opioid Prescriptions and Benzodiazepines, 2014* (February 2016), http://www healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Benzodiazepenes_Report.pdf, at 3.

prescriptions increased to 498,973[113]—the equivalent of giving a prescription to every 1.3 people living in Vermont, including infants.

283. These high levels of prescription opioid sales reflect more than legitimate medical use. Increased sales and availability of these drugs in Vermont communities have been accompanied by increased abuse and diversion, leading many Vermonters to misuse opioids, to become addicted to them, and to escalate to the use of heroin and fentanyl. These patterns have led to overdoses and premature death.

284. Increased rates of prescription opioid diversion—and the serious public health consequences—were foreseeable consequences of the Defendants' promotion of these opioids and their failure to implement effective systems to detect and prevent diversion of these dangerous drugs.

A. Prescription opioid diversion is widespread in Vermont.

285. Prescription opioids are diverted away from legitimate medical channels in several ways. Some prescription drugs are stolen from warehouses and pharmacies. Some are prescribed to persons posing as medical patients, who then sell the pills to illegal dealers. But the vast majority of people who misuse prescription opioids obtain their drugs (1) from friends or family members, or (2) through their own prescriptions. This means that, for most people who misuse opioids, the source of their drugs can typically be found in the excess supply of drugs in the community, beyond what is needed for legitimate medical purposes.

286. More than twenty years ago, when the prescription and sale of opioids were limited to a narrow set of patients who suffered from severe medical conditions and had close oversight from treating physicians—who had been educated to understand that opioids were dangerous and addictive, and should be prescribed in relatively narrow circumstances—there

[113] *Id.*

was little or no excess supply of prescription opioids in communities available for misuse. But when Purdue Pharma introduced its extended-release oxycodone formulation branded as OxyContin ER in 1996, the company launched a massive marketing campaign that changed the landscape of opioid prescribing and over-use for decades to follow. Prescription opioid diversion became a serious problem as over-prescribing rose for less serious conditions—both acute and chronic—and physician oversight and vigilance decreased. This change in culture was driven by aggressive marketing of these drugs—not only by the manufacturers, but also, as it turns out, by distributors like Cardinal and McKesson. As a result of this marketing, and the resulting shift in the medical consensus around opioid prescribing, it became common for healthcare providers to prescribe opioids for long-term conditions like chronic lower-back pain, minor injuries like sprains, and post-surgical pain from minor procedures, like removal of wisdom teeth. The supply of opioids available in communities across Vermont and the United States ballooned.

287. By 2002 to 2003, more than 5% of Vermonters had **misused** prescription pain relievers in the preceding twelve months. Opioid misuse was particularly prevalent among young people: in 2005 to 2006, for example, an estimated 7% of teens (ages 12-17) and 15% of young adults (ages 18-25) had misused prescription pain relievers in the preceding year.

288. These numbers remained consistently high for nearly a decade. In 2010 and 2011, it was still the case that more than 5% of all Vermonters—roughly 30,000 people—had misused prescription opioids within the prior twelve months.

289. Since then, through increased awareness, regulatory efforts, and addiction treatment, the rate of prescription opioid misuse in Vermont has begun to decrease—but not by enough. Many Vermonters still struggle with prescription opioid abuse and addiction, and many have escalated to abuse of heroin and other illicit opiates.

B. Defendants knew or should have known that inappropriately high levels of opioid sales would lead to increased diversion and harm to public health.

290. Because of their place in the closed system of prescription drug distribution and their significant market share, Cardinal and McKesson were in a unique position to see that an epidemic of prescription opioid overprescribing and diversion was unfolding.

291. Defendants tracked news coverage of the opioid epidemic as early as [redacted] [114] [redacted] [115]

292. [redacted], discussing an FDA proposal intended to reduce the misuse and abuse of long-acting painkillers like OxyContin. [redacted]

[114] Deposition of Nicholas B. Rausch, Nov. 16, 2018, CAH_MULTISTATE_0017218, at 28:10-15.
[115] Deposition of Mark Hartman, Nov. 15, 2018, CAH_MULTISTATE_0016766, at 320:21-322:8.

293. Cardinal personnel continued [redacted][116]

294. [redacted][117]

295. Cardinal also knew about the devastating effects that the opioid crisis was having in Vermont in particular. [redacted]

296. [redacted]

[116] CAH_MDL2804_01103324
[117] CAH_MDL2804_03171557-03171563 [redacted] CAH_MDL2804_03179982 (article stating: [redacted]

[redacted]

297. Cardinal also tracked and circulated articles internally about the abuse and diversion of specific drugs. [redacted]

298. Both Defendants were aware of Vermont's efforts to restrict prescribing of certain high-risk drugs. For example, in 2014, Vermont put prescribing restrictions in place for Zohydro ER, a hydrocodone drug, only permitting physicians to prescribe Zohydro if they could document that other avenues for treatment had been ineffective for the patient. [redacted] McKesson—which was also a member of HDA, and would presumably have received the same information—continued to promote [redacted]

299. As for McKesson, the company knew of the opioid epidemic as early as 2001. The company admitted [redacted]

300. Later, in August 2013, McKesson [redacted][118][redacted]

301. Defendants also utilized sophisticated data visualization and analysis to track exactly how many opioids were being prescribed and sold in every geographic area they serviced, thereby making Defendants aware of the scope of the opioid epidemic and the flow of opioids into communities, including in Vermont. During this same time, the DEA repeatedly told Defendants that their internal controls were insufficient to detect, report, and prevent increasing opioid diversion. *See infra* Section V.A–B.

302. Specifically, Defendants had access to data from IQVIA (previously IMS Health Incorporated and Quintiles) and Symphony Health, which provide data analytics to the healthcare industry.[119] IQVIA has a databank of over "520 million non-identified patient records" and prescription drug data "to state, county, zip code or prescriber granularity."[120] In addition, IQVIA provides services that allow corporations such as Defendants to determine where individual products are sold,[121] "granular prescription performance," and "weekly

[118] MCK-AGMS-069-0001025.
[119] https://www.iqvia.com/about-us; https://symphonyhealth.prahs.com/about/
[120] https://www.iqvia.com/institute/research-support
[121] https://www.iqvia.com/locations/united-states/commercial-operations/essential-information/sales-information

prescription dispensing" through various proprietary databases, such as DDD, Xponent, and National Prescription Audit.[122]

303. Symphony Health offers similarly extensive information, with databases including medical, hospital, and prescription claims data along with "point-of-sale prescription data, non-retail invoice data, and demographic data."[123]

304. McKesson used [redacted] In fact, [redacted]

305. [redacted][125]

[122] https://www.iqvia.com/locations/united-states/commercial-operations/essential-information/sales-information
[123] https://symphonyhealth.prahs.com/product/idv/
[124] MCK-AGMS-028-0128169; *see also* MCK-AGMS-028-0045067.
[125] MCK-AGMS-028-0128171, -177.

306. Symphony is cited as a [redacted] In addition, [redacted] Symphony Health provided [redacted]

307. In addition, [redacted]

308. Cardinal likewise [redacted]

309. Defendants tracked the flow of opioids closely, and understood the connection between increasing opioid sales and diversion. Yet Defendants designed their own diversion control systems to allow the shipment of prescription opioids in quantities that vastly exceeded any plausible medical need in the communities they served without triggering red flags or regulatory reporting. Defendants set excessively high thresholds and then relied on these flawed

thresholds as the primary indicator of potential diversion. As detailed in Section II *supra*, they made no attempt to set these thresholds at levels consistent with legitimate medical use of opioids. Instead, initial thresholds were tied to [redacted], which at the time set records for opioid overprescribing. And even then, Defendants routinely permitted, and in fact encouraged, prescription opioid sales that surpassed their excessive thresholds. *See supra* Section II.

310. Defendants knew or should have known that diffuse channels of prescription opioid diversion—including sharing of the drugs with friends and family members—were the most common.

311. Defendants knew or should have known that continuing to promote and market opioids to prescribers, pharmacists, and directly to consumers would lead to increased supply of opioids in Vermont communities and to increased diversion. Cardinal and McKesson were sophisticated purveyors of opioid marketing—they knew how effective Purdue and other manufacturers had been in expanding the use of prescription opioids, and they built opioid marketing services into their distribution contracts with the manufacturers. Overprescribing, driven by reckless and deceptive marketing tactics, was already a well-documented and pervasive problem.

312. Defendants also knew that the marketing of controlled substances in general—and opioids in particular—was a problematic practice. Both Cardinal and McKesson implemented marketing policies and internal guidelines [redacted] of controlled substances. Cardinal's regulatory compliance personnel even understood—[redacted]

However, despite the risks associated with this marketing—which both Defendants appear to have known and understood—they continued to market opioids.

313. Defendants also knew or should have known that their diversion control systems did not work: their anti-diversion and suspicious order monitoring programs were designed with loopholes to minimize the detection of suspicious orders. Defendants actively helped their pharmacy customers to subvert the systems' protections against diversion, and the protections that did exist were deliberately flawed from the start. It is no surprise that Defendants' anti-diversion systems did not prevent the diversion of prescription opioids, as explained in Section II *supra*.

314. As licensed distributors of controlled substances and giants in the prescription drug distribution industry, Defendants knew or should have known the risks of the controlled substances that they sold and failed to control. Prescription opioids present such serious health risks to consumers, and are so prone to diversion, that the federal government requires drug distributors (like Cardinal and McKesson) to store them in a locked vault with walls, floors, and ceilings made of "at least 8 inches of reinforced concrete;"[126] to transport them with extensive security precautions;[127] and to sell them only to DEA-registered pharmacies whose orders distributors must carefully monitor and investigate (and report to DEA, if suspicious).[128] Defendants knew and accepted the rules when they entered the marketplace to sell these dangerous controlled substances.

315. The resulting harm—to both Vermont consumers and to the State—was foreseeable to the Defendants and could have been prevented. Defendants instead prioritized profit above their legal responsibilities and the well-being of the public, with devastating results.

[126] 21 C.F.R. § 1301.72(a)(2)(3)(i).
[127] *See, e.g.*, 21 C.F.R. §§ 1301.74(e) & 1301.77.
[128] *See supra* Part I.

C. Vermont has suffered the devastating effects of widespread prescription opioid diversion.

316. Widespread prescription opioid diversion—and the resulting epidemic of addiction—have caused devastating consequences for Vermont and its citizens.

317. This high volume of opioid use and diversion leads to increased incidence of dependence and addiction—a significant public health problem in Vermont. In a 2014 survey by the U.S. Department of Health and Human Services, more than three percent of Vermonters—approximately 18,000 people—reported a dependence on a controlled substance.[129] Vermont ranks as the 8th-highest state for drug dependence nationwide,[130] despite other favorable health indicators like better access to health care and insurance coverage as compared to other states. [131]

318. Opioids have been killing Vermont citizens at skyrocketing rates, and a common origin is prescription opioids. Drug-related fatalities involving opioids nearly tripled between 2010 and 2018.[132] While the national average of opioid-related overdose deaths in 2016 was 13.3 per 100,000 persons, the rate in Vermont was 18.4, 38% higher than the national average.[133] And these overdose deaths have a broad impact—in a state like Vermont, there are no anonymous deaths.

319. The link between prescription opioids and "street drugs" like heroin and fentanyl fuels the opioid crisis. Many addicts begin with a legal opioid prescription from their doctor or

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[129] amfAR Opioid & Health Indicators Database, *Percent of people 12+ Reporting Drug Dependence*, http://opioid.amfar.org/indicator/drugdep.
[130] *Id.*
[131] *See State Health Assessment Plan - Healthy Vermonters 2020* (December 2012), http://www healthvermont.gov/sites/default/files/documents/2016/11/Healthy%20Vermonters%202020%20Report.pdf, at 13, 5, 27.
[132] Vermont Department of Health, *Opioid-Related Fatalities Among Vermonters* (updated February 2019), http://www healthvermont.gov/sites/default/files/documents/pdf/ADAP_Data_Brief_Opioid_Related_Fatalities.pdf.
[133] National Institute on Drug Abuse, *Vermont Opioid Summary* (March 2018), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/vermont-opioid-summary.

by taking a pill from a prescription bottle belonging to a family member or friend.[134] Prescription opioid users also are far likelier to use illegal opioids like heroin and fentanyl. U.S. Centers for Disease Control and Prevention ("CDC") statistics show that people addicted to prescription opioids are **40 times more likely** also to be addicted to heroin. The same CDC report shows that **nearly half** (45%) of people who used heroin also were addicted to prescription opioid painkillers.[135] In 2017, the Vermont Department of Health reported that 80% of new heroin users also had a history of misusing prescription opioids.[136]

320. The heroin/fentanyl problem in Vermont is acute—in 2018, fentanyl was involved in three-fourths of all opiate-related fatalities, and heroin was involved in over half of all opiate-related fatalities.[137] The number of fatal overdoses involving fentanyl in particular has skyrocketed in recent years—a **twentyfold increase** from 4 fatalities in 2010 to 83 fatalities in 2018.[138]

321. Beyond just addiction, there are additional and serious health dangers associated with illicit heroin and fentanyl use, including collapsed veins, bacterial infections of the blood and heart, lung complications, and depression. When heroin is administered by injection, the sharing of needles or bodily fluids puts users at heightened risk for HIV and Hepatitis B and C—serious diseases that can be transmitted to sexual partners and children.[139] The concern about rising rates of HIV and Hepatitis C is very real in Vermont: in 2016, the CDC identified **two**

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[134] Nora Volkow and Francis Collins, National Institute on Drug Abuse, "*All Scientific Hands On Deck*" *to End the Opioid Crisis*, May 31, 2017, https://www.drugabuse.gov/about-nida/noras-blog/2017/05/all-scientific-hands-deck-to-end-opioid-crisis ("While there were nearly 20,000 overdoses in 2015 due to heroin or fentanyl, the trajectory of opioid addiction usually begins with prescription opioid misuse. Some people with opioid addiction began by taking diverted pills from friends and family members, but others began with an opioid prescription of their own").
[135] Centers for Disease Control and Prevention, *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/.
[136] Vermont Department of Health, *Opioid Misuse, Abuse & Dependence in Vermont Data Brief*, April 2017, http://www healthvermont.gov/sites/default/files/documents/pdf/ADAP_data_brief_opiodmisuse.pdf.
[137] *Opioid-Related Fatalities Among Vermonters, supra* n.133, at 1.
[138] *Id.* at 2.
[139] National Institute on Drug Abuse, *What are the medical complications of chronic heroin use?* (June, 2018) at 11, https://www.drugabuse.gov/publications/research-reports/heroin/what-are-medical-complications-chronic-heroin-use.

Vermont counties—Essex and Windham—out of the more than 3,100 counties across the entire United States as among those **in the 95th percentile (top 5% nationwide) at greatest risk** for outbreaks of HIV and Hepatitis C.[140]

322. While heroin and fentanyl have contributed to the increasing number of opioid deaths in Vermont, the majority of opioid fatalities are causally linked to opioid prescriptions—which many heroin and fentanyl abusers have in their system at the time of their fatal overdose or have used at some point prior to their fatal overdose. A study by the Vermont Prescription Monitoring System found that 85% of opioid-related accidental fatalities in Vermont had received an opioid prescription within the last five years[141] and that 25% percent had received an opioid prescription within 30 days prior to their death.[142]

323. In Vermont, 90.6% of opioid-related fatalities in 2015 occurred in people who had controlled substance prescription histories. Of the decedents who had been given an opioid prescription during the year prior to their death, the average opioid prescription supply was 261 days.[143]

324. In the most recent years for which data from the Vermont Department of Health is available (2015, 2016, 2017, and 2018), prescription opioids have been involved in roughly one-third of opioid-related deaths in Vermont.[144]

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[140] Michelle M. Van Handel *et al.*, *County-level Vulnerability Assessment for Rapid Dissemination of HIV or HCV Infects among Persons who Inject Drugs, United States*, Journal of Acquired Immune Deficiency Syndromes, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5479631/; American Foundation for AIDS Research, *Vermont Opioid Epidemic*, http://opioid.amfar.org/VT.

[141] Vermont Prescription Monitoring System, *Controlled Substance Prescription Histories for Opioid-Related Accidental Fatalities in 2015* at 3, http://www.healthvermont.gov/sites/default/files/documents/2017/01/HSRV_VPMS_10_28_16_opioid_related_accidental_fatality_brief.pdf.

[142] *Id.*

[143] Anne VanDonsel, Shayla Livingston, and John Searles (Vermont Department of Health), *Opioids in Vermont: Prevalence, Risk, and Impact* (October 27, 2016), http://www healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Prevalence_Risk_Impact.pdf, at 31 ("Prescription History of Individuals with Opioid-related Accidental Fatalities").

[144] *Opioid-Related Fatalities Among Vermonters, supra* n.133, at 2.

325. Opioid use disorder in pregnant women has become prevalent in Vermont as opioid use has proliferated more broadly, with potentially devastating health consequences for women and their infants. The number of women with diagnosed opioid use disorder at the time of delivery has increased dramatically over time in Vermont: from 0.5 per 1,000 deliveries in 2001 to 48.6 per 1,000 deliveries in 2014—over **seven times** the national average, and the highest among the 30 states that have compiled this data.[145] This widespread prevalence of opioid use disorder in pregnant Vermonters is a major public health concern, because of the serious potential adverse maternal and neonatal outcomes associated with opioid use during pregnancy: preterm labor, stillbirth, neonatal abstinence syndrome, and maternal mortality.[146]

326. The number of infants born in Vermont who are diagnosed with Neonatal Abstinence Syndrome ("NAS")—a condition in which a newborn baby suffers withdrawal symptoms—also far exceeds the national average. Based on available data from 2012, the Vermont Department of Health estimated that the rate of NAS in Vermont was **five times higher** than the national average, and the Vermont statistics have continued to rise.[147]

327. In 2008, there were 17.0 infants with NAS per 1,000 live births (to Vermont residents in Vermont hospitals). By comparison, in 2014, that number had **more than doubled** to 35.3 per 1,000 live births (to Vermont residents in Vermont hospitals).[148]

328. Infants exposed to opioids *in utero* also face serious health consequences. At least 60–80% of these babies will experience symptoms such as seizures, respiratory distress,

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[145] *Opioid Use Disorder Documented at Delivery Hospitalization—United States, 1999-2014*, CDC Morbidity and Mortality Weekly Report (August 10, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6731a1 htm?s_cid=mm6731a1_e, at 847.
[146] *Id.* at 845.
[147] *Opioids in Vermont: Prevalence, Risk, and Impact, supra* n.144, at 44 ("Improved treatment and screening have helped to identify more infants exposed to opioids").
[148] Vermont Department of Health, *Neonates Exposed to Opioids in Vermont* (April 2017), http://www healthvermont.gov/sites/default/files/documents/pdf/ADAP_Opioids_Neonate_Exposure.pdf, at 1.

diarrhea, hypertonia, feeding intolerance, tremors, and vomiting because of their exposure to opioids in the womb.[149]

329. Infants born with NAS require longer and costlier hospital stays than those who are born without exposure to opioids. In 2012, the average length of hospital stay for non-NAS infants born to Vermont residents in Vermont hospitals was 3.0 days, at a cost of $5,590. But Vermont infants with NAS faced hospital stays more than 2 times longer and nearly 3 times more expensive, averaging 7.4 days and $15,456 (respectively).[150]

330. More than 50% of Vermont children under the age of five who have been taken into the custody of the Vermont Department of Children and Families (DCF) have been removed from their homes because of opioid-related issues.[151] As reported in 2016, the reporting of incidences to DCF's Child Protection Line have increased by 30%—from 15,760 reports in 2012 to 20,583 in 2016—and during those same years, approximately 30% of the calls related to substance abuse.[152]

331. Moreover, Vermont's efforts to prevent and treat opioid addiction, and to reduce the overall impact of the opioid epidemic on its citizens, have come at a significant cost to the State.

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[149] Stephen W. Patrick et al., *Neonatal Abstinence Syndrome and Associated Health Care Expenditures*, Journal of the American Medical Association (2012), https://www ncbi.nlm.nih.gov/pubmed/ 22546608.
[150] Vermont Department of Health, *Neonates Exposed to Opioids in Vermont, supra* n.149, at 2.
[151] Vermont Opioid Coordination Council, *Initial Report of Recommended Strategies* (January 2018), http://www healthvermont.gov/sites/default/files/documents/pdf/OCC%202018%20Report%202018-1-9.Final_.pdf, at 3 n.1.
[152] Howard Weiss-Tisman, *Opioid Abuse Continues to Strain Vermont's Child Welfare System*, Vermont Public Radio (December 5, 2017), http://digital.vpr net/post/opioid-abuse-continues-strain-vermonts-child-welfare-system#stream/0; Vermont Dept. for Children and Families Family Services Div., *2016 Report on Child Protection in Vermont*, http://legislature.vermont.gov/assets/Legislative-Reports/Child-Protection-Report-2016.pdf.

332. The demand for opioid addiction treatment has risen dramatically. In 2006, 1,897 Vermonters were treated for opioid use in state-funded treatment facilities. By 2015, that number had **more than tripled**, to 6,084.[153]

333. Opioid overprescribing, misuse, and prescription diversion are draining Vermont's health care system. For example, one study estimated the 2007 total health care spending associated with opioid abuse in Vermont as exceeding $38 million.[154] From 2007 to 2018, opioid prescribing rose dramatically, as did the numbers of persons using, misusing, and abusing both prescription and illegal opioids.

334. The health care costs associated with opioid overprescribing, addiction, and abuse are crushing. Vermont consumers—individuals, employers, and private insurers—have paid millions for opioid prescriptions. Vermont's opioid treatment programs cost more than $70 million between 2012 and 2017 alone.[155] Vermont consumers have likewise borne substantial healthcare costs due to this epidemic of addiction.

335. It is well-established that health care costs for persons addicted to opioids are much higher than health care costs for the general population.[156] For example, overall health care costs are approximately 3 times higher among patients receiving Medication Assisted Treatment for opioid addiction than is true for the general Medicaid population. The average national private payer cost per person with opioid use disorder was $63,356 (in 2015).[157]

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[153] Vermont Department of Health, *People Treated for Opiate Use in Vermont by Fiscal Year*, http://www healthvermont.gov/sites/default/files/documents/2016/12/adap_TotalOpiatebyFY.pdf.
[154] Matrix Global Advisors, *Health Care Costs from Opioid Abuse: A State-by-State Analysis* (April 2015), https://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf, at 5.
[155] Harry Chen, MD (Commissioner, Vermont Dept. of Health), *Status of Opioid Treatment Efforts – Health Reform Oversight Committee* (October 25, 2016), http://www.leg.state.vt.us/jfo/healthcare/Health%20Reform%20Oversight%20Committee/2016_10_25/Status%20of%20Opioid%20Treatment%20Efforts%20-%20Chen.pdf, at 22.
[156] Vermont Department of Health, *The Opioid Addiction Treatment System* (January 13, 2013), http://www.leg.state.vt.us/reports/2013externalreports/285154.pdf, at 9.
[157] *Status of Opioid Treatment Efforts, supra* n.156.

336. The prevalence of opioids in Vermont also places a greater burden on law enforcement—increased costs associated with investigating and prosecuting crimes related to opioid use and abuse, as well as increased costs for treating incarcerated residents for opioid use disorder.

337. The costs of incarceration—which include Medication Assisted Treatment for addiction and other related costs—are largely paid by the State. Crimes associated with prescription drugs—chiefly robbery and burglary—have risen.[158] Data collected by the Vermont Intelligence Center show that law enforcement consistently averages between one and two seizures of illicit opioids per day. In a small state like Vermont, this steady drumbeat of opioid seizures has become a focal point of police time and attention.

V. Defendants Fraudulently Concealed Their Unlawful Conduct.

338. Defendants misrepresented their conduct with respect to promoting opioids and their compliance with their legal obligations to monitor and prevent diversion. These actions misled Vermont and the public—preventing the State, through the exercise of reasonable diligence, from discovering the facts essential to its claims.

A. Cardinal concealed its failure to comply with its duty to prevent diversion.

339. In December 2006, Cardinal agreed to pay $11 million to settle an investigation by the New York Office of the Attorney General over Cardinal's secondary market trading of prescription drugs. As part of the settlement, Cardinal vowed to undertake a series of reforms to its distribution business, including maintaining "a comprehensive compliance manual addressing means to prevent and detect diversion and assure the safety and integrity of prescription pharmaceuticals." Cardinal also agreed to:

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[158] Vermont Department of Health, *Issue Brief: Prescription Drug Misuse in Vermont*, at 12 (Feb. 12, 2013), http://thehungryheartmovie.org/wp-content/uploads/2013/09/SEOW_Rx_Issue_Brief_Final_02_12_13.pdf.

> gather, monitor, and analyze sales data to detect instances of possible diversion of prescription pharmaceuticals, . . . including sales volume, volume changes over time or other significant changes in purchasing patterns, purchases of frequently diverted products, consistency with the customers' business ... and any other available relevant information.[159]

340. Less than two years later, in September 2008, Cardinal agreed to pay $34 million to settle an investigation by seven U.S. Attorney's Offices and the DEA over Cardinal's failure to comply with its diversion prevention duties. As part of the settlement, Cardinal vowed to "[m]aintain a compliance program designed to detect and prevent diversion of controlled substances," including procedures to review orders by trained employees to determine whether the order is suspicious and should be cancelled and reported to the DEA, and "[r]eview distributions of [opioids] to retail pharmacy customers and physicians" and identify and investigate any customer that has exceeded Cardinal's distribution thresholds.[160]

341. Cardinal proffered that, over the previous year, it had "invested more than $20 million to significantly enhance its controls across its network to prevent the diversion of controlled substances .... Specifically, the company has expanded its training, implemented new processes, introduced an electronic system that identifies and blocks potentially suspicious orders pending further investigation, and enhanced the expertise and overall staffing of its pharmaceutical distribution compliance team."[161]

342. In 2012, Cardinal entered into a settlement with the DEA to resolve an investigation into its distribution center in Florida. As part of the settlement, Cardinal vowed to "maintain a compliance program designed to detect and prevent diversion of controlled

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[159] New York Office of the Attorney General Assurance of Discontinuance (Dec. 26, 2006) at 14, https://ag.ny.gov/sites/default/files/press-releases/archived/Assurance%20of%20Discontinuance.pdf.
[160] Settlement and Release Agreement and Administrative Memorandum of Agreement, Sept. 30, 2008, CAH_MDL2804_01444908 at 3–5.
[161] Press Release, Cardinal Health Resolves Controlled Substance License Suspension (Oct. 2, 2008), https://cardinalhealth.mediaroom.com/newsreleasearchive?item=122576.

substances as required under the CSA and applicable DEA regulations."[162] Cardinal also vowed to "commence procedures to ensure that any pharmacy, chain or retail, placing orders of controlled substances ... that Cardinal knows or should know are suspicious in nature, given the totality of the circumstances, will receive a site visit or an anonymous site inspection by a Cardinal employee or a qualified third-party inspector to provide an independent assessment of whether that customer's orders are being diverted."[163]

343. That same year, Cardinal issued a press release touting its anti-diversion system, claiming that the company has "robust controls and performs careful due diligence." Specifically, Cardinal described its system as follows:

> The company's controls feature a system of advanced analytics and teams of anti-diversion specialists and investigators to identify red flags that could signal diversion. When the company's program raises a red flag, its teams immediately investigate. Cardinal Health's anti-diversion specialists use their professional judgment and expertise to determine the appropriate action.[164]

344. Cardinal wrote that it "spent millions of dollars" to build its monitoring system,[165] and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[166]

345. In a 2017 document published to shareholders, Cardinal acknowledged its role in "maintaining a vigorous program to prevent opioid pain medications from being diverted to improper uses."[167] During an earnings call that same year, George Barrett, Cardinal's Chairman

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[162] Administrative Mem. of Agreement between DEA and Cardinal at 3, CAH_MDL2804_02465982.
[163] *Id.*
[164] Press Release, Cardinal Health Inc. Seeks Restraining Order to Avoid Disruption in Controlled Medicine Shipments from Florida (Feb. 3, 2012), https://cardinalhealth.mediaroom.com/newsreleasearchive?item=122803.
[165] Press Release, Cardinal Health Statement in Response to Preliminary Injunction Hearing: February 29, 2012, https://cardinalhealth mediaroom.com/newsreleasearchive?item=122811.
[166] Bernstein, Lenny, *et al.*, *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: No One Was Doing Their Job*, Wash. Post (Oct. 22, 2016), https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story html?utm_term=.b5b04da86c80.
[167] Cardinal Health Proxy, Form 14A at 9 (filed Oct. 23, 2017).

and then-CEO, vowed to "operate a very strong, robust, suspicious order monitoring system and process that not only meets [] regulatory requirements," but also "exceeds what is required of distributors."[168]

346. In a subsequent 2017 earnings call, Cardinal stated: "[W]e have spent nearly a decade continuously enhancing our best-in-class suspicious order monitoring tools and analytics to keep pace with the ever-changing shape of the crisis .... We ... take very seriously our responsibilities to serve our health care system. Our anti-diversion systems and controls are substantial, they are well-funded and they are best-in-class."[169]

347. To this day, Cardinal continues to publicly portray itself as "committed to fighting opioid addiction and misuse."[170] Cardinal's website holds the company out as an "industry leader" that uses "constantly adaptive, rigorous systems supported by program specialists who monitor and investigate suspicious orders using advanced analytics and other tools."[171]

348. Cardinal was aware that all of these public promises about what it purported to be doing with its compliance program and its efforts to address the opioid crisis did not align with its actions. Through its repeated statements, Cardinal fraudulently concealed its misconduct—violations of its obligations to monitor and prevent diversion.

B. McKesson concealed its failure to comply with its duty to prevent diversion.

349. Similarly, McKesson has publicized the quality of its anti-diversion efforts since 2005, claiming that it "focuses intensely on ... systems and processes that enable full compliance with the laws and regulations that govern [its] operations .... [because it is] especially aware of

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[168] Cardinal Health Quarterly Earnings Call Tr. at 22 (Aug. 2, 2017).
[169] Cardinal Health Quarterly Earnings Call Tr. at 4–5 (Nov. 6, 2017).
[170] Cardinal, Cardinal Health Opioid Action Program, https://www.cardinalhealth.com/en/about-us/corporate-citizenship/opioid-action-program.html (last visited Feb. 24, 2019).
[171] Cardinal, Addressing the Opioid Crisis, https://www.cardinalhealth.com/en/about-us/corporate-citizenship/ethics-and-governance/board-engagement-and-governance.html (last visited Feb. 24, 2019).

[its] responsibility to maintain the integrity of the pharmaceutical supply chain and consumer and patient safety."[172]

350. In May 2008, McKesson entered into a settlement to resolve a DEA investigation over its failure to maintain effective controls at distribution centers in six states. As part of the settlement, McKesson vowed to "maintain a compliance program designed to detect and prevent diversion of controlled substances" and review orders that "exceed established thresholds and criteria" to determine whether the orders were suspicious and "should not be filled and reported to DEA."[173] McKesson also vowed to "follow the procedures established by its Controlled Substance Monitoring Program."[174]

351. McKesson subsequently reassured the public in 2016 that it "put significant resources towards building a best-in-class controlled substance monitoring program to help identify suspicious orders and prevent prescription drug diversion in the supply chain."[175] And McKesson claimed it is "deeply passionate about curbing the opioid epidemic in our country."[176]

352. McKesson continued to hold itself out as committed to preventing diversion, assuring the public in 2017 that it is "doing everything [it] can to help address [the opioid] crisis in close partnership with doctors, pharmacists, government and other organizations across the

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[172] McKesson Corporate Citizenship Report 2005, https://www.slideshare net/finance2/mckesson-corporate-citizenship-report-74m-2005.

[173] Settlement and Release Agreement and Administrative Mem. of Agreement at 3–4 (May 2, 2008), https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20McKesson%20-%202008_0.pdf.

[174] Administrative Mem. of Agreement between McKesson and DEA at 3 (Jan. 17, 2017); https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20McKesson%20-%202017_0.pdf.

[175] Higham, Scott, *et al.*, *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story html?utm_term=.b40d6961d1df.

[176] Higham, Scott, *et al.*, *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story html?utm_term=.b40d6961d1df.

supply chain."[177] McKesson also claimed it "invested millions of dollars to build a first class Controlled Substance Monitoring Program [], allowing the company to monitor suspicious ordering patterns, block the shipment of controlled substances to pharmacies when certain thresholds are reached, report suspicious orders to the DEA, and educate customers on identifying opioid abuse."[178]

353. Also in 2017, as part of an agreement with the Department of Justice and DEA to resolve an investigation into some of McKesson's distribution centers, McKesson vowed to "maintain a compliance program intended to detect and prevent diversion of controlled substances."[179] Specifically, McKesson vowed to make specific staffing and organizational improvements to ensure rigorous compliance and eliminate conflicts of interest, maintain customer due diligence files, refrain from shipping suspicious orders, increase customer thresholds only through an established regulatory review process, and conduct periodic auditing.

354. To this day, McKesson continues to tout its commitment to preventing diversion, claiming that it "uses sophisticated algorithms designed to monitor for suspicious orders." McKesson also claims to have "developed a cutting-edge controlled substances threshold management program, using complex and dynamic data analytics."[180]

355. Through these public promises about what McKesson purported to be doing with its compliance program and its efforts to address the opioid crisis, all of which were knowingly in contradiction to the actual facts, McKesson fraudulently concealed its misconduct—violations of its obligations to monitor and prevent diversion.

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[177] Morgenson, Gretchen, *Hard Questions for a Company at the Center of the Opioid Crisis*, NY Times (July 21, 2017), https://www nytimes.com/2017/07/21/business/mckesson-opioid-packaging.html.
[178] *McKesson Announces Preliminary Voting Results From 2017 Annual Meeting of Stockholders* (July 26, 2017), https://www.businesswire.com/news/home/20170726005746/en/.
[179] Administrative Mem. of Agreement at 5 (Jan. 17, 2017), https://www.justice.gov/usao-nj/press-release/file/928636/download.
[180] McKesson's Controlled Substance Monitoring Program, https://www.mckesson.com/about-mckesson/fighting-opioid-abuse/controlled-substance-monitoring-program (last visited Feb. 24, 2019).

C. Defendants concealed their marketing and promotion of prescription drugs.

356. As recently as 2018, at a hearing on "Combatting the Opioid Epidemic: Examining Concerns About Distribution and Diversion," Cardinal's Chairman testified before Congress that Cardinal does not market any medications to patients, a statement now known to be deceptive. As detailed in Section III.A.1 *supra*, Cardinal has run marketing programs for drug manufacturers—including promoting opioids—for many years. Cardinal's Chairman also testified that opioid prescriptions are written by healthcare providers and filled by pharmacies, suggesting distributors have no role in this decision-making process. He claimed that, "[a]s an intermediary in the pharmaceutical supply chain, Cardinal Health does not ultimately control either the supply of or the demand for opioids."[181] However, as detailed in Section III.A.1 *supra*, Cardinal has worked for years to drive increased demand for opioids through its marketing programs.

357. These misstatements are emphasized on the Cardinal website, where the company styles itself a transporter of prescription medications, responsible for secure delivery, and claims that it does not promote prescription medications to members of the public.

358. At the same Congressional hearing, McKesson's Chairman likewise testified that McKesson does not market prescription drugs to doctors or patients, nor "any particular category of drugs, such as opioids, to pharmacies."[182] The State now knows this to be deceptive. As discussed in Section III.B *supra*, McKesson markets prescription drugs to pharmacies through multiple programs and to consumers through the Pharmacy Information Program. McKesson's Chairman also testified that the company does not ship prescription drugs absent a pharmacy

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[181] Testimony of George S. Barrett, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, United States House of Representatives, May 8, 2018.
[182] Testimony of John Hammergren, Chairman, President, and Chief Executive Officer McKesson Corporation, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, United States House of Representatives, May 8, 2018.

order.[183] However, McKesson has, in the past, auto-shipped opioids to pharmacies, through one of its marketing programs, as detailed in Section III.B.1.

359. Defendants' trade lobbying association, HDA, has also falsely denied that Defendants marketed opioids. In publicly denying distributors' role in the opioid epidemic, HDA stated: "Distributors have no ability to influence what prescriptions are written. The fact is that distributors don't make medicines, **market medicines**, prescribe medicines or dispense them to consumers."[184]

360. Defendants' deceptive and misleading public statements, including to the U.S. House of Representatives Oversight Committee, were intended to and did conceal their conduct, preventing the State of Vermont from discovering facts essential to its claims.

D. Defendants fought to safeguard the market for opioids, further ensuring that their misconduct remained concealed.

361. Defendants spent millions of dollars to protect the market for opioids and ensure their misconduct remained concealed.

362. From 2008 through 2018, Defendants' lobbying expenditures increased, corresponding with the increase in opioid use and abuse. To further their interests, including decreased enforcement, Cardinal spent $19.17 million and McKesson spent $17.27 million on lobbying during these deadly years. Meanwhile, law enforcement actions related to opioids declined—civil case filings by the DEA against distributors, manufacturers, pharmacies, and doctors dropped from 131 in fiscal year 2011 to just 40 in fiscal year 2014.[185]

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[183] *Id.*

[184] HDA Press Release, *HDA Statement On Attorneys General Opioid Investigations*, Sept. 19, 2017, https://www.prnewswire.com/news-releases/hda-statement-on-attorneys-general-opioid-investigations-300522358.html

[185] *See* Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowedenforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.e2d89d4ccd07.

363. Cardinal and McKesson also worked with trade associations and other organizations. Chief among them is their powerful lobbying association: HDA.

364. Defendants are members of HDA, and Defendants' executives have long maintained leadership positions in HDA's management. These privileged and powerful positions have enabled Defendants to influence the agendas pushed by the trade association.

365. Paul Julian, who was an Executive Vice President and Group President at McKesson, was chairman of HDA from 2008 to 2010, on the HDA Board of Directors from 2000 to 2013, and on its Executive Committee from 2005 to 2013. For his service in furthering distributors' agendas, Julian received HDA's Nexus Award for Lifetime Achievement in 2015. While President of McKesson, Mark Walchirk served on HDA's Board of Directors and Executive Committee for multiple years, beginning in 2014. Layne Martin currently serves on the HDA Research Foundation's Board of Directors in addition to his duties as Vice President and General Manager of Supply Chain Solutions at McKesson.

366. Cardinal senior executives also have served as HDA leaders. While employed as CEO of Cardinal's Medical Segment, Jon Giacomin concurrently served as the Vice Chairman of the HDA Board of Directors from 2014 to 2016, and as its Chairman from 2016 to 2017. Cardinal's Executive Vice President of Global Sourcing, Craig Cowman, currently serves on the HDA Research Foundation's Board of Directors. And Cardinal's current CEO, Mike Kaufman, is a former member of HDA's Board of Directors as well as its Executive Committee.

367. In addition to maintaining leadership positions in HDA, Defendants made significant financial contributions to the association. In 2017 alone, McKesson paid about [redacted] to HDA for dues and other expenses. McKesson [redacted] Also in 2017,

Cardinal and McKesson each contributed $1,161,667 for HDA's Education and Communications Campaign.

368. Part of HDA's stated mission was to prevent [redacted]—legislation that could have brought Defendants' misconduct to light much sooner. [redacted][186]

369. Not surprisingly then, by 2014, HDA had a state government affairs budget of almost [redacted]

370. In 2016, HDA submitted an amicus brief to the United States Court of Appeals in *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). In the brief, the HDA represented that Cardinal and McKesson "take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process."[187]

371. Significantly, while acknowledging distributors' duties regarding suspicious orders, HDA also requested the Court of Appeals to limit those duties. HDA asked the court to renounce "any attempt to impose additional obligations on [Defendants] to investigate and halt suspicious orders."[188] The court rejected HDA's arguments. *Id.* at 222–223.

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[186] Deposition of Joseph Ganley, July 27, 2018, MCK-AGMS-032-0000550 at 118-119; MCK-AGMS-032-0000878 at 4.
[187] Brief for Healthcare Distribution Alliance and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017) (No. 15-1335), 2016 WL 1321983 at *25.
[188] *Id.* at *26.

372. In addition to its own matters, HDA supported the activities of other front groups. It was a member of the Pain Care Forum, a lobbying consortium that spent more than $880 million from 2006 through 2015 on campaign contributions and lobbying expenses at the state and federal level in an effort to increase the flow of dangerous opioids to consumers. From 2007 to 2014, the number of registered lobbyists in Vermont employed by members of the Pain Care Forum ranged from 16 to 29.

373. The Pain Care Forum lobbied both state and federal governments to prevent restrictions on opioid prescribing. For example, the group paid a PR consultant to draft patient testimonials to encourage the state medical boards to adopt more lax guidelines on opioid dosage. According to reporting by the Associated Press and the Center for Public Integrity, as early as 2008, the Pain Care forum was developing a strategy to "inform the process" at FDA, generating 2,000 comments opposing new barriers to opioids. According to the article, the Pain Care Forum has, for over a decade, met with some of the highest-ranking health officials in the federal government, while quietly working to influence proposed regulations on opioids and promote legislation and reports on the problem of untreated pain. The group is coordinated by the chief lobbyist for Purdue Pharma, the maker of OxyContin. From 2006 through 2015, participants in the Pain Care Forum spent over $740 million on lobbying.

374. Through these efforts, Cardinal and McKesson not only concealed their own misconduct in marketing and promoting opioids and failing to comply with their duties to prevent diversion, but actively lobbied against increased regulation of the opioids market and enforcement of existing laws and regulations, for the purpose of protecting their lucrative market and ensuring that their wrongdoing did not come to light.

CAUSES OF ACTION

COUNT I
Unfair Acts and Practices
Violations of the Vermont Consumer Protection Act

375. The State realleges and incorporates by reference each of the allegations contained in all paragraphs of this Complaint, as though fully set forth herein.

376. Defendants engaged in unfair acts or practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), by:

- Transporting and selling opioids in the State of Vermont while failing to comply with their duties, under federal and state law, to detect, prevent, and report diversion of opioids to other than legitimate channels, including by:
    - Designing suspicious order monitoring programs that failed to monitor, identify, report, and prevent fulfillment of suspicious orders by, *inter alia*, utilizing inflated order thresholds that failed to account for known characteristics of suspicious orders, allowing for manipulation of order thresholds by and/or for the benefit of pharmacy customers, and failing to require adequate investigations of pharmacies; and
    - Failing to adhere to the terms of their suspicious order monitoring programs by, *inter alia*, assigning inadequate staffing to compliance responsibilities, conducting inadequate due diligence of their customers, raising customers' order thresholds without conducting an appropriate investigation, and exempting chain pharmacies from important aspects of the anti-diversion programs;
- Advertising and promoting opioids in the State of Vermont, for the purpose of increasing sales, while failing to design and maintain effective systems to detect, prevent, and report diversion of opioids to other than legitimate channels—as required by federal and state law;
- Disseminating advertising and promotional messages in the State of Vermont that failed, despite the known, serious risks of addiction and adverse effects posed by opioids, to present a fair balance of benefit and risk information; and
- Promoting the initiation of opioid use and/or long-term continuation of opioid use by providing Savings Cards to reduce patients' out-of-pocket expense for these drugs.

377. These acts or practices may be deemed "unfair" in that they offend public policy reflected in (a) established legal standards that require the truthful and balanced marketing of

prescription drugs; and (b) Vermont and federal law, which require licensed wholesale distributors of controlled substances to take steps to combat drug abuse, to regulate legitimate and illegitimate traffic in controlled substances, and to detect, prevent, and report diversion of controlled substances to other than legitimate channels. *See* 20-4 Vt. Code R. § 1400, Part 17; the Controlled Substances Act, 21 U.S.C. § 801, *et seq.*, and its implementing regulations.

378. These acts or practices were unfair because they represented a dereliction of the Defendants' duties to monitor, prevent, and report diversion of the dangerous and addictive opioids that they sold in the State. Defendants understood that they had a critical role in the federal- and state-mandated system to prevent diversion, and that they were responsible for not sending more opioids into Vermont communities than were reasonably necessary to meet legitimate demand for medical use. However, their financial interests were best served by (1) increasing sales of these expensive and profitable drugs, and (2) avoiding damage to customer relationships (and potential loss of market share) that could result from holding or investigating suspiciously-high orders. Defendants chose to prioritize their financial interests ahead of consumer health and safety, designing and implementing ineffective diversion control systems, and marketing and promoting opioids on behalf of their manufacturer clients. This conduct is immoral, unethical, oppressive, and unscrupulous.

379. By reason of Defendants' conduct, Vermont consumers have suffered substantial injury by reason of the health risks associated with opioid abuse and misuse, including the pain and suffering associated with opioid addiction, injury, disability, overdose, and death, as well as the associated financial costs.

COUNT II
Deceptive Acts and Practices
Violations of the Vermont Consumer Protection Act

380. The State realleges and incorporates by reference each of the allegations contained in all paragraphs of this Complaint, as though fully set forth herein.

381. Defendants engaged in unfair and deceptive trade practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), by making material misrepresentations and omissions regarding the risks and benefits of its opioid products, including by:

- Making and disseminating false or misleading statements about the benefits, risks, and diversion-potential of opioids; and
- Making statements to promote the use of opioids that omitted or concealed material facts, including the risks of diversion and misuse, dependence, addiction, overdose, and death associated with these drugs.

382. Defendants' material omissions rendered even seemingly truthful or neutral statements about opioids false and misleading, because they were materially incomplete. At the time Defendants made these statements and disseminated these promotional materials, Defendants failed to include material facts about the risks and benefits of opioid use and failed to provide "fair balance," as required by law.

383. These misrepresentations and omissions were likely to mislead the prescribers and pharmacists to whom they were directed, affecting their decisions regarding the prescribing, dispensing, and use of opioids. The meaning Plaintiff ascribes to Defendants' misrepresentations herein is reasonable, given the nature thereof.

COUNT III
Negligence

384. The State incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

385. Defendants have a duty under the common law of Vermont to exercise the degree of care that a reasonably prudent person would under the circumstances. The scope of this common law duty of ordinary care expands according to the foreseeability of the consequences of a defendant's acts or omissions.

386. Defendants distribute large quantities of addictive prescription opioid narcotics, which have been designated as controlled substances under state and federal law. It is foreseeable that Defendants' failure to design and operate effective controls to monitor, identify, report, and prevent the fulfillment of suspicious orders of prescription opioids would create a risk of abuse, misuse, and injury to the State and its citizens. The very purpose of state and federal laws regulating Defendants' activities is to prevent the abuse of controlled substances and to prevent the diversion of those substances. Thus, Defendants have a common law duty to prevent the diversion of controlled substances into illegitimate channels.

387. This common law duty of care is fully supported by and incorporates State laws governing distributors of controlled substances, which impose a statutory duty on such distributors to provide effective controls and procedures to guard against diversion. The statutory duty includes the explicit requirements that a distributor must: (a) design and operate a system to identify suspicious orders of controlled substances; (b) report the identification of all suspicious orders of controlled substances; and (c) exercise sufficient diligence to prevent the fulfillment of any suspicious orders. 26 V.S.A. § 2068; 20-4 Vt. Code R. § 1400:17.25 (incorporating the security requirement set forth under federal law).

388. State laws regulating the distribution of controlled substances are "safety statutes" under Vermont law, the violation of which gives rise to a rebuttable presumption of negligence.

389. Defendants breached their common law and statutory duties by failing to maintain effective controls over prescription opioids by, *inter alia*, the following acts and omissions:

- creating ineffective anti-diversion and suspicious order monitoring systems that utilized inflated order thresholds that failed to account for known characteristics of suspicious orders, allowed for manipulation of order thresholds by and/or for the benefit of pharmacy customers, and failed to require adequate investigations of pharmacies;
- failing to effectively implement their anti-diversion programs, including by assigning inadequate staffing to compliance responsibilities, conducting inadequate due diligence of their customers, raising customers' order thresholds without conducting an appropriate investigation, and applying, different, even looser rules to their chain pharmacy customers;
- failing to report to the proper authorities all suspicious orders identified by their own monitoring protocols; and
- failing to prevent the shipment of suspicious orders by, among other things, failing to conduct proper diligence prior to filling suspicious or potentially suspicious orders.

390. Defendants' breach of their duties fueled the widespread circulation of opioids into illegitimate channels in Vermont. The structure of Vermont's controlled substances regulations—and of the federal regulations incorporated by Vermont law—acknowledges that preventing the abuse, misuse, and diversion of controlled substances can only occur where every participant in the distribution chain maintains effective controls. Defendants' failure to satisfy their duties to monitor, identify, report, and prevent the fulfillment of suspicious orders for prescription opioids has caused or substantially contributed to the abuse, misuse, and diversion of those opioids. Had Defendants effectively carried out their duties, opioid abuse, misuse, diversion, and addiction would not have become so widespread in Vermont, and the costs borne by the State in addressing and abating the opioid epidemic would have been averted or much less severe.

391. The State has expended millions of dollars in addressing and attempting to abate a wide-spread public health epidemic that has been fueled by the drugs that Defendants sent into Vermont. These expenses are the foreseeable and proximate result of Defendants' failure to design and implement effective diversion controls in accordance with their legal duties. A reasonably prudent distributor of controlled substances would foresee that failing to maintain effective controls against the diversion of highly addictive narcotics would fuel over-prescription, would lead to overpayment by payors, and would result in the attendant costs of addressing an opioid crisis.

392. As a direct result of Defendants' misleading representations regarding their purported compliance with their duties to prevent diversion, the State was unaware of, and could not reasonably know or have learned at an earlier time through reasonable diligence, the risks described herein.

COUNT IV
Public Nuisance

393. The State incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

394. Defendants, through their actions described throughout the Complaint, have created—or were a substantial factor in creating—a public nuisance by unreasonably interfering with a right that is common to the general public.

395. The State and its citizens have a public right to be free from the substantial injury to public health, safety, peace, comfort, and convenience that has resulted from Defendants' actions and omissions.

396. Defendants have interfered with the above enumerated right by creating a long-lasting and continuing public nuisance through distributing prescription opioids that they knew,

or reasonably should have known, were being overprescribed, misused, or abused while illegally failing to maintain appropriate controls over such distribution. By causing or substantially contributing to the opioid crisis in Vermont, Defendants have created an unreasonable public nuisance. Without Defendants' actions, opioid use would not have become so widespread in Vermont, and the opioid epidemic which the State now faces would have been averted or would be much less severe.

397. As a direct and proximate result of Defendants' actions and omissions, the State and its citizens suffered harms including, *inter alia*, the following:

- Normalization of over-prescribing and over-dispensing of prescription opioids by prescribers and pharmacists in the State;
- Increased availability and sales of prescription opioids, accompanied by increased diversion;
- Dependence and addiction to prescription opioids leading to escalation to non-prescription or "street" opioids such as heroin and fentanyl;
- Higher rates of opioid misuse, abuse, injury, overdose, and death, and their impact on Vermont families and communities;
- Heightened rates of opioid use disorder in pregnant women and resulting neonatal abstinence syndrome in their children;
- Increased health care costs for individuals, families, employers, and the State; and
- Greater demand for law enforcement, including the costs of treating prisoners with addiction.

398. Public resources have been, and are being, consumed in efforts to address the opioid epidemic, reducing the available resources that could be used to benefit the Vermont public at large.

399. At all times relevant, Defendants controlled the instrumentalities of the nuisance: distribution channels that moved prescription opioids from manufacturers to pharmacies in the

State and the systems (or lack thereof) for monitoring and identifying suspicious orders of prescription opioids and the protocols for halting, investigating, and reporting those orders.

400. At all times relevant, Defendants knew that prescription opioids are regulated controlled substances that have a high potential for abuse and may lead to severe psychological or physical dependence. Defendants were further aware—because they helped create it—that a national opioid epidemic had led to widespread addiction, overdoses, hospitalizations, and fatalities. The harms alleged herein were therefore foreseeable to Defendants as a direct and proximate result of their actions and omission. It was unreasonable for them to move prescription opioids from manufacturers to pharmacies and other dispensaries without systems in place to detect, investigate, halt, and report suspicious orders. It was also unreasonable for Defendants to fail to design and operate a system that would disclose the existence of suspicious orders of prescription opioids and to fail to report, investigate, and halt those orders, as required under Vermont law.

401. Defendants' actions and omissions were a material element in allowing prescription opioids to become available throughout the State on an unnecessary and dangerously large scale.

402. As a direct result of Defendants' misleading representations regarding their purported compliance with their duties to prevent diversion, the State was unaware of, and could not reasonably know or have learned at an earlier time through reasonable diligence, the risks described herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff State of Vermont respectfully requests the Court enter judgment in its favor and the following relief:

(A) A judgment in the State's favor and against Defendants on each cause of action asserted in the Complaint;

(B) With respect to Counts I and II, a permanent injunction prohibiting Defendants from engaging in the unfair and deceptive acts and practices described in the Complaint;

(C) With respect to Counts I and II, a judgment requiring Defendants to disgorge all funds acquired or retained as a result of any acts or practices found to be unlawful;

(D) With respect to Counts I and II, statutory penalties of $10,000 for each violation of the Vermont Consumer Protection Act;

(E) With respect to Count III, all damages allowable under common law;

(F) With respect to Count IV, an order providing for abatement of the nuisance that Defendants created or were a substantial factor in creating, enjoining Defendants from further conduct contributing to the nuisance, and damages as compensation for funds the State has already used to abate the nuisance;

(G) The award of investigative and litigation costs and fees, including attorneys' fees, to the State; and

(H) Such other, further, and different relief as this Court may deem appropriate.

JURY TRIAL DEMANDED

The State demands a trial by jury.

Dated: March 26, 2019

Respectfully submitted,

THOMAS J. DONOVAN JR.
ATTORNEY GENERAL

By: _____
Thomas J. Donovan Jr.

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Deputy Attorney General
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STATE OF VERMONT

SUPERIOR COURT
CHITTENDEN UNIT

CIVIL DIVISION
DOCKET NO.

STATE OF VERMONT,

Plaintiff,

v.

RICHARD S. SACKLER, BEVERLY SACKLER, DAVID A. SACKLER, ILENE SACKLER LEFCOURT, JONATHAN D. SACKLER, KATHE SACKLER, MORTIMER D. A. SACKLER, AND THERESA SACKLER,

Defendants.

COPY

COMPLAINT

The Vermont Attorney General brings this suit against Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler (collectively, the "Sacklers" or "Defendants") for violations of Vermont's Consumer Protection Act, unjust enrichment, and creating a public nuisance. Defendants have violated the Vermont Consumer Protection Act by engaging in unfair and deceptive trade practices, Purdue unjustly enriched themselves by accepting and keeping ill-gotten gains, and created a public nuisance in the State of Vermont through the deceptive marketing of opioids, for which the Attorney General seeks civil penalties, injunctive relief, disgorgement, fees and costs, and other appropriate relief.

INTRODUCTION

A. Defendants Succeeded in Mainstreaming Opioids Prescribing

1. For 20 years, Purdue Pharma L.P. ("Purdue"),[1] a privately-held company, has been a leading force in the prescription opioid market, both nationwide and in Vermont. During this time, the pharmaceutical giant Purdue manufactured, sold, and aggressively marketed prescription opioids, including the brand-name drugs OxyContin, Butrans, and Hysingla ER.

2. Before the 1990s, opioids were not widely prescribed because it was correctly believed that their use involved serious risks—including addiction, withdrawal, and overdose—that were not justified by the benefits. Opioids typically were used only to treat short-term, acute pain (*e.g.*, trauma and post-surgical) or for palliative care (*e.g.*, end-of-life) because they were considered too addictive and debilitating for long-term use. This prevailing medical and popular understanding operated as an appropriate constraint on the market for prescription opioids.

[1] Technically, Purdue is a group of three related companies: Purdue Pharma, L.P., Purdue Pharma Inc., and The Purdue Frederick Company.

and Vermont with disinformation about opioids. The Sacklers directed Purdue employees to get doctors to write more prescriptions for higher doses for more patients, and the company did exactly these things. And over the years, the Sacklers distributed billions of dollars earned from the sale of Purdue opioids to themselves and other family members.

6. Before the introduction of OxyContin in 1996, the opioid market was for post-surgical, end-of-life, or cancer pain. By 2012, opioids were among the most prescribed drugs; approximately 90% of prescription opioids were given for chronic pain conditions, and only 10% of prescription opioids were dispensed for post-surgical, palliative, and cancer pain treatments.[2] This was an almost complete reversal of long-standing medical practice.

7. According to the U.S. Centers for Disease Control and Prevention ("CDC"), nearly 62 million Americans received at least one opioid prescription in 2016.[3]

8. In the late 1990s, federal and state law enforcement agencies began investigating Purdue for deceptive marketing and misbranding. During the time period covered by the investigations, at least three Sackler board members were among the highest executives inside the company: Richard Sackler was Chief Executive Officer, and Jonathan and Kathe Sackler were Vice Presidents. As explained below, they were intimately involved in the launch of OxyContin and the marketing campaigns that led to the explosion of over-prescribing.

9. The investigations culminated in a series of settlements in 2007 under which Purdue and three of its executives pleaded guilty to federal criminal charges for deceptive conduct in the sale and marketing of opioids. Purdue paid more than $600 million to resolve the government

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[2] Laxmaiah Manchikanti *et al.*, *Opioid Epidemic in the United States*, 15 Pain Physician ES9-ES38, at ES27 (2012).

[3] Centers for Disease Control and Prevention, Annual Surveillance Report of Drug-Related Risks and Outcomes (2017), https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf, at 7.

3. Beginning in the late 1990s, Purdue set out to effect a sweeping change in the public and medical community's perception of opioids—by downplaying the risks and aggressively encouraging much broader use. Purdue orchestrated and enacted a plan of massive expansion—designed to change opioids' limited use from acute and palliative care to a wide-ranging and often front-line option for long-term, chronic conditions like back pain, migraines, and arthritis. Purdue executed this scheme at the direction of eight people in a single family that owned the company and controlled a majority of the seats on the company's board of directors: the Sacklers.

4. The Sacklers' ambition was to become unimaginably rich from the sale of opioids. To that end, they masterminded a strategy, carried out by Purdue, that changed the way the medical profession viewed opioid prescribing. The Sacklers exploited newly-emerging concerns in the profession that pain was an undertreated priority. Purdue helped to institutionalize this patient-centric shift, and then capitalized on the platform it had created to push its message that health care providers should prescribe more opioids to treat this undertreated chronic pain. Purdue designed an array of deceptive messages that reduced concerns about opioids generally, and that promoted Purdue's opioids specifically as safe, effective, and appropriate for long-term use and for moderate pain conditions. Purdue's massive marketing scheme, which occurred alongside similar efforts of other industry players, was profoundly successful at shifting the medical and public consensus regarding the use of opioids.

5. The Sacklers fully understood the addictive and dangerous qualities of the drugs they manufactured, but the risks presented by their drugs to individual consumers and public health did not constrain their marketing and promotional plans. The Sacklers shaped the marketing campaigns that Purdue carried out, and they set sales objectives. The Sacklers directed and approved the hiring of hundreds of workers to carry out their wishes and blanketed the country

enforcement actions. The Sacklers decided which executives would offer guilty pleas, approved the settlement agreements, and then drew back from their roles as employees of the company to serve exclusively on the Board of Directors. As described below, in the years that followed, the Sacklers approved several large payments—in the millions of dollars—to the executives who pled guilty. At the same time, the Sacklers continued to manage the Company's core business activities: marketing, sales, and product development.

10. Although Purdue made some concessionary adjustments to the marketing statements that had prompted its prosecution, it never stopped misrepresenting the risks and benefits of its blockbuster drug, OxyContin, and other opioids. Purdue failed to correct, and actually persisted in building upon and profiting from, its earlier deceptions and the platform of misunderstanding it had created. Even worse, Purdue began directing its deceptive marketing in pursuit of new target patients: specifically, it began focusing its efforts on the elderly and patients who had not previously used these powerful drugs (labeled by Purdue as the "opioid naïve").

11. From 2007 into 2018, the Sacklers charted a new—but equally crooked—course for Purdue. The Sacklers directed and approved the hiring of—and were involved in guiding the strategic opioid marketing plans of—a large sales force, which was directed to visit health care providers nationwide and in Vermont on a frequent basis and convince them to prescribe Purdue's opioids at increasing dosages and for longer periods of time. The specific messages that Purdue's sales representatives carried changed after 2007 but were still unfair and deceptive and consistently misrepresented the risks and benefits of OxyContin and Purdue's other opioids.

12. The Sacklers also devised several additional unconscionable schemes to fortify their market. First, they directed sales representatives to capture new initiates: the elderly and the opioid naïve (those who have not previously used these powerful drugs). Second, they directed

sales representatives to promote the routine and speedy escalation of doses—under the guise of "individualized dosing"—to increase sales of Purdue's more expensive products. And third, they directed sales representatives to promote and distribute "savings cards" that provided substantial price discounts not just for initial prescriptions but for a number of refills engineered to induce dependence and addiction.

13. The Sacklers met regularly as the Board of Directors and received detailed briefings from the staff on not just the company's finances, but on the size, distribution, daily activities, and compensation of the sales force. Over the years 2008–2017, the Sacklers approved routine increases in the number of sales representatives and increases to their compensation while delivering unequivocal orders to meet with prescribers more frequently, to concentrate special efforts on the most prolific prescribers, and to persuade all prescribers to write more opioid prescriptions, for longer periods of use, and at increasing doses. The Sacklers' communications were not limited to quarterly Board meetings. They were in touch with Purdue marketing employees on a regular and consistent basis.

14. The Sacklers' personal involvement in the running of the company was so long- and well-established that the effort, in 2017, to issue a press statement denying the family's involvement in the company's affairs was abandoned. The Sacklers' draft statement—"Sackler family members hold no leadership roles in the companies owned by the family trust"—was watered down to "Sackler family members hold no management positions."

15. The Sacklers are now poised to profit from the public health crisis that they created. Richard Sackler was awarded a patent in January 2018 for a new formulation of buprenorphine—one of the most effective drugs used to treat opioid addiction. In his patent application, Dr. Sackler described the background of his new invention:

17. The Hub-and-Spoke System is unique in its comprehensiveness and has been recognized nationally as "visionary."[6] Vermont's success is the result of state and local actors working cooperatively to design and implement a multi-faceted, cutting-edge approach to addressing opioid addiction that reaches even the most rural areas in the State.[7] Despite Vermont's success in developing and administering these programs, the problem of opiate addiction is overwhelming, and the demand for these treatment programs continues to increase. Vermont's Blueprint for Health reports that more than 6,000 Vermonters are participating in the Hub-and-Spoke System through the State's Medicaid program,[8] and additional Vermonters are treated in the Hub-and-Spoke System through private insurance and Medicare. Demand for opioid treatment in Vermont has continued to rise.[9] Vermont has engaged in an ongoing effort to keep up with the need and reduce wait times for patients seeking treatment.[10]

18. Vermont has elected to invest its treatment funds in evidence-based approaches, and is the nation's most proactive state at providing buprenorphine (a key component of Medication Assisted Treatment) to patients in need. The State averages 204 buprenorphine

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[6] Vermont Opioid Coordination Council, *Initial Report of Recommended Strategies* (January 2018), http://www.healthvermont.gov/sites/default/files/documents/pdf/OCC%202018%20Report%202018-1-9.Final_.pdf, at 3.

[7] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, *supra* n.5.

[8] Pat Bradley, *Vermont Governor Testifies in Washington on Opioid Treatment Programs* (Feb. 7, 2018), http://wamc.org/post/vermont-governor-testifies-washington-opioid-treatment-programs; State of Vermont, *Blueprint for Health*, http://blueprintforhealth.vermont.gov/about-blueprint/hub-and-spoke.

[9] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, *supra* n.5.

[10] Harry Chen, MD (Commissioner, Vermont Dept. of Health), *Status of Opioid Treatment Efforts* – Health Reform Oversight Committee (October 25, 2016), http://www.leg.state.vt.us/jfo/healthcare/Health%20Reform%20Oversight%20Committee/2016_10_25/Status%20of%20Opioid%20Treatment%20Efforts%20-%20Chen.pdf, at 11 ("Hub Census and Waitlist: September 26, 2016").

> Over the last decades, prejudices in the medical community as to the use of strong opioids for treating chronic pain in patients has significantly decreased. Many of these prejudices were due to some of the characteristics being inherent to opioids. While opioids have always been known to be useful in pain treatment, they also display an addictive potential in view of their euphorigenic activity. Thus, if opioids are taken by healthy human subjects with a drug seeking behavior, they may lead to psychological as well as physical dependence.

The application goes on to link addiction to crime before presenting his invention—in a shocking echo of OxyContin marketing—as less prone to diversion and abuse than other treatment drugs. Buprenorphine sales in the United States topped $2.6 billion in 2017 and are expected to rise as the infrastructure and funding for addiction treatment expands to meet current and projected needs.

B. Vermont Is Leading the Nation with Its Innovative and Effective Approach to Combating the Opioid Crisis

16. In 2012, Vermont passed legislation[4] authorizing its Department of Health to establish a state-wide integrated care system for opioid addiction treatment, creating the treatment "Hubs" (for high-intensity Medication Assisted Treatment and counseling) and "Spokes" (for treatment by a team consisting of Community Drug Addiction Treatment Act-waivered prescribers—which include physicians, nurse practitioners, and physician assistants—supported by a treatment team consisting of a nurse and a credentialed substance abuse counselor for every 100 persons receiving MAT).[5]

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[4] Act No. 135 (available at https://legislature.vermont.gov/assets/Documents/2012/Docs/ACTS/ACT135/ACT135%20As%20Enacted.pdf).

[5] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, March 2017 (available at http://www.healthvermont.gov/sites/default/files/documents/2017/03/ADAP_Opioid_Strategy_Brief.pdf).

members and others most likely to be present in the event of an overdose.[15] To date, more than 17,000 kits have been distributed at 30 sites in Vermont—all free of charge to the recipients. [16]

21. In August 2016, the Vermont Commissioner of Health issued a statewide, standing order authorizing every pharmacy to dispense naloxone to anyone—without a prescription.[17]

22. Statewide rules and protocols for Emergency Medical Services (EMS) personnel were changed in 2013 to allow EMT providers at all license levels to administer nasal naloxone. Additional legislation passed in 2016 allowed VDH to provide all EMS agencies and law enforcement entities with naloxone at no charge.[18]

23. In June 2013, the Vermont Legislature passed Act 75 which, among other things, mandated every health care provider who prescribes or dispenses any Schedule II, III, or IV controlled substances to register for and use the Vermont Prescription Monitoring System (VPMS).[19] This law was amended in 2016, through Act 173, to increase the mandatory reporting frequency for dispensers from at least once per week to daily.[20] Today, when a prescription is

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[15] Vermont Department of Health, *Naloxone Pilot Project – Data Brief* (April 18, 2014), https://legislature.vermont.gov/assets/Documents/2014/WorkGroups/House%20Human%20Services/Bills/S.295/Witness%20Testimony/S.295~Barbara%20Cimaglio~Naloxone%20Pilot%20Project%20%E2%80%93%20Data%20Brief~4-24-2014.pdf.

[16] Vermont Opioid Coordination Council, *Initial Report of Recommended Strategies, supra* n.6, at 30; Naloxone Distribution and Administration in Vermont – Data Brief, updated May 2018, http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Naloxone_Data_Brief_0.pdf.

[17] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders* (March 2017), *supra* n.5.

[18] *Id.*

[19] Act No. 75. An act relating to strengthening Vermont's response to opioid addiction and methamphetamine abuse. (H. 522) (2013), http://www.leg.state.vt.us/docs/2014/Acts/Act075.PDF.

[20] Act. No. 173, An act relating to combating opioid abuse in Vermont. (S. 243) (2016), https://legislature.vermont.gov/assets/Documents/2016/Docs/ACTS/ACT173/ACT173%20As%20Enacted.

prescriptions per 1,000 persons, which is 524% higher than the national average of 39 per 1,000.[11] Vermont also leads the nation in funding access to buprenorphine for its citizens. Medicaid funding is used by patients filling over 68% of the total buprenorphine prescriptions in Vermont—nearly 3x the national average of 24.2%.[12]

19. Vermont also has elevated its outreach to high-risk patients for comprehensive, specialty support. Pregnant women are eligible for not simply treatment, but also for supportive programming, including housing and transportation, which can vastly improve health outcomes for mothers and infants.[13] The State has been providing up to 120 days of addiction treatment to inmates and has pioneered efforts to divert low-level drug offenders from prosecution and incarceration if they agree to treatment shortly after arrest. As of July 1, 2018, all Vermont inmates who enter the correctional system on Medication-Assisted Treatment and/or are diagnosed with opioid use disorder will continue to be provided with Medication-Assisted Treatment while incarcerated, for as long as treatment is medically necessary.[14]

20. In December 2013, the Vermont Department of Health launched an overdose reversal pilot project to distribute naloxone to people at risk for overdose, along with their family

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[11] IMS Institute for Healthcare Informatics, *Use of Opioid Recovery Medications* (September 2016), https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/use-of-opioid-recovery-medications.pdf, at 5.

[12] *Id.*

[13] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders, supra* n.5, at 7.

[14] S. 166, An act relating to the provision of medication-assisted treatment for inmates, https://legislature.vermont.gov/assets/Documents/2018/WorkGroups/House%20Corrections%20and%20Institutions/Bills/S.166/S.166~Ed%20Paquin%20~As%20Introduced,%201-31-2018~3-29-2018.pdf.

Health also produced Public Service Announcements to promote the safe use, safe storage, and safe disposal of prescription drugs and promote naloxone to prevent overdose deaths.[23]

26. Additionally, the Vermont Department of Health launched ParentUpVT.org, which provides strategies and actions for parents and caregivers to help prevent drug use among youth. And the State is establishing educational campaigns to increase the perception of risk associated with prescription pain reliever misuse and increase awareness on the responsible use of prescription pain relievers.[24]

27. Yet, much more remains to be done. The cost and effort of remediating the opioid crisis require tremendous resources and persistence. For decades, Purdue—with the Sacklers at its helm—cultivated the demand for its opioids and opioids generally, and profited from their overprescribing, misuse, and abuse. The State has filed this lawsuit to expose the misconduct of the individual members of the Sackler family—because the public deserves to know how it has been deceived, and because it is not sufficient for the corporate entity to be held accountable when individuals who steered, directed, and profited from the company's misdeeds were also personally involved in the misconduct. The Sacklers should be required to pay their share of the extraordinary costs required to abate the opioids crisis.

28. Purdue's success in promoting opioids is particularly astonishing in light of the efforts Vermont had made to curb the influence of drug manufacturers on prescribing. In 2009, Vermont passed a law banning gifts from manufacturers of prescription drugs and products to health care professionals and providers. *See* Vt. Stat. Ann. tit. 18 § 4631a. These prohibitions include a ban on any payment, food, entertainment, travel, subscription, service, or anything else

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[23] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, *supra* n.5.

[24] *Id.*

dispensed to a patient, information about the drug, recipient, prescriber, and pharmacy is uploaded into VPMS within 24 hours so that this data can be tracked and monitored, which improves a prescriber's ability to detect abuse and diversion. The Vermont Department of Health works to ensure compliance with data uploading and data quality.[21]

24. Act 75 also required professional licensing authorities for healthcare providers to develop evidence-based standards to guide them in the prescription of Schedule II, III, and IV controlled substances for the treatment of chronic pain, which was later supplemented by Act 173 to include development of guidelines for treatment of acute pain. Act 173 also created the Controlled Substances and Pain Management Advisory Council to advise the Department of Health on the drafting of guidelines for prescribing opioids for acute and chronic pain. Rules for responsible prescribing of opioids for chronic and acute pain were finalized in December 2016. The rules provide information to prescribers on appropriate treatment of pain and guidance on how to reduce the likelihood of drug dependence. Importantly, the rules require prescribers to consider non-opioid alternatives before prescribing opioids and to re-evaluate treatment at least every 90 days, if not more frequently.[22]

25. Finally, the State has undertaken many initiatives to increase public awareness and education about the dangers of opioids. The Vermont Department of Health launched Vermont's Most Dangerous Leftovers campaign in 2014, to increase awareness of the safe use, safe storage, and proper disposal of prescription drugs, including promoting the "Vermont 2-1-1" informational telephone line as a source to find local drug disposal sites. The Department of

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[21] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, *supra* n.5.

[22] Vermont Department of Health, Rule Governing the Prescribing of Opioids for Pain, July 1, 2017, R. §§ 6.2, 6.2.1, 6.2.1.1, 6.2.2.

with the marketing of opioids; and disgorge the ill-gotten gains they reaped from Purdue's opioids revenue.

PARTIES

A. Plaintiff

31. The State of Vermont brings this action by and through its Attorney General, Thomas J. Donovan Jr., who is authorized to represent the State in all civil matters at common law and as allowed by statute. 3 V.S.A. § 152. The Attorney General is charged with the responsibility of enforcing the state laws at issue, including the Consumer Protection Act ("CPA") and all regulations promulgated thereunder. 9 V.S.A. § 2458.

32. The Attorney General also has standing on behalf of the State as *parens patriae* to protect the health and well-being, both physical and economic, of its residents. Opioid use and abuse have affected a substantial segment of the population of Vermont.

B. Defendants

33. Defendant Dr. Richard S. Sackler became a member of the Purdue board in 1990 and became its Co-chair in 2003, a position in which he remained until he left the board in 2018. He was also Purdue's head of research and development from at least 1990 through 1999 and its President from 1999 through 2003. At all times material to this Complaint, acting alone or in concert with others, Richard Sackler was personally aware of, was responsible for, engaged in, or directed the deceptive and unconscionable acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, Richard Sackler approved and oversaw deceptive and unconscionable conduct that was purposely directed at Vermont and gave rise to the State's claims as alleged in this Complaint. He resides in New York, Florida, and Texas.

34. Defendant Jonathan D. Sackler was a member of Purdue's board from 1990 through 2018. At all times material to this Complaint, acting alone or in concert with others, Jonathan

of value with limited exceptions for things like research grants and teaching honoraria that must be disclosed to the Attorney General's Office.[25] But Purdue did not rely exclusively on gifts to persuade doctors. Purdue used front groups disguised as independent patient advocacy organizations, paid spokespeople disguised as experts, and biased studies disguised as legitimate academic research to reach doctors and patients. It is important that all of this conduct be exposed.

29. Even today, the Sacklers seek to obscure their own culpability for this crisis, as set forth in Section F. The Sacklers have tried to distance themselves from their company and have directed Purdue to distance itself from its past misconduct. Purdue attempts to portray itself as a responsible corporate citizen by falsely portraying the opioid epidemic as mainly a problem of illicit drug diversion and abuse. But the genesis of this crisis can be placed squarely on Purdue's doorstep, and more accurately, in the Sacklers' mailbox. The Sacklers directed and approved the corporate entity's efforts to change the medical consensus and public perception about the inherent dangers of opioids were tremendous in their scope, strategy, and success.

30. The Sacklers' specific unfair and deceptive conduct detailed herein, which fomented and perpetuates the opioid crisis, has violated and continues to violate Vermont law. To achieve redress for Defendants' misconduct, the Attorney General of Vermont seeks an Order requiring the Sacklers to permanently cease their unlawful promotion of opioids; to correct the deceptive statements previously made by the corporate entity at their direction or with their approval under their governance; to abate the public nuisance their conduct has created, pay civil penalties for their continuous, pervasive, deceptive and unfair business practices in connection

[25] 18 V.S.A. § 4631a.

Purdue's Board of Directors, Mortimer Sackler approved and oversaw deceptive and unconscionable conduct that was purposely directed at Vermont and gave rise to the State's claims as alleged in this Complaint. He resides in New York.

38. Defendant Beverly Sackler was a member of Purdue's board from 1993 through 2017. At all times material to this Complaint, acting alone or in concert with others, Beverly Sackler was personally aware of, was responsible for, engaged in, or directed the deceptive and unconscionable acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, Beverly Sackler approved and oversaw deceptive and unconscionable conduct that was purposely directed at Vermont and gave rise to the State's claims as alleged in this Complaint. She resides in Connecticut.

39. Defendant Theresa Sackler was a member of Purdue's board from 1993 through 2018. At all times material to this Complaint, acting alone or in concert with others, Theresa Sackler was personally aware of, was responsible for, engaged in, or directed the deceptive and unconscionable acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, Theresa Sackler approved and oversaw deceptive and unconscionable conduct that was purposely directed at Vermont and gave rise to the State's claims as alleged in this Complaint. She resides in New York and the United Kingdom.

40. Defendant David A. Sackler was a member of Purdue's board from 2012 through 2018. For the period 2012 through 2018, acting alone or in concert with others, David Sackler was personally aware of, was responsible for, engaged in, or directed the deceptive and unconscionable acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, David Sackler approved and oversaw deceptive and unconscionable conduct that was purposely directed

Sackler was personally aware of, was responsible for, engaged in, or directed the deceptive and unconscionable acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, Jonathan Sackler approved and oversaw deceptive and unconscionable conduct that was purposely directed at Vermont and gave rise to the State's claims as alleged in this Complaint. He resides in Connecticut.

35. Defendant Ilene Sackler Lefcourt was a member of Purdue's board from 1990 to 2018. At all times material to this Complaint, acting alone or in concert with others, Ilene Sackler Lefcourt was personally aware of, was responsible for, engaged in, or directed the deceptive and unconscionable acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, Ilene Sackler Lefcourt approved and oversaw deceptive and unconscionable conduct that was purposely directed at Vermont and gave rise to the State's claims as alleged in this Complaint. She resides in New York.

36. Defendant Dr. Kathe A. Sackler was a member of Purdue's board from 1990 through 2018. At all times material to this Complaint, acting alone or in concert with others, Kathe Sackler was personally aware of, was responsible for, engaged in, or directed the deceptive and unconscionable acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, Kathe Sackler approved and oversaw deceptive and unconscionable conduct that was purposely directed at Vermont and gave rise to the State's claims as alleged in this Complaint. She resides in New York and Connecticut.

37. Defendant Mortimer D.A. Sackler was a member of Purdue's board from 1993 through 2018. At all times material to this Complaint, acting alone or in concert with others, Mortimer Sackler was personally aware of, was responsible for, engaged in, or directed the deceptive and unconscionable acts or practices set forth in this Complaint. As a member of

life—were proven, even though Purdue had no evidence to support these assertions.[26] By the mid-2000s, Purdue had succeeded in drastically changing medical and public opinion about opioids. Purdue's marketing convinced prescribers, educators, and patients that opioids were safe and effective for long-term use and also that they were an appropriate, first-line treatment for routine chronic pain conditions.

45. During this entire period, the Sacklers held a majority of the seats on the Board of Directors. Three of the Defendants—Richard, Kathe, and Jonathan Sackler—were high-ranking executives in the company until 2003. Richard was not only the Chief Executive Officer of the company between 1999 and 2003, but he had served as the head of research and development from 1990 to 1999. A fourth family member, the father of Defendant Mortimer D.A. Sackler, was also a senior Vice-President in the company during this time period. The other Sacklers were less visible, but no less culpable. As described below, as members of the Board they shaped the company's deceptive marketing strategies, received detailed reports on the implementation of those strategies, and continued to sanction this conduct, month after month and year after year. From these positions—as Board members and high-ranking executive employees of Purdue—the Sacklers were personally aware of, condoned and directed, and were responsible for the deceptive and unfair marketing activities described below.

1. Purdue Mainstreamed Opioids for Chronic Pain

46. Purdue marketed its opioids directly to health care providers and patients, nationwide and in Vermont. Purdue's sales representatives, also known as "detailers," made

[26] Centers for Disease Control and Prevention, *Guideline for Prescribing Opioids for Chronic Pain* (2016), https://www.cdc.gov/drugoverdose/prescribing/guideline.html (hereafter, "CDC Guideline"), at 2, 20, 25. (confirming, based on existing research and evidence, that opioid use presents a "serious risk" of addiction, use for three months or more "substantially increases" that risk, and there never has been "good evidence that opioids improve pain or function with long-term use").

at Vermont and gave rise to the State's claims as alleged in this Complaint. He resides in New York.

JURISDICTION AND VENUE

41. The Court has personal jurisdiction over Defendants because they purposely directed business activities into Vermont that gave rise to the claims in this case and that resulted in unlawful practices in Vermont and against Vermont consumers.

42. Defendants generated millions of dollars of revenue through sales of Purdue opioid pain medications in Vermont. Defendants approved and participated in the marketing strategy that authorized the hiring and compensation of at least 24 different Purdue sales representatives and sales managers in Vermont between 2007 and 2018. In that period, Purdue's Vermont sales force made more than 10,000 sales visits regarding OxyContin and other Purdue opioids to Vermont health care providers.

43. Venue in this Court is proper, pursuant to 9 V.S.A. § 2458(a), because Defendants directed business into Chittenden County. Among other things, Purdue made nearly 2,000 sales visits regarding opioids to health care providers in Chittenden County during the years covered by this Complaint.

GENERAL ALLEGATIONS COMMON TO ALL COUNTS

A. Cementing the Foundation: From the Late 1990s to 2007, Purdue – with the Sacklers at Its Helm – Engaged in a Campaign of Deception to Create and Sustain a Market for Its Opioids

44. Beginning in 1996, Purdue presented OxyContin—and later its other opioids—as the solution to the problem of chronic pain. (As used in this Complaint, "chronic pain" means non-cancer pain lasting twelve weeks or longer.) Through marketing that was as pervasive as it was deceptive, Purdue convinced health care providers that the risks of long-term opioid use were overblown and also that the alleged benefits—reduced pain, improved function, and quality of

distributed directly to prescribers. These advertising campaigns deceptively underplayed the risks and overemphasized benefits of chronic opioid therapy. For example, in 1998 and 2000, Purdue distributed to doctors thousands of copies of videos, titled "I Got My Life Back," which made the unsubstantiated claim that opioid addiction occurred in less than 1% of patients.[30] In 2003, FDA warned Purdue about advertisements Purdue paid to run in the *Journal of the American Medical Association*, expressing concern that they would lead to ill-considered prescribing of OxyContin because the body of the advertisement text nowhere referred to the "serious, potentially fatal risks associated with OxyContin."[31] In 2005, Purdue also paid to run an advertisement that ran in pain journals that misleadingly implied long-term improvement in patients' pain, function and quality of life, touting OxyContin as an "around-the-clock analgesic . . . for an extended period of time" and featuring a man and a boy fishing under the tagline "There Can Be Life With Relief."

49. Purdue's advertising also included the claim that OxyContin provides "Consistent Plasma Levels Over 12 Hours."[32] That claim was accompanied by a chart, shown below, that depicted plasma levels on a logarithmic scale. However, this presentation visually distorted and obscured the steep decline in OxyContin's efficacy over 12 hours, by depicting 10 milligrams in a way that it appeared to be half of 100 milligrams in the table's y-axis, falsely making the absorption rate appear more steady or consistent over 12 hours:

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[30] United States General Accounting Office Report to Congressional Requesters, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, December 2003, https://www.gao.gov/products/GAO-04-110, at 27.

[31] Letter from Thomas Abrams, Dir. FDA Div. of Drug Mktg., Advert. and Commc'n, to Michael Friedman, Exec. Vice President and Chief Operating Officer, Purdue Pharma L.P. (Jan. 17, 2003).

[32] Jim Edwards, *How Purdue Used Misleading Charts to Hide OxyContin's Addictive Power*, CBSNews.com (Sept. 28, 2011), http://www.cbsnews.com/news/how-purdue-used-misleading-charts-to-hide-oxycontins-addictive-power/.

thousands of in-person sales calls to Vermont healthcare providers in which they misleadingly portrayed opioids as safe, effective, and appropriate for the treatment of chronic pain. In Vermont especially, Purdue targeted generalists—primary care physicians, nurse practitioners, and physician assistants—as opposed to other healthcare professionals with specialized training and knowledge about the use and risks of opioids. Purdue's deceptive marketing created a cadre of primary care doctors, nurse practitioners, and physician assistants who were "educated" by Purdue's sales representatives and marketing literature to look for pain and to treat it with opioids. This, in turn, created a patient population that came to expect and specifically request opioids.

47. Purdue misrepresented key facts about the safety of its opioids—in particular, the risk of addiction. Purdue admitted, in 2007, that its sales representatives, as a matter of course:

- falsely told health care providers that OxyContin had a less euphoric effect, and less abuse potential, than short-acting opioids;[27]
- falsely told prescribers that OxyContin—the first "extended-release," a/k/a "long-acting" ("ER/LA") opioid—had fewer "peak and trough" effects than short-acting opioids, also known as immediate release ("IR") opioids;[28]
- falsely told prescribers that patients could discontinue OxyContin therapy abruptly without experiencing withdrawal symptoms; and
- falsely told prescribers that OxyContin was more difficult to abuse intravenously than generic oxycodone.[29]

48. In addition to making deceptive claims through its sales force, Purdue also widely advertised OxyContin, including in print advertisements in medical journals and in videos

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[27] Agreed Statement of Facts, *U.S. v. The Purdue Frederick Company, Inc.*, May 9, 2007, at 6; Press Release, U.S. Attorney's Office, Western District of Virginia, The Purdue Frederick Company, Inc. and Top Executives Plead Guilty to Misbranding OxyContin, Will Pay Over $600 Million (May 10, 2007), https://media.defense.gov/2007/May/10/2001711223/-1/-1/1/purdue_frederick_1.pdf, at 3.

[28] *Id.* at 6.

[29] *Id.* at 6.

(incorrectly) that the materials were published by neutral researchers, clinicians, and legitimate patient advocacy groups.

51. As part of its unbranded marketing scheme, Purdue recruited and paid physicians to make presentations on opioids to their peers at lunch and dinner events. It funded the biased research that formed the basis of these presentations and sponsored Continuing Medical Education programs ("CMEs") that misleadingly portrayed the risks and benefits of chronic opioid therapy. Purdue collaborated with professional associations and pain advocacy organizations, such as the American Pain Foundation, to develop and disseminate pro-opioid educational materials and guidelines for prescribing opioids.

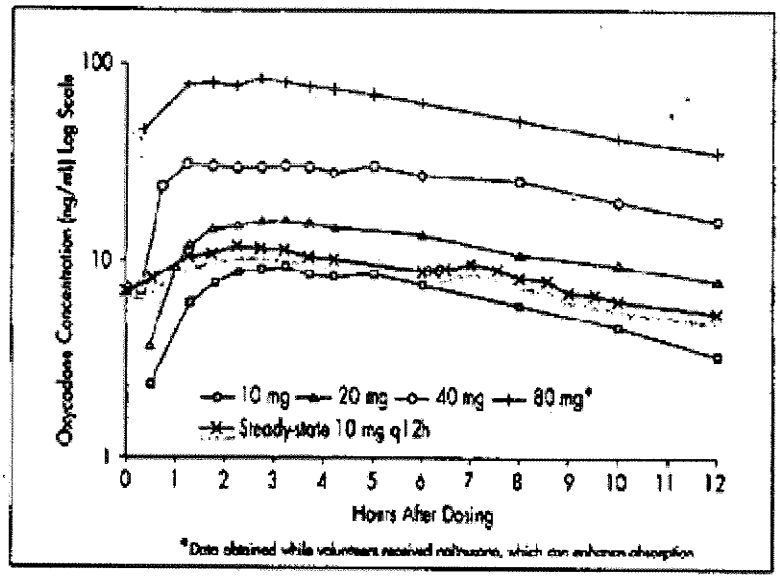
52. Purdue had a particularly close relationship with the American Pain Foundation ("APF"), which was highly dependent on pharmaceutical company funding and produced numerous publications touting the use of opioids to treat chronic pain. Purdue was APF's second-biggest donor, with donations totaling $3.6 million between 1999 and 2012. As early as 2001, Purdue grant letters informed APF that the contributions reflected Purdue's effort to "strategically align our investments in nonprofit organizations that share our business interests," making clear that funding depended on APF continuing to support Purdue's objectives. Purdue also engaged APF as a paid consultant on various initiatives.

53. Purdue created a range of unbranded materials—from websites to glossy pamphlets—that were copyrighted by Purdue but on their face implied that the recommendations and research contained therein were the work of independent organizations with names like *Partners Against Pain.* Purdue ensured that these unbranded materials supported Purdue's branded marketing efforts to promote the use of opioids.

For moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time

Consistent Plasma Levels Over 12 Hours

Plasma concentrations (ng/mL) over time of various dosage strengths



- **OxyContin® 80 and 160 mg Tablets FOR USE ONLY IN OPIOID-TOLERANT PATIENTS requiring minimum daily oxycodone equivalent dosages of 160 mg and 320 mg, respectively. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids**

Steady state achieved within 24 to 36 hours

In fact, OxyContin works by releasing a greater proportion of oxycodone (about 40%) into the body when administered, followed by a steep decline over the subsequent hours.[33]

2. Purdue's Pervasive and Deceptive Unbranded Marketing

50. In addition to its branded marketing efforts that showcased specific Purdue opioids, Purdue also undertook or financially supported a number of "unbranded" marketing initiatives that were designed to promote opioids generally, and to convey Purdue's key messages about opioids without properly disclosing that Purdue created, funded, directed, or was in any way involved with these endeavors. Purdue intended patients and prescribers to read these materials and to perceive

[33] New Zealand Ministry of Medicine Data Sheet (http://www.medsafe.govt.nz/Profs/Datasheet/o/OxyContintab.pdf); *How Purdue Used Misleading Charts to Hide OxyContin's Addictive Power*.

movement, and in turn they promoted the aggressive treatment of chronic pain, especially with opioids.

57. Purdue already had laid the groundwork for this strategy by financially supporting researchers who were willing to advocate for the expanded use of opioids without adequate scientific support. Chief among these was Dr. Russell Portenoy, who wrote a seminal 1986 paper supporting chronic opioid therapy while receiving Purdue funding and serving as Purdue's consultant. Dr. Portenoy concluded—based on a review of just 38 patients—that "opioid maintenance therapy can be a safe, salutary and more humane alternative" to not treating patients with chronic pain.[35]

58. Dr. Portenoy's promotion of opioids for chronic pain lacked scientific support. As reported by *The Wall Street Journal* on December 17, 2012, Dr. Portenoy admitted to spreading misinformation. The article includes a quotation from a 2010 videotaped interview of Dr. Portenoy by another doctor in which he said that he gave "innumerable lectures in the late 1980s and '90s about addiction that weren't true." The assertions made by Dr. Portenoy and his followers included that opioids were easy to discontinue.

59. Beginning in 1995, the American Pain Society ("APS"), of which Dr. Portenoy later would become president, launched a national campaign to make pain a "vital sign"—an indicator doctors should monitor alongside blood pressure, temperature, heartbeat, and breathing. Purdue provided substantial funding to APS both to promote pain awareness generally and, on information and belief, to support the group's "Pain as the 5th Vital Sign" campaign. The Veterans

[35] Russell K. Portenoy & Kathleen M. Foley, *Chronic use of opioid analgesics in non-malignant pain: report of 38 cases*, 25(2) Pain 171-86 (May 1986).

54. Among these tactics, all of which originated in the late 1990s and early 2000s, three stand out for their lasting influence on opioid prescribing nationwide and in Vermont: Purdue's capture, for its own ends, of healthcare providers' increased focus on pain treatment; Purdue's efforts to seed the scientific literature on chronic opioid therapy; and Purdue's corrupting influence on authoritative treatment guidelines issued by professional associations.

55. As described in more detail below, the Defendants were personally aware of, engaged in, and responsible for Purdue's decisions to invest in unbranded promotion through third parties. They approved budgets for grants to the professional associations and advocacy groups and received reports on the relationships and effectiveness of the communications that the associations and groups undertook. [redacted]

a. Co-opting the Medical Community's Focus on Pain

56. As Purdue marketed OxyContin in the late 1990s, it both capitalized on and co-opted a movement in the medical community to make pain identification and treatment a priority for all patients. Purdue provided financial support to the organizations and people leading the

[34] [redacted]

62. Vermont health care providers interviewed by the State recall learning about "Pain as the Fifth Vital Sign" and the importance of treating pain, through training and medical literature, during the 1990s and early 2000s. Many of these providers credit such initiatives with driving an increased focus on treatment of pain and increased use of opioids but did not know that Purdue had played a key role in launching these initiatives.

b. Corrupting the Science Regarding Opioids with Flawed and Biased Research

63. Rather than rigorously test the safety and efficacy of opioids for long-term use, Purdue created scientific support for its marketing claims by sponsoring studies that were methodologically flawed, were biased, and drew inappropriate conclusions from prior evidence. These studies, once published, formed a seemingly objective, research-based foundation for liberalized opioid prescribing and were cited in subsequent studies, resulting in an incomplete, inaccurate, and deceptive body of literature on which other researchers, and then ultimately physicians, relied.

64. Some of these methodologically flawed studies made unsubstantiated claims that the risk of psychological dependence or addiction is <u>low</u> in opioid use, absent a patient history of substance abuse.[38] One such study making this claim, published in the journal *Pain* in 2003 and widely referenced since (with more than 600 citations in Google Scholar),[39] ignored existing

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[38] Seddon R. Savage *et al.*, *Definitions related to the medical use of opioids: Evolution towards universal agreement*, 26 J. Pain and Symptom Mgmt. 1:655-667 (2003); Watson, C. Peter N., *et al.*, *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy*, 105 Pain 71 (2003).

[39] C. Peter N. Watson *et al.*, *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy*, 105 Pain 71 (2003).

Health Administration adopted this concept in its facilities nationwide in 1999, and "Pain as the 5th Vital Sign" spread from there to the private sector.

60. In 2001, Joint Commission on the Accreditation of Healthcare Organizations ("JHACO") issued pain treatment standards requiring the assessment of pain in all patients and in each physician-patient interaction and made hospital accreditation decisions contingent on adherence to those standards. Purdue worked closely with JCAHO to promote the pain standards and JCAHO licensed Purdue—exclusively—to distribute educational videos about how to comply with the new pain management standards.[36] Purdue also sponsored various guides for implementing the JCAHO standards, such as *Pain Assessment and Management: An Organizational Approach.* This book promoted the use of opioids, claiming that "[s]ome clinicians have inaccurate and exaggerated concerns about addiction, tolerance, respiratory depression, and other opioid side effects . . . . despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control." (Emphasis added.) JCAHO distributed the book to hospital officials and physicians nationwide at a series of Purdue-sponsored "leadership summits" on pain management.[37]

61. Both the APS "Pain as the 5th Vital Sign" campaign and the JCAHO pain standards were widely integrated into medical practice. Although the JCAHO standards were developed to apply strictly in hospital settings, they influenced the entire medical profession through hospital-based residency training.

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[36] United States General Accounting Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* n.30, at 23.

[37] American Pain Society Press Release, 10-May-2000, *National summit on pain management to discuss new standards for pain assessment and treatment*, https://www.eurekalert.org/pub_releases/2000-05/PN-Nsop-1005100.php; United States General Accounting Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* n.30, at 23.

research showing actual addiction rates between 8% and 13%,[40] and instead relied heavily on a 1980 letter to the editor—not a peer-reviewed study or in-depth article, but a letter—in the *New England Journal of Medicine*. That letter, J. Porter & H. Jick, "Addiction Rare in Patients Treated with Narcotics," 302(2) New Eng. J. Med. 123 (1980) ("Porter-Jick Letter"), is reproduced below:

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

65. The Porter-Jick Letter does not reflect any study, but simply describes a review of the charts of hospitalized patients who had received opioids. One of the authors of the letter[41] and

[40] *See, e.g.*, Lawrence Robbins, *Long-Acting Opioids for Severe Chronic Daily Headache*, 10(2) Headache Q. 135 (1999); Lawrence Robbins, *Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache*, 19 Headache Q. 305 (1999).

[41] NPR, *Doctor Who Wrote 1980 Letter on Painkillers Regrets That It Fed The Opioid Crisis* (June 16, 2017), http://www.npr.org/sections/health-shots/2017/06/16/533060031/doctor-who-wrote-1980-letter-on-painkillers-regrets-that-it-fed-the-opioid-crisis.

the *New England Journal of Medicine*[42] have repudiated the misuse of the Porter-Jick letter, but it became a mainstay in scientific literature in large part due to Purdue's efforts,[43] with more than 1,000 citations in Google Scholar.[44]

c. Funding and Influencing Professional Associations

66. Treatment guidelines directly inform doctors' prescribing practices, are cited throughout the scientific literature, and are referenced by third-party payors when determining which prescriptions should be covered by insurance. Purdue financed and collaborated with three groups in particular on guidelines that have been, and continue to be, broadly influential in Vermont and nationwide: the American Academy of Pain Medicine (AAPM), the American Pain Society (APS), and the Federation of State Medical Boards (FSMB).

AAPM/APS Guidelines

67. The American Academy of Pain Medicine and American Pain Society each received substantial funding from Purdue. From 2009 to 2012, Purdue gave APS nearly $500,000, and AAPM more than $400,000. An internal Purdue request to its CEO for approval of "2009 funds for AAPM and APS proposals" described each group as "one of our top tiered organizations."

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[42] *Editor's Note* (added May 31, 2017), available at http://www.nejm.org/doi/10.1056/NEJM198001103020221.

[43] Purdue, for example, has cited it in support of Purdue's patently false marketing claim that "less than 1%" of opioid patients become addicted, most prominently in its 1998 "I Got My Life Back" video. Yet Purdue failed to disclose both the nature of the citation (a letter, not a study) and any of its serious limitations.

[44] Purdue has also relied upon the Porter-Jick letter in its marketing efforts. Purdue, for example, has cited it in support of Purdue's patently false marketing claim that "less than 1%" of opioid patients become addicted, most prominently in its 1998 "I Got My Life Back" video. Yet Purdue failed to disclose both the nature of the citation (a letter, not a study) and any of its serious limitations. *See* OxyContin Promotional Video, "I got my life back," Purdue Pharma L.P. (1998), https://www.youtube.com/watch?v=Er78Dj5hyeI.

68. In 1997, AAPM and APS issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," that endorsed using opioids to treat chronic pain and claimed that the risk of patients becoming addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was, at the time, a paid speaker for Purdue and shortly thereafter became a senior executive for the company. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained, though it lingers on the Internet elsewhere.[45]

69. AAPM and APS also issued a 2001 set of recommendations, titled "Definitions Related to the Use of Opioids for the Treatment of Pain," which advanced the unsubstantiated (and since discredited) concept of "pseudoaddiction." The term, coined by Dr. Haddox in a 1989 journal article, reflects the idea that signs of addiction may actually be the manifestation of undertreated pain and will resolve once the pain is effectively treated—*i.e.*, with more or higher doses of opioids.[46] The 2001 AAPM/APS recommendations asserted that "clock-watch[ing]," "drug seeking," and "[e]ven such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain [pain] relief." The lack of evidentiary support for this definition has since been exposed and the treatment approach has been definitively discredited.[47]

70. In 2009, AAPM and APS issued comprehensive opioid prescribing guidelines ("2009 AAPM/APS Guidelines"), drafted by a 21-member panel, that promoted opioids as "safe

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[45] Available for purchase at http://journals.lww.com/clinicalpain/toc/1997/03000.

[46] David E.Weismann & J. David Haddox, *Opioid pseudoaddiction—an iatrogenic syndrome*, 36 Pain 363-366 (1989).

[47] The CDC Guideline makes clear that the scientific literature does not support the concept of pseudoaddiction, explaining that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," (CDC Guideline, *supra* n.26, at 13) and that physicians should "reassess[] pain and function within 1 month" to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit" (CDC Guideline, *supra* n.26, at 25).

and effective" for treating chronic pain. The panel made "strong recommendation[s]" regarding management of chronic opioid therapy, even while acknowledging "low quality evidence," to support its positions, and it concluded that the risk of addiction is manageable for patients, even patients with a prior history of drug abuse. Six of the panel members, including Dr. Portenoy, received financial backing from Purdue, and another eight received funding from other opioid manufacturers.[48]

71. The 2009 AAPM/APS Guidelines were reprinted in the *Journal of Pain* and widely distributed nationally.[49] The guidelines have been a particularly effective channel of deception and, in addition to influencing prescribers, they have now been cited nearly 1,700 times in academic literature.

FSMB Guidelines

72. The Federation of State Medical Boards ("FSMB") is an association of the various state medical boards in the United States. The state boards that comprise the FSMB membership, including Vermont's, have the power to license doctors, investigate complaints, and discipline physicians. The FSMB has financed opioid- and pain-specific programs through grants from pharmaceutical manufacturers, including more than $800,000 from Purdue between 2001 and 2008.

73. In 1998, the FSMB developed its *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which the FSMB acknowledged were produced "in collaboration with" pharmaceutical companies and allied groups such as the

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[48] *See* John Fauber, *Chronic Pain Fuels Boom in Opioids*, Milwaukee Journal Sentinel (Feb. 19, 2012), https://www.medpagetoday.com/neurology/painmanagement/31254.

[49] Roger Chou *et al.*, *Opioid Treatment Guidelines, Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, The Journal of Pain, Vol 10, No 2 (February), 2009: pp 113-130.

American Pain Society (a professional society that received funding from Purdue). The FSMB Guidelines stated that opioids "may be essential" for treatment of both acute and chronic pain, but failed to mention risks of respiratory depression and overdose death; addressed addiction only to define the term as separate from physical dependence; and stated that an "inadequate understanding" of addiction can lead to "inadequate pain control."

74. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from them, *Responsible Opioid Prescribing*, repeated the 1998 version's claims. The book also stated that opioids would improve patients' function and included the now-discredited concept of pseudoaddiction, suggesting that signs of addiction may actually reflect undertreated pain that should be addressed with more opioids.

75. *Responsible Opioid Prescribing* was sponsored by Purdue, among other opioid manufacturers, and Purdue had editorial input into its contents. In particular, Dr. David Haddox, by then employed directly by Purdue, edited the book to ensure that pseudoaddiction was presented as an accepted medical concept. Dr. Scott Fishman, however, is listed as the book's sole author. Purdue's relationship with Fishman was such [redacted]

76. Through at least 2015, the FSMB website described the book (a Second Edition of which was republished in 2012) as the "leading continuing medical education (CME) activity for prescribers of opioid medications." Purdue provided an "educational grant" of $100,000 in 2007—

[50] [redacted]

sponsored internally by David Haddox—to support FSMB's distribution of *Responsible Opioid Prescribing* to physicians nationwide through state medical boards.

77. The FSMB Guidelines and *Responsible Opioid Prescribing* were widely distributed in Vermont. The Vermont Board of Medical Practice's first Policy for the Use of Controlled Substances for the Treatment of Pain, published in January 2006, was largely based on the 2004 FSMB model Guidelines.[51] FSMB (with the help of Purdue's grant funding) distributed *Responsible Opioid Prescribing* to 4,412 Vermont prescribers, through the Vermont Board of Medical Practice and other channels. Vermont prescribers interviewed by the State recalled receiving, reviewing, and relying upon the book well into recent years.

B. The Sacklers Drove the Misconduct that Led to the 2007 Convictions and Settlements

78. From the 1990s until 2007, Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler directed and sanctioned misconduct that led to criminal convictions, a judgment of the Superior Court in Washington County, Vermont, and commitments that Purdue would not deceive doctors and patients again. Their misconduct since 2007 is all the more reprehensible that background confirms that their misconduct since 2007 was knowing and intentional.

79. The Sackler family's first drug company was the Purdue Frederick Company, which they bought in 1952. In 1990, they formed Purdue Pharma Inc. and Purdue Pharma L.P. Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler took seats on the Board.

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[51] Vermont Board of Medical Practice, *Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain* (2014), http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioid_Pain_Treatment_Policy_0.pdf, at 1.

For events before July 2012, this Complaint uses "the Sacklers" to refer to them. David Sackler joined the Board in July 2012. From that time forward, "the Sacklers" includes him as well.

80. The Sacklers always insisted that their family control Purdue. From 1990 through 2018, their family always held the majority of seats on the Board. In 1994, Jonathan Sackler issued a memorandum to Purdue staff requiring that the Sacklers "should receive all Quarterly Reports and any other reports directed to the Board."[52]

81. When Purdue launched OxyContin in 1996, the FDA scientist who evaluated the drug wrote in his original review: "Care should be taken to limit competitive promotion."[53] The Sacklers did not agree. From the beginning, the Sacklers viewed limits on opioids as an obstacle to greater profits. To make more money, the Sacklers considered whether they could sell OxyContin in some countries as an uncontrolled drug. Staff [54] informed Richard Sackler that selling OxyContin as "non-narcotic," without the safeguards that protect patients from addictive drugs, would provide "a vast increase of the market potential."[55] The inventor of OxyContin, Robert Kaiko, wrote to Richard Sackler to oppose this dangerous idea. Kaiko wrote that he was "very concerned" about the danger of selling OxyContin without strict controls. Kaiko warned: "I don't believe we have a sufficiently strong case to argue that OxyContin has minimal or no abuse liability." To the contrary, Kaiko wrote, "oxycodone containing products are still among the most abused opioids in the U.S." Kaiko predicted, [redacted]

[52] 1994-04-26 memo from Jonathan Sackler, PWG004340621.

[53] 1995-10 Overall Conclusion to 1995 FDA review, Curtis Wright, PWG004340602.

[54] As used herein, the term "staff" means one or more Purdue employees.

[55] 1997-02-27 email from Walter Wimmer, PWG004340624.

[redacted] "If OxyContin is uncontrolled …, it is highly likely that it will eventually be abused."[56] Richard Sackler responded: "How substantially would it improve your sales?"[57]

82. At the OxyContin launch party, Richard Sackler spoke as the Senior Vice President responsible for sales. He asked the audience to imagine a series of natural disasters: an earthquake, a volcanic eruption, a hurricane, and a blizzard. [redacted], he said: "[T]he launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white …."[58] Over the next twenty years, the Sacklers made Richard Sackler's boast come true.

83. From the beginning, the Sacklers were behind Purdue's decision to deceive doctors and patients. In 1997, Richard Sackler and other Purdue executives determined that doctors had the crucial misconception that OxyContin was weaker than morphine, which led them to prescribe OxyContin much more often. In fact, OxyContin is more potent than morphine. Richard Sackler recognized that correcting doctors' misperceptions could reduce OxyContin sales [redacted]

84. From the start, the Sacklers were also the driving force behind Purdue's strategy to push opioids with the false promise that they create an enhanced "lifestyle." In 1998, Richard Sackler told Purdue's executives that OxyContin tablets provide more than merely "therapeutic" value and instead "enhance personal performance," like Viagra.[59]

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[56] 1997-02-27 email from Robert Kaiko, PWG004340624.

[57] 1997-03-02 email from Richard Sackler, PWG004340624 (original in all caps).

[58] [redacted] PWG004343839.

[59] 1998-09-28 email from Richard Sackler, PWG004340622.

85. Most of all, the Sacklers cared about money. Millions of dollars were not enough. They wanted billions. In 1999, when CEO Michael Friedman reported to Richard Sackler that Purdue was making more than $20 million per week, Richard replied immediately, at midnight, that the sales were "not so great." "After all, if we are to do 900M this year, we should be running at 75M/month. So it looks like this month could be 80 or 90M. Blah, humbug. Yawn. Where was I?"[60]

86. In 1999, Richard Sackler became the President and CEO of Purdue. Jonathan, Kathe, and Mortimer Sackler were Vice Presidents. The company hired hundreds of sales representatives and taught them false claims to use to sell drugs. Purdue managers tested the sales representatives on key messages during training at company headquarters. On the crucial issue of addiction, which would damage so many lives, Purdue trained its sales representatives to deceive doctors that the risk of addiction was "less than one percent." [redacted] Purdue mailed thousands of doctors promotional videos with that same false claim:

> There's no question that our best, strongest pain medicines are the opioids. But these are the same drugs that have a reputation for causing addiction and other terrible things. Now, in fact, the rate of addiction amongst pain patients who are treated by doctors is much less than one percent. They don't wear out, they go on working, they do not have serious medical side effects."[62]

A sales representative told a reporter: "We were directed to lie. Why mince words about it?

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[60] 1999-06-17 email from Michael Friedman, PWG004340593.

[61] [redacted]

[62] "I Got My Life Back" video, John Christopher Prue Dep. Tr., Jan. 30, 2004, PWG004341925-26.

Greed took hold and overruled everything. They saw that potential for billions of dollars and just went after it."[63]

87. In addition to using the sales force to deceptively promote Purdue's opioids, [redacted]

88. In 2000, the Sacklers were warned that a reporter was "sniffing about the OxyContin abuse story."[64] The Sacklers put the threat on the agenda for the next Board meeting and began covering their tracks. They planned a response that "deflects attention away from the company owners."[65]

89. In January 2001, staff forwarded to Richard Sackler a plea for help from a Purdue sales representative. The sales representative described a community meeting at a local high school, organized by mothers whose children overdosed on OxyContin and died: "Statements were

[63] 2017-10-16, Christopher Glazek, "The Secretive Family Making Billions From The Opioid Crisis," *Esquire* Magazine (quoting Purdue sales representative Shelby Sherman).

[64] 2000-12-01 email from Michael Friedman, PWG004342094 (internal quotations omitted).

[65] 2000-12-01 email from Mortimer D. Sackler, PWG004342094. Defendant Mortimer Sackler's father, the late Mortimer D. Sackler, was also involved in Purdue Pharma during his lifetime.

made that OxyContin sales were at the expense of dead children and the only difference between heroin and OxyContin is that you can get OxyContin from a doctor."[66]

90. The next month, a *New York Times* article reported on OxyContin abuse, citing a federal prosecutor who reported 59 deaths from OxyContin in a single state. Richard Sackler wrote to Purdue executives: "This is not too bad. It could have been far worse."[67]

91. That same month, Richard Sackler wrote down his solution to the overwhelming evidence of overdose and death: blame and stigmatize people who become addicted to opioids. In a confidential email, he wrote: "[W]e have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals."[68]

92. [redacted]

[66] 2001-01-26 email from Joseph Coggins, PWG004340598.

[67] 2001-02-08 email from Richard Sackler, PWG004342049.

[68] 2001-02-01 email from Richard Sackler, PWG004342047.

[69] [redacted]

93. Not long after the *New York Times* report on OxyContin abuse, the Sacklers achieved a long-sought goal: the front page of the *Times* reported that "OxyContin's sales have hit $1 billion, more than even Viagra's." The same article noted that "OxyContin has been a factor in the deaths of at least 120 people, and medical examiners are still counting."[70]

94. When *Time* magazine published an article about OxyContin deaths in New England, Purdue employees expressed concern. Richard Sackler responded with a message to his staff. He wrote that *Time*'s coverage of people who lost their lives to OxyContin was not "balanced." He added: "We intend to stay the course and speak out for people in pain—who far outnumber the drug addicts abusing our product [redacted]"[71] This narrative—that escalating addiction and overdoses are a function of abuse, not overprescribing—has served as the cornerstone for Purdue's response to the opioid crisis through to the present day.

95. That spring, Purdue executives met with the U.S. Drug Enforcement Agency ("DEA"). A senior DEA official sat across from Richard Sackler. Before the meeting ended, she leaned over the table and told Richard Sackler: "People are dying. Do you understand that?"[72]

96. [redacted]

[70] 2001-03-05 article in *New York Times,* PWG004411394.

[71] 2001-01 letter from Richard Sackler, PWG004341421.

[72] 2001 meeting described in Barry Meier, Pain Killer (1st ed. 2003) at 158. The DEA official was Laura Nagel, head of the DEA Office of Diversion Control.

[redacted][73]

97. As Purdue kept pushing opioids and people kept dying, the company was engulfed in a wave of investigations by state attorneys general, the DEA, and the U.S. Department of Justice. In 2003, Richard Sackler left his position as President of Purdue. After a few more years of investigation, Jonathan, Kathe, and Mortimer Sackler resigned from their positions as Vice Presidents, but the Sacklers nevertheless kept active control of the company. Their family owned Purdue. They controlled the Board. They paid themselves the profits. And, as alleged in detail below, they continued to direct Purdue's deceptive marketing campaign.

98. By 2006, prosecutors found damning evidence that Purdue intentionally deceived doctors and patients about its opioids. The Sacklers voted that their first drug company, the Purdue Frederick Company, should plead guilty to a felony for misbranding OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause adverse events and side effects than other pain medications. The Sacklers also voted that three Purdue executives (Michael Friedman, Paul Goldenheim, and Howard Udell)—but no member of the Sackler family—should plead guilty as individuals.

99. In May 2007, the Sacklers voted again to have the Purdue Frederick Company plead guilty and enter a series of agreements that Purdue Pharma L.P. and its related and associated entities would never deceive doctors and patients about opioids again. The Purdue Frederick Company confessed to a felony and effectively went out of business.[74] The Sacklers continued their opioid business in two other companies: Purdue Pharma Inc. and Purdue Pharma L.P.

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[73] [redacted]

[74] 2007-05-03 Board minutes, PWG004343851; 2007-5-10, Purdue Frederick Company Plea Agreement, PWG003978960 at -8998.

100. The Sacklers voted to admit in an Agreed Statement Of Facts that, for more than six years, supervisors and employees intentionally deceived doctors about OxyContin: "Beginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain PURDUE supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications . . . ."[75]

101. To remove any doubt, the Sacklers voted to enter into a plea agreement that stated: "PURDUE is pleading guilty as described above because PURDUE is in fact guilty . . . ."[76] Those intentional violations of the law happened while Richard Sackler was CEO; Jonathan, Kathe, and Mortimer were Vice Presidents; and Richard, Jonathan, Kathe, Mortimer, Ilene, Beverly, and Theresa Sackler were all on the Board.

102. The Sacklers also voted for Purdue to enter a Corporate Integrity Agreement with the U.S. government. The agreement required the Sacklers to ensure that Purdue did not deceive doctors and patients again. The Sacklers promised to comply with rules that prohibit deception about Purdue opioids. They were required to complete hours of training to ensure that they understood the rules. They were required to report any deception. Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler each certified in writing to the government that he or she had read and understood the rules and would obey them.[77]

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[75] 2007-05-09 Agreed Statement of Facts, paragraph 20, *available at* https://www.documentcloud.org/documents/279028-purdue-guilty-plea.

[76] 2007-05-09 Plea Agreement, at 2, *available at* https://www.documentcloud.org/documents/279028-purdue-guilty-plea.

[77] 2007-05-09 Plea Agreement, *available at* https://www.documentcloud.org/documents/279028-purdue-guilty-plea; 2007-05-04 Associate General Counsel's Certificate, PWG004342101; Purdue Corporate Integrity Agreement §§ III.C, III.H.

103. Finally, the Sacklers voted to enter into a Consent Judgment in Vermont, in Washington County Superior Court ("2007 Judgment"). The 2007 Judgment ordered that Purdue "shall not make any written or oral claim that is false, misleading or deceptive" in the promotion or marketing of OxyContin. The judgment further required that Purdue provide fair balance regarding risks and benefits in all promotion of OxyContin. That judgment required fair balance about the risks of taking higher doses for longer periods and the risks of addiction, overdose, and death.

104. The 2007 Judgment further required that Purdue establish and follow an abuse and diversion detection program to identify high-prescribing doctors who show signs of inappropriate prescribing, stop promoting drugs to them, and report them to the authorities:

> Upon identification of potential abuse or diversion," Purdue must conduct an inquiry and take appropriate action, "which may include ceasing to promote Purdue products to the particular Health Care Professional, providing further education to the Health Care Professional about appropriate use of opioids, or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities."

105. The 2007 Judgment and related agreements should have ended the Sacklers' misconduct for good. Instead, the Sacklers decided to break the law again and again, expanding their deceptive sales campaign to make more money from more patients on more dangerous doses of opioids.

C. After the 2007 Settlements, The Sacklers Devised New Unconscionable Practices and Directed the Purdue Sales Force to Carry Them Out

106. After the 2007 Judgment, the Sacklers could have fundamentally reformed the company. Instead, they devised and/or sanctioned new deceptive and unfair practices.

107. Continuing their pattern of deep involvement in Purdue's operations, the Sacklers directed the company to hire hundreds more sales representatives to visit doctors thousands more

times. They insisted that sales representatives repeatedly visit the most prolific prescribers. They directed representatives to encourage doctors to prescribe more of the highest doses of opioids. They studied tactics to keep patients on opioids longer—including through the use of savings cards—and then ordered staff to use them. [redacted] They asked for detailed reports about doctors suspected of misconduct, how much money Purdue made from them, and how few of them Purdue had reported to the authorities. They sometimes demanded more detail than anyone else in the entire company, so staff had to create special reports just for them. Richard Sackler even went into the field to promote opioids to doctors and supervise representatives face to face.

108. In particular, Richard Sackler's micromanagement was so intrusive that staff appealed to the CEO to intervene. The VP of Sales and Marketing wrote to the CEO:

> "Anything you can do to reduce the direct contact of Richard into the organization is appreciated."[78]

Richard Sackler's directions moved straight through the company. When he berated sales managers, the managers turned around and fired straight at representatives in the field. For example, when Richard Sackler wrote to managers, "This is bad,"[79] to criticize the sales of Purdue's Butrans opioid in another state, the managers in turn drafted a warning for employees:

> "Just today, Dr. Richard sent another email, 'This is bad,' referring to current Butrans trends. I am quite sure that Dr. Richard would not be sympathetic to the plight of the Boston District."[80]

The manager then threatened to fire every sales representative in that Boston district:

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[78] 2012-03-07 email from Russell Gasdia, PWG004335349.

[79] 2012-03-07 email from Richard Sackler, PWG004335348.

[80] 2012-03-07 email from Windell Fisher, PWG004335107.

> "I am much closer to dismissing the entire district than agreeing that they deserve a pass for poor market conditions."[81]

On information and belief, Richard Sackler's displeasure over Butrans sales was communicated to Vermont sales representatives as well.

109. The Sacklers cared most of all about money. From 2007 to 2018, they voted to direct Purdue to pay their family billions of dollars, including profits earned from opioids sold in Vermont. These payments were the motivation for the Sacklers' misconduct, and the payments reflected deliberate decisions to benefit from deception in Vermont, at great cost to patients and families.

110. As detailed below, the Sacklers' misconduct continued from the 2007 convictions into 2018.

111. [redacted][83]

112. [redacted]

[81] 2012-03-07 email from Windell Fisher, PWG004335107.

[82] [redacted]

[83] [redacted]

[redacted][84] [redacted]

[redacted] Vermont.

113. The impact of Purdue's sales representatives in Vermont was direct and profound.

[redacted]

114. **In May 2007**, while still in the midst of the criminal proceedings, [redacted]

[redacted]

115. **July 2007**: Staff told the Sacklers that more than 5,000 cases of adverse events had been reported to Purdue in just the first three months of 2007. Staff also told the Sacklers that Purdue received 572 Reports of Concern about abuse and diversion of Purdue opioids during Q2 2007— [redacted] Staff reported to the Sacklers that they completed only 21 field inquiries in response. Staff also told the Sacklers that they received 101 calls to Purdue's compliance hotline during the quarter, which was a "significant quarterly increase," but Purdue did not report any of the hotline calls or Reports of Concern to the FDA, DEA, Department of Justice, or state authorities.[86] Quarter after quarter, over the ensuing decade, Purdue and the

[84] [redacted]

[85] [redacted]

[86] 2007-07-15 Board report, pgs. 33, 41, 54, PWG004330365.

Sacklers would not deviate from this pattern: Staff would tell the Board that there had been hundreds of Reports of Concern; staff would further note that only a handful had been investigated, with none reported to authorities; and, on information and belief, the Board accepted this inaction.

116. Purdue's self-interested failure to report abuse and diversion continued, even though the 2007 Judgment subjected Purdue to an anti-diversion program that required it, among other steps, to report "potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities" as appropriate. Instead of reporting dangerous prescribers, or even directing sales representatives to stop visiting them, the Sacklers chose to keep pushing opioids to whoever prescribed the most, as described below.

117. By July of 2007, [redacted]

118. Also in July, staff reported to the Sacklers that they continued to mail out thousands of marketing materials, including 12,528 publications in the first half of 2007. The single most-distributed material was volume #1 of Purdue's "*Focused and Customized Education Topic Selections in Pain Management*" (FACETS).[88] In FACETS, Purdue falsely instructed doctors and patients that physical dependence on opioids is not dangerous and instead improves patients' "quality of life"—just as Richard Sackler had been saying since the 1990s. In the same material,

[87] [redacted]

[88] 2007-07-15 Board report, pg. 34, PWG004330365.

Purdue also falsely told doctors and patients that signs of addiction are actually "pseudoaddiction," and that doctors should respond by prescribing more opioids.[89]

119. Purdue sent these misleading publications to doctors [redacted]

120. At the same time, staff also reported to the Sacklers that Purdue was making more money than expected. A few months earlier, they had projected a profit of $407,000,000; now they expected more than $600,000,000.[90]

121. Staff reported to the Sacklers that [redacted] were key reasons that profits were high.[91] Staff also reported to the Sacklers that Purdue employed 301 sales representatives to promote opioids and that sales representatives were the largest group of Purdue employees by far. By comparison, Purdue employed only 34 people in drug discovery.[92]

122. **August 2007:** Howard Udell was still serving as Purdue's top lawyer, even after his criminal conviction (described in paragraph 98 above). Mr. Udell wrote to Richard, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler: "Over the last week there have been numerous news stories across the nation reporting on the Associated Press's analysis of DEA data showing very large increases in the use of opioids analgesics (particularly OxyContin) between the years 1997 and 2005. Many of these articles have suggested that this increase is a negative development suggesting overpromotion and increasing abuse and diversion of these products."[93]

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[89] 2007-08 FACETS Vol. 1, pgs. 51-53, PWG004327698.

[90] 2007-07-15 Board report, pg. 46, PWG004330365.

[91] 2007-07-15 Board report, pg. 46, PWG004330365.

[92] 2007-07-15 Board report, pg. 52, PWG004330365.

[93] 2007-08-30 email from Howard Udell, PWG004330084.

123. **October 2007:** Staff told the Sacklers that Purdue received 284 Reports of Concern about abuse and diversion of Purdue's opioids in Q3 2007, and they conducted only 46 field inquiries in response. Staff reported to the Sacklers that they received 39 tips to Purdue's compliance hotline during the quarter, but Purdue did not report any of them to the authorities.[94]

124. Staff told the Sacklers that Purdue had hired more sales representatives and now employed 304. They also reported to the Sacklers that Purdue was succeeding at promoting its highest doses of opioids: "OxyContin 80mg is at Rx levels not seen in over 2 years."[95] From 2007 into 2018, encouraging prescriptions of the highest doses of opioids—which were the most lucrative to Purdue and the Sacklers—was a primary focus of the sales force, including in Vermont, as discussed in Section D(3).

125. In preparation for an upcoming Board meeting, Richard Sackler instructed staff to give him the spreadsheets underlying their sales analysis, so that he could do his own calculations. The spreadsheets showed that, in 2007, Purdue expected to collect more than half its total revenue from sales of 80mg OxyContin—its most powerful, most profitable, and most dangerous pill.

126. **November 2007:** the Sacklers voted to spend $86,900,000 to employ sales representatives in 2008. The Sacklers also voted for a resolution regarding salary increases and bonus targets for the representatives. Every time the Sacklers voted to spend tens of millions of dollars on sales representatives, they knew and intended that they were sending representatives to promote opioids, including in Vermont, and that those reps would pursue the objectives set by the Sacklers using the tactics on which the Sacklers had been briefed.

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[94] 2007-10-15 Board report, PWG004333542 at pgs. 36, 60

[95] 2007-10-15 Board report, PWG0004333542 at pgs. 4, 58.

127. **January 2008:** Staff told the Sacklers that Purdue still employed 304 sales representatives and they were succeeding at the goal of promoting higher doses of opioids: "OxyContin 80mg continues to grow." Staff told the Sacklers that, in 2007, Purdue's net sales were just over $1 billion, almost "DOUBLE" what the company had planned. OxyContin accounted for more than 90% of those sales.[96]

128. In January, staff also told the Sacklers that Purdue received 689 Reports of Concern about abuse and diversion of Purdue's opioids in Q4 2007, and they conducted only 21 field inquiries in response. Staff also reported to the Sacklers that they received 83 tips to Purdue's compliance hotline during the quarter, but Purdue did not report any of them to the authorities.[97]

129. Despite the high sales reported to the Board, Richard Sackler wanted more details on tactics for pushing sales even higher. He wrote to Russell Gasdia, Vice President of Sales and Marketing (hereinafter "Sales VP"), demanding information about Purdue's opioid savings cards. Richard Sackler asked Gasdia how long the opioid savings cards lasted, how much savings they offered a patient, and whether there had been any changes since he had last been briefed on the opioid savings cards. Richard Sackler sent Gasdia [redacted] and a detailed hypothetical scenario to make sure he understood the sales tactic down to the smallest details. [redacted] staff followed up with a presentation about opioid savings cards to the Sacklers. From 2007 to the present, savings cards were a key element of Purdue's strategy to keep patients on opioids longer, including in Vermont, as discussed in Section D(4)(b).

[96] 2008-01-15 Board report, PWG004343257 at pgs. 4, 24.

[97] 2008-01-15 Board report, PWG004343257 at pg. 16, 24.

130. Meanwhile, when staff proposed a plan to get pharmacies to increase their inventory of OxyContin from 2 bottles to 3 bottles, Richard Sackler questioned why they could not get up to 4 bottles or more.

131. **February 2008:** The Sacklers used their power on the Board of Directors to "begin expanding [Purdue's] sales force by an additional 100 sales representatives beginning effective as of April 1, 2008."[98]

PURDUE PHARMA INC.

Minutes of a Meeting
of the Board of Directors

February 8, 2008

RESOLVED that the Partnership be and it hereby is authorized and directed to begin expanding the sales force by an additional 100 sales representatives beginning effective as of April 1, 2008 at an additional cost in 2008 of $12.5 million, and in connection with the addition of such 100 sales representatives, to add 12 District Managers, 2 Regional Managers, 2 regional administrators, 2 trainers and 1 marketing/convention manager starting July 1, 2008; and further

132. The Sacklers knew and intended that, because of their orders, more sales representatives would promote opioids to prescribers, including prescribers in Vermont, and that those sales representatives would pursue the objectives set by the Sacklers using the tactics on which the Sacklers had been briefed. In preparation for the Sacklers' vote, staff told them that

[98] 2008-02-08 Board minutes, PWG004409681. The Sacklers had long experience controlling the company's sales force. They voted to direct Purdue to hire 50 more sales representatives in 1998, and directed the company to prepare for a 100-representative expansion in 2007. 1998-04-27 Board minutes, PWG004818005; 2007-04-26 Board minutes, PWG004339182.

adding 100 sales representatives would allow Purdue to make 12,000 more sales visits to prescribers every month, nationwide.[99]

133. From 2008 to the present, sales representatives hired in the 2008 expansion ordered by the Sacklers promoted Purdue opioids [redacted], as depicted below:

134. As the company expanded its sales force in 2008, it rewarded sales representatives who generated the most opioid prescriptions with bonuses and all-expense-paid trips to tropical islands, using them as examples to motivate other representatives to sell more opioids.

[99] 2007-10-26 Sales & Marketing presentation, PWG004504770.

135. The Sacklers also knew and intended that the sales representatives would push higher doses of Purdue's opioids. That same month, Richard Sackler directed Purdue management to "measure our performance by Rx's by strength, giving higher measures to higher strengths."[100] He copied Jonathan and Mortimer Sackler on the instruction. The Sacklers knew higher doses put patients at higher risk. As far back as the 1990s, Jonathan and Kathe Sackler knew that patients frequently suffer harm when "high doses of an opioid are used for long periods of time."[101]

136. On Valentine's Day in 2008, the Sacklers voted to pay $3 million to former CEO Michael Friedman, one of the three Purdue executives to plead guilty. It was one of several multi-million-dollar payments to the convicted executives to maintain their loyalty and protect the Sackler family.

137. Also in February, [redacted].[102] Mortimer Sackler wrote to Richard Sackler [redacted]: "Purdue should be leading the charge on this type of research and should be generating the research to support our formulation. Why are we playing catch up …? Shouldn't we have studies like this …?"[103] [redacted] Later that month, Stewart wrote to Richard Sackler that reformulating OxyContin "will not stop patients from the simple act of taking

[100] 2008-02-13 email from Richard Sackler, PWG004335364.

[101] 1997-03-12 memo from John Stewart, PWG004340626.

[102] 2008-02-07 email from Robert Kaiko, PWG004333606.

[103] 2008-02-12 email from Mortimer Sackler, PWG004333606.

too many pills."[104] As discussed in Section D(1)(c), Purdue and the Sacklers deployed the abuse-deterrent formulation ultimately developed by the company as a marketing tool, despite the fact that its efficacy in reducing abuse was unproven. Further, as discussed in Section F, Purdue—at the Sacklers' direction—used its abuse-deterrent technology to deflect blame for the opioid crisis.

138. Meanwhile, on February 26, 2008, staff gave Jonathan, Kathe, Mortimer and Richard Sackler projections indicating that OxyContin sales could plateau.[105] Mortimer Sackler demanded answers to a series of questions about why sales would not grow. Richard Sackler weighed in at 8:30 p.m. to instruct the staff to find answers "before tomorrow."[106] Staff emailed among themselves about how the Sacklers' demands were unrealistic and harmful and then decided it was safer to discuss the problem by phone.

139. **March 2008:** Richard Sackler dug into Purdue's strategy for selling more OxyContin. He directed sales and marketing staff to turn over thousands of pieces of data about sales trends, including data to distinguish the kilograms of active drug from the number of prescriptions, so he could analyze higher doses. Staff delivered the data early Sunday morning; Richard Sackler responded with detailed instructions for new data that he wanted that same day. An employee sent Richard Sackler the additional data only a few hours later and pleaded with him: "I have done as much as I can."[107] The employee explained that he needed to attend to family

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[104] 2008-02-22 email from John Stewart, PWG004332845. Five years later, Purdue published two studies about the crush-proof formulation. Neither concluded the crush-proof tablets lowered the risks of addiction, overdose and death associated with OxyContin use; they simply found that reformulated OxyContin "might be less attractive to recreational drug abusers." PWG004407116 at 4-11; PWG004407116 at 15. Purdue amended its OxyContin label to reference these studies in 2013.

[105] 2008-02-26 email from Edward Mahony, PWG004522170; attachment PWG004522172 at slide 17-18.

[106] 2008-02-26 email from Richard Sackler, PWG004335366.

[107] 2008-03-09 email from David Rosen, PWG004334576 at 2-3.

visiting from out of town. Richard Sackler responded by calling him at home, insisting that the sales forecast was too low, and threatening that he would have the Board reject it. On Monday, staff emailed among themselves to prepare for meeting with Richard Sackler, indicating that the results he was looking for [redacted] more sales representatives. Meanwhile, Richard Sackler met with Acting President John Stewart to discuss his analysis of the weekend's data and new graphs Richard Sackler had made.

140. Sales VP Russell Gasdia was struggling to handle the pressure. When Richard Sackler sent Gasdia a list of seven sales questions to answer on Saturday, March 8, 2008 (and copied Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler), Gasdia wrote to Acting President John Stewart:

> John, I know it is tricky, but Dr. Richard has to back off somewhat. He is pulling people in all directions, creating a lot of extra work and increasing pressure and stress. I will draft a response but he is not realistic in his expectations and it is very difficult to get him to understand.[108]

141. Richard Sackler did not back off. Instead, he pushed staff to sell more of the highest doses of opioids and increase the pills in each prescription. That same Saturday night, Richard Sackler sent Gasdia yet another set of instructions, directing him to [redacted] for "exceeding 2007 Rx numbers on an adjusted basis (adjusted for strength and average number of tablets per Rx)."[109] The very next day, Gasdia [redacted], such as adding sales representatives, promoting Purdue's existing opioid savings cards, and promoting more intermediate doses of OxyContin.

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[108] 2008-03-08 email from Russell Gasdia, PWG004335376.

[109] 2008-03-08 email from Richard Sackler, PWG004334595 at 3.

142. Richard Sackler followed through on his weekend threat that he would have the Board reject the sales plan. Two days later, Richard Sackler circulated his own sales analysis to the Board, ordered the Secretary to "put this high in the Board agenda," and proposed that he and Mortimer Sackler oversee a redo of the annual plan as well as the 5-year plan for Purdue's opioids.[110]

143. At the same time, Jonathan, Kathe, and Mortimer Sackler were also pushing staff to grow sales. Staff told those three Sacklers that they would use opioid savings cards to meet the challenge of keeping OxyContin scripts at the same level in 2008 as in 2007, "in spite of all the pressures."[111] Kathe Sackler demanded that staff identify the "pressures" and provide "quantification of their negative impact on projected sales."[112]

144. **April 2008:** Staff reported to the Sacklers that Purdue employed 304 sales representatives. Staff also reported to the Sacklers that Purdue received 853 Reports of Concern about abuse and diversion of Purdue opioids in Q1 2008, and that they had conducted only 17 field inquiries in response. The same report also informed the Sacklers that Purdue received 83 tips to its compliance hotline during the quarter, but did not report any of them to the authorities.[113]

145. On April 18, 2008, Richard Sackler sent Kathe, Ilene, David, Jonathan, and Mortimer Sackler a secret memo about how to maintain their profits. Richard Sackler wrote that Purdue's business posed a "dangerous concentration of risk." After the criminal investigations that almost reached the Sacklers, Richard Sackler wrote that it was crucial to install a CEO who would be loyal to the family: "People who will shift their loyalties rapidly under stress and temptation

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[110] 2008-03-10 email from Richard Sackler, PWG004334731 at 1-5.

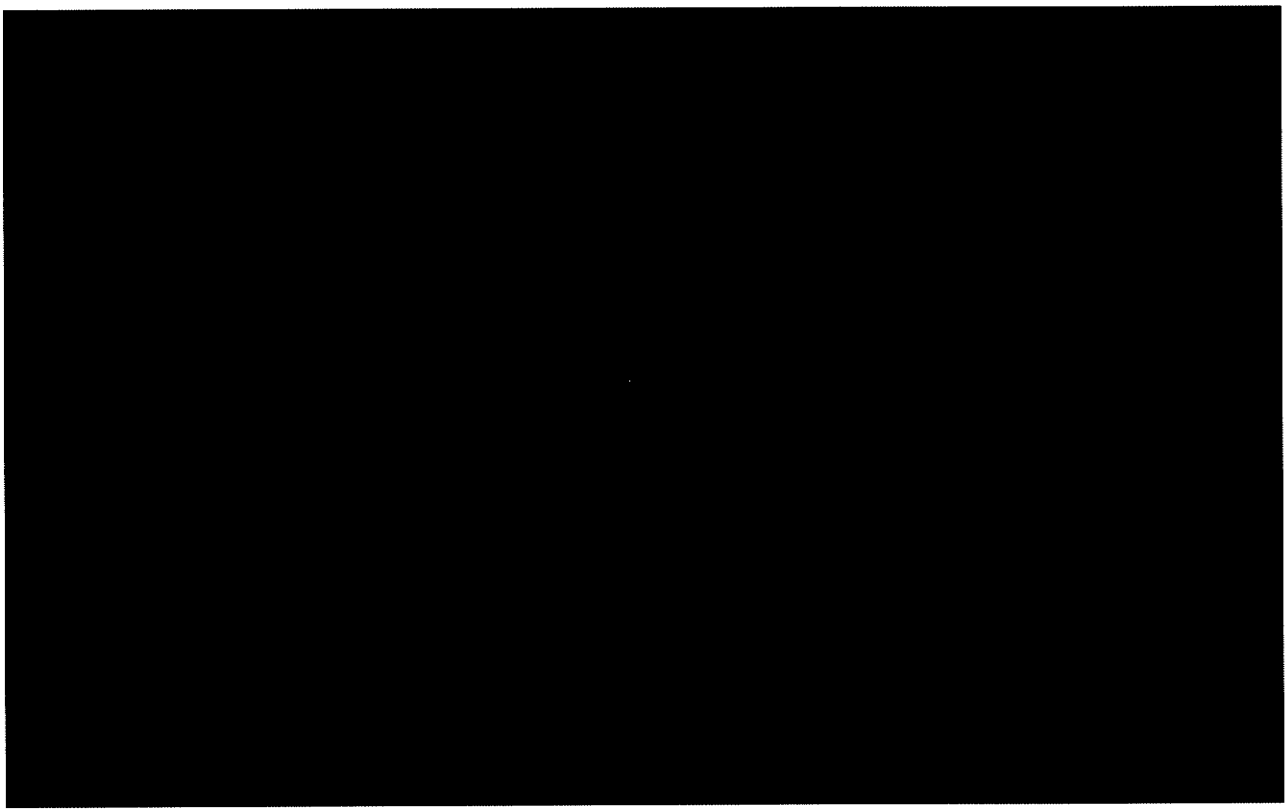
[111] 2008-03-09 email from Edward Mahony, PWG004334595 at 1-2.

[112] 2008-03-11 email from Kathe Sackler, PWG004334595.

[113] 2008-04-15 Board report, pgs. 17, 23, 24, 27, PWG004410792.

can become a liability from the owners' viewpoint." Richard Sackler recommended John Stewart for CEO because of his loyalty. Richard also proposed that the family should either sell Purdue in 2008 or, if they could not find a buyer, milk the profits out of the business and "distribute more free cash flow" to themselves.[114]

146. That month, the Sacklers voted to have Purdue pay their family $50,000,000. From the 2007 convictions until 2018, the Sacklers voted dozens of times to pay out Purdue's opioid profits to their family—in total **more than four billion dollars**.



147. On April 18, 2008, the Sacklers voted to increase the 2008 Purdue budget for Sales and Promotion to $155,802,000. Then, Richard Sackler sent Sales VP Russell Gasdia a series of questions about Purdue's efforts to get patients to take higher doses and stay on opioids for longer

[114] 2008-04-18 email and attached memo from Richard Sackler, PWG004343783; PWG004343784 at 1-2.

times. [redacted] He requested that sales staff be assigned to answer his questions "by tomorrow morning."[115] When the sales staff asked for more time to collect the data, Richard Sackler agreed to give them until the end of the day.

148. Meanwhile, Purdue was in the process of seeking FDA approval for the abuse-deterrent reformulation of OxyContin. [redacted]

149. Also in April, Purdue's executives considered more ideas about ways to promote Purdue's opioids. The proposal matched the Sacklers' own plan, which Richard Sackler had concocted as CEO: deflect blame from Purdue's addictive drugs by stigmatizing people who become addicted. The proposal identified "KEY MESSAGES THAT WORK," including this dangerous lie: "It's not addiction, it's abuse[.] It's about personal responsibility[.]"[117] On information and belief, staff sent the proposal to the Sacklers. Richard Sackler's narrative became the underpinning for Purdue's various deceptive messages designed to minimize the risk of addiction, as discussed in Section D(1). It also was the spark for Purdue's public relations strategy to obscure its misconduct by emphasizing all the company was doing to combat the straw man of

[115] 2008-04-22 email from Richard Sackler, PWG004335363.

[116] [redacted]

[117] 2008-04-16 Executive Committee notes, PWG004332813; 2008-04-16 presentation by Luntz, Maslansky Strategic Research, slide 28, PWG004414396.

illicit drug abuse, even as it ignored the fundamental problem of marketing-driven overprescribing, as discussed in Section F.

150. **May 2008:** Purdue received pushback from an FDA advisory panel convened to consider the company's application for approval of an abuse-deterrent formulation of OxyContin. The FDA's experts opined that they unconvinced that the new formulation would be effective in the real world, and that indicating the tablets were somehow tamper-resistant might give doctors and patients the impression that the drugs were not abusable or did not carry risks of addiction or overdose.[118] Jonathan Sackler, [redacted]

151. **June 2008:** The Sacklers voted to appoint John Stewart as President and CEO of Purdue Pharma Inc. and Purdue Pharma LP. The appointment followed through on Richard Sackler's suggestion in his secret memo that the Sacklers should put a premium on loyalty to the family. On the same day, the Sacklers voted to pay their family $250,000,000. The payment followed Richard Sackler's suggestion in the memo to "distribute more free cash flow" to themselves.

152. Meanwhile, Richard Sackler asked sales staff for information about [redacted] opioid savings card program. Staff explained to Richard, Jonathan, Kathe, and Mortimer Sackler that [redacted] 67,951 unique opioid savings cards had been used in Purdue's current program, and that the cards provided a discount on a patient's first five prescriptions.

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[118] Bethany Halford, *Formulations for Fighting Abuse*, Chemical & Engineering News (Vol. 86, Issue 23), https://cen.acs.org/content/cen/articles/86/i23/Formulations-Fighting-Abuse.html.

[119] [redacted]

153. As explained above, many patients would face significant withdrawal symptoms if they tried to stop taking opioids after using five prescriptions' worth of them. Staff informed Richard, Jonathan, Kathe, and Mortimer Sackler that 27% of the savings cards had been used for all five prescriptions.

154. Also in June, [redacted] As discussed in Section D(5), Purdue promoted its lowest-dose pills (10 and 15mg) for use by the elderly and opioid-naïve, even though it had no proof those doses were effective.

155. **July 2008:** Staff reported to the Sacklers that Purdue received 890 Reports of Concern regarding abuse and diversion of Purdue's opioids in Q2 2008 and had conducted only 25 field inquiries in response. Staff reported to the Sacklers that they received 93 tips to Purdue's compliance hotline during the quarter, but did not report any of them to the authorities.[121]

156. **September 2008:** The Sacklers voted to pay their family $199,012,182.

157. **October 2008:** Staff reported to the Sacklers that surveillance data monitored by Purdue indicated a "wide geographic dispersion" of abuse and diversion of OxyContin "throughout the United States." Staff reported to the Sacklers that "availability of the product" and "prescribing practices" were key factors driving abuse and diversion of OxyContin." The same report informed

[120] [redacted]

[121] 2008-07-15 Board report, pgs. 19, 25, 27, PWG004333314.

the Sacklers that Purdue had begun a new "Toppers Club sales contest" for sales representatives to win bonuses, based on how much a representative increased OxyContin use in his or her territory. It also reported to the Sacklers that Purdue received 163 tips to its compliance hotline during Q3 2008, but did not report any of them to the authorities.[122]

158. Staff also told the Sacklers that the Board-ordered sales force expansion had been implemented and Purdue now employed 414 sales representatives.[123] The Sackler-mandated reinforcements to the sales force ensured that the number of sales visits to Vermont prescribers during Q3 2008 [redacted]

159. **November 2008:** The Sacklers turned to expanding the sales force again. Purdue's 2009 budget identified expanding the sales force as the #1 sales and marketing objective. The Sacklers voted to spend [redacted] Staff reported to the Sacklers that an average sales representative's salary would be $89,708 with an average bonus of $43,470, and the sales representatives would visit prescribers more than 518,000 times.

160. That same month, the Sacklers voted to pay their family $325,000,000. They also voted to pay $5,000,000 to Howard Udell—Purdue's lawyer and a convicted criminal.

161. **March 2009:** The Sacklers voted to pay Purdue sales representatives and sales managers bonuses of 103 percent of Purdue's target because they sold so many opioids in 2008. The Sacklers also voted to increase the base pay of sales staff for 2009. On the same day, the Sacklers voted to pay their family $200,000,000.

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[122] 2008-10-15 Board report, pgs. 19, 24, 28, PWG004410762.

[123] 2008-10-15 Board report, pg. 26, PWG004410762.

162. **April 2009:** Staff reported to the Sacklers that Purdue employed 412 sales representatives and had made dramatic progress promoting higher doses. [redacted] "For the first time since January 2008, OxyContin ® 80mg strength tablets exceeded the 40mg strength."[124] [redacted] a detailed conversation with Sales VP Russell Gasdia about the staffing of the sales force, how many sales representatives the company should employ, and how many prescribers each representative would visit each year. The Sacklers authorized sales executives to hire a new staff member who would contact prescribers electronically and would promote Purdue opioids through the deceptive *Partners Against Pain*, a website that misleadingly asserted a distinction between addiction and physical dependence and suggested prescribing *more* opioids as treatment for the latter.

163. Staff reported to the Sacklers that they received 122 tips to Purdue's compliance hotline during Q1 2009, and revealed one of them to an outside monitor. The report also informed the Sacklers that the compliance problems included improper use of OxyContin marketing materials and opioid savings cards.[125]

164. **May 2009:** Staff reported to the Sacklers that Purdue had violated its Corporate Integrity Agreement with the U.S. government by failing to supervise its sales representatives. Because sales representatives lobbying doctors poses a high risk of misconduct (there are no witnesses, and the representative is paid to increase opioid sales), the United States required that Purdue managers supervise sales representatives in person at least 5 days each year.[126] Purdue management, however, did not even set up a system to track Purdue's compliance with the

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[124] 2009-04-16 Board report, pgs. 5, 28, PWG004343171.

[125] 2009-04-16 Board report, pgs. 24-25, PWG004343790.

[126] Purdue Corporate Integrity Agreement section III.K, *available at* http://www.pharmacomplianceforum.org/docs/resources/PurdueCIA.pdf.

obligation. Even though Purdue executives had failed to monitor compliance with the requirement, they responded to the violation by firing three [redacted] employees in the field and letting all the executives [redacted] keep their jobs.

165. **June 2009:** Richard Sackler asked sales staff how a competing drug company had increased sales: "What is happening???"[127] Staff replied that it was all about sales representatives:

> They have 500 reps actively promoting to top decile MDs … Their messaging is "we are not OxyContin," alluding to not having the "baggage" that comes with OxyContin.
>
> Interestingly, their share is highest with MDs we have not called on due to our downsizing [before 2008] and up until last year, having half as many reps. Where we are competing head to head, we decrease their share by about 50%.[128]

166. A few days later, staff reported to the Sacklers that Purdue had expanded its sales force at the Board's direction: "As approved in the 2009 Budget, 50 New Sales Territories have been created." Staff told the Sacklers the expansion was focused on the most prolific opioid prescribers, because "there are a significant number of the top prescribers" that Purdue had not been able to visit with its smaller force of sales representatives.[129] Later that month, the Sacklers voted to pay their family $162,000,000.

167. **July 2009:** Staff reported to the Sacklers that Purdue employed 429 sales representatives. Richard Sackler [redacted] that he was not satisfied with OxyContin sales and requested a plan to "boost" them. He asked for the topic to be added to the agenda for the Board.[130]

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[127] 2009-06-12 email from Richard Sackler, PWG004334670 at 3.

[128] 2009-06-13 email from Russell Gasdia, PWG004334670 at 3.

[129] 2009-06-16 email from Pamela Taylor, PWG004455956; 2009-05-20 Executive Committee notes, PWG004332859.

[130] 2009-07-20 email from Richard Sackler, PWG004335536 at 2.

168. **August 2009:** Richard Sackler convened a meeting of Board members and staff about "all the efforts Sales and Marketing is doing and planning to do to reverse the decline in OxyContin tablets market." He emphasized that $200,000,000 in profit was at stake.[131] At the meeting, staff told the Sacklers that the 80mg OxyContin pill was far-and-away Purdue's best performing drug. Purdue sold many more kilograms of active ingredient in the 80mg dose than any other dose (almost 1,000 kilograms per month: literally a ton of oxycodone).

169. [redacted] informing the Sacklers about Purdue's newest OxyContin sales campaign, with the slogan: *Options*. The *Options* campaign set the pattern that Purdue would follow for years: leading doctors and patients up the ladder to higher doses. To make it easy for sales representatives to promote higher doses, the campaign materials emphasized the "range of tablet strengths," provided a picture of each dose, and said: "You can adjust your patient's dose every 1 to 2 days." Staff told the Sacklers that they would advertise the *Options* campaign in medical journals reaching 245,000 doctors.[132]

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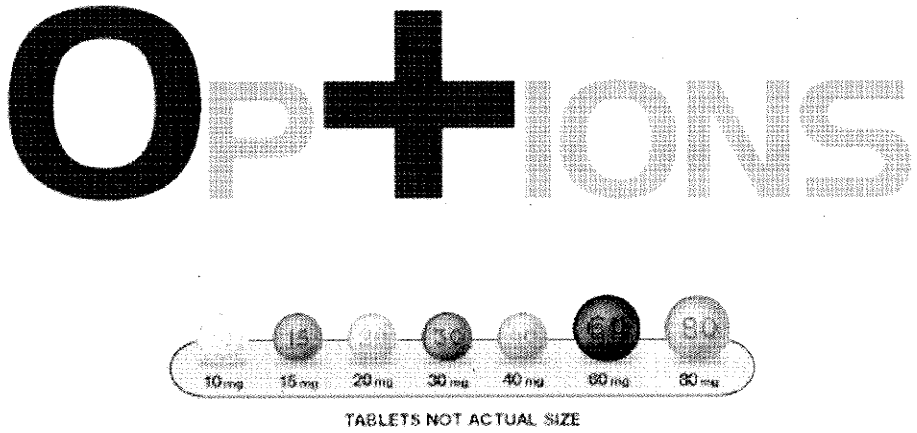
[131] 2009-08-12 email from Richard Sackler, PWG004447584 at 1-2; *see also* 2009-08-10 email from John Stewart, PWG004335521 ("Richard has asked me about this at least 5 times over the past few weeks ....").

[132] 2009-08-19 Board slides, slide 29, PWG004504770; *Options* marketing materials, PWG004276871, at -871.



Purdue's 2009 marketing campaign "Options"

170. Staff also reported to the Sacklers that more than 160,000 patients had used Purdue's opioid savings cards, more than doubling the result reported to the Sacklers the summer before. Staff also told the Sacklers that they would advertise OxyContin using a special television network: thousands of doctors would be given free digital video recorders for their home televisions, in exchange for watching advertisements for drugs.[133]

[133] 2009-08-19 Board slides, slide 32, PWG004504770. Purdue spent approximately $100 for each doctor who watched the advertisement, but it made the money back when the doctors prescribed Purdue's opioids. 2009-04-27 email from Lindsay Wolf, PWG004335408 at 3-4.

171. Immediately after meeting with sales staff, Richard Sackler asked for the raw data underlying their presentation. When staff had not responded within five minutes, he asked again.

172. **September 2009:** The Sacklers voted to pay their family $173,000,000. But Mortimer Sackler demanded to know why staff predicted a decline in OxyContin sales when he believed the market should grow.

173. Also in September, [redacted] Purdue's public position on abuse-deterrent formulations furthered the Sackler-created narrative that abusers, not overprescribing, are the root of the opioid crisis, as discussed in Sections D(1)(c) and F.

174. **October 2009:** Staff told the Sacklers that Purdue had expanded its sales force by an additional 50 territories and now employed 475 sales representatives.[135] Richard Sackler directed staff to send him weekly reports on OxyContin sales. No one in the company received reports that often, so staff were not sure how to reply.[136] Staff considered telling Richard Sackler that there were no weekly reports, but they decided to make a new report just for him instead.[137]

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[134] [redacted]

[135] 2009-10-22 Board report, PWG004333259 at pgs. 4, 21.

[136] 2009-10-08 email from Robert Barmore, PWG004818188; *see also* PWG004334736.

[137] 2009-10-08 email from David Rosen, PWG004818189 ("Hi, guys … Someone needs to alert Dr. Richard that we no longer do a weekly report. Can either one of you help …); 2009-10-08 email from Dipti Jinwala, PWG004334408 ("we have not been providing the OxyContin weekly report since May 09"); 2009-10-08 email from Richard Sackler, PWG004334739 ("I'd like to have the weekly updates."); 2009-10-08 email from David Rosen, PWG004334739 ("If we do as dr. richard requests, we will be adding work and providing him near worthless data"); 2009-10-08 email from Russell Gasdia, PWG004334739 ("Tell her not to respond."); 2009-10-08 email from John Stewart, PWG004335532;

The CEO also instructed the Sales Department to report to the Board of Directors with more explanation about its activities.

175. **November 2009:** The Sacklers voted to spend $121,628,000 to employ sales representatives in 2010. Kathe and Richard Sackler were designated to review the sales projections. They also voted to pay disgraced former employee Howard Udell up to another $1,000,000.

176. At the Board meeting that month, Kathe and Richard Sackler asked staff to "identify specific programs that Sales and Marketing will implement to profitably grow the OER [extended-release oxycodone] market and OxyContin in light of competition; provide analytics around why/how the proposed increase in share-of-voice translates into sales and profitability growth; clarify the situation with respect to OxyContin being used by 35% of new patients, but only retaining 30% of ongoing patients;" and provide a copy of a report from McKinsey & Company, a worldwide management consulting firm, which Purdue had engaged to develop tactics to increase OxyContin sales and market share.[138] The McKinsey report instructed sales representatives to maximize profits by "emphasizing [the] broad range of doses" [139]—which, on information and belief, was code for promoting the doses that were highest and most profitable.

177. At the same meeting, the Sacklers also asked staff, "What are OxyContin's clinical advantages vs. Opana ER, MS Contin, Kadian, Exalgo, Avinza, Nucynta and Duragesic? How are

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2009-10-09 email from Rob Barmore, PWG004334573 ("For the record, my concerns regarding workload and being able to meet demands of all the reporting, primary research, ad hocs while maintaining quality and reasonable levels of group morale remain.").

[138] 2009-11-02 budget presentation, PWG004332849 at pg. 1; 2009-12-22 email from Edward Mahony, PWG004332848 ("a list of questions raised at the November Board meeting and answers or actions on each").

[139] 2009-10-26 steering committee meeting presentation by McKinsey, PWG004334307 at slide 19.

these differences communicated?" In response, staff reported to the Sacklers a list of purported advantages of OxyContin over competing products, including that OxyContin purportedly reduces pain faster, has less variability in blood levels, and works for more pain conditions than competing drugs. These were all improper and deceptive claims.

178. The Sacklers also asked staff why Purdue's operating margin in 2010 was less than in 2009. Staff responded to the Sacklers that one of the biggest reasons for the reduced margin was the cost of the expanded sales force—which the Sacklers had ordered.

179. **December 2009:** Kathe and Richard Sackler met with sales staff to review plans for 2010. Staff warned the two Sacklers that, although OxyContin sales were at record-breaking levels (nearly $3 billion per year), the decade-long rise in the total kilograms of oxycodone ER prescribed in America was beginning to flatten—[redacted]. Higher doses contain more of that active ingredient and are more profitable to Purdue.

180. **January 2010:** Richard Sackler started the year by asking sales staff for new customized reports. Staff complained to each other until Sales VP Russell Gasdia asked CEO John Stewart to intervene: "Can you help with this? It seems like every week we get one off requests from Dr. Richard."[140] Stewart [redacted][141] Days later, Richard Sackler was writing to the sales employee on Saturday morning, ordering that [redacted] and saying it was "urgent" and should be provided "this weekend."[142]

[140] 2010-01-05 email from Russell Gasdia, PWG004334388 at pg. 2.

[141] 2010-01-08 email from John Stewart, PWG004334388 at pg. 1.

[142] 2010-01-16, email from Richard Sackler, PWG004334621 at pg. 2.

181. That same month, [redacted]

182. Also in January, [redacted] As described in Section D(2), Purdue and the Sacklers knew that promoting 12 hours of pain relief was deceptive because OxyContin does not provide 12 hours of pain relief in some patients.

183. **February 2010:** Purdue's Sales and Marketing Department told the Sacklers that a key objective for 2010 would be to "Meet or exceed total prescriber call targets of 545,000" visits to prescribers to promote Purdue opioids. For the next four years or more, a key objective for the sales employees was to meet a quota of sales visits, and the Sacklers tracked their performance. The target rose from 545,000 prescriber visits in 2010, to 712,000 visits in 2011, 752,417 visits in 2012, and 744,777 visits in 2013.[145]

184. To achieve the target for sales visits, staff told the Sacklers that another sales force expansion ordered by the Board had been implemented and Purdue employed 490 sales representatives.

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[143] [redacted]

[144] 2010 Marketing Plan, PWG004459086.

[145] 2010-02-01 Board report, PWG004333155 at pg. 23; 2011-05-02 Board report, PWG004415402 at pgs. 3, 5; 2012-04-30 Board report, PWG004332587 at pgs. 3, 5; 2013-05-13 Board report, PWG004334509 at pg. 7.

185. Staff also told the Sacklers that McKinsey estimated that new tactics by Purdue sales representatives would generate $200,000,000 to $400,000,000 more sales of OxyContin [redacted] and that sales representatives had been practicing the new tactics in front of management. McKinsey had reported to Purdue on opportunities to increase prescriptions by convincing doctors that opioids provide "freedom" and "peace of mind" and give patients "the best possible chance to live a full and active life." McKinsey also suggested sales "drivers" based on the ideas that opioids reduce stress and make patients more optimistic and less isolated.[146] In fact, becoming addicted to opioids makes patients more stressed, more isolated, and less likely to survive.

186. The Sacklers voted to spend $226,000,000 on Sales and Promotion in 2010, and to pay their family $236,650,000.

187. **March 2010:** Richard Sackler instructed sales staff to send him monthly reports on sales of OxyContin and its competitors. They complied within ten minutes.[147] The report showed that sales of Purdue's 80mg OxyContin (the highest dose) [redacted]

188. Staff also told the Sacklers that a key selling point for OxyContin compared to a competitor's product was that OxyContin could be used by patients who had not taken opioids before.[148] From 2007 to the present, expanding Purdue's captive customer base by promoting opioids for the opioid-naïve was a key tactic of the sales force, including in Vermont, as discussed in Section D(5).

189. **April 2010:** The Sacklers voted to pay their family another $141,000,000.

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[146] 2009-09-11 McKinsey presentation, PWG004334759 at slide 22.

[147] 2010-03-15 emails from Richard Sackler and Mike Innaurato, PWG004335513.

[148] 2010-04-12 email from Pamela Taylor, PWG004458879; 2010-03-17 Executive Committee notes, PWG004332867 at pg. 2.

190. Meanwhile, staff told the Sacklers that Purdue was pushing back against the "threat" of public health rules that would limit high doses of opioids. They told the Sacklers [redacted]

191. [redacted][0]

192. In Vermont, Purdue was [redacted]

193. **April 2010:** Staff gave the Sacklers one of many detailed reports on sales representatives' visits to prescribers. As with every reference to "the Sacklers" before July 2012, that includes Beverly, Ilene, Jonathan, Kathe, Mortimer, Richard, and Theresa Sackler.

194. Acting on the Sacklers' repeated insistence on increasing sales projections, Purdue required each sales representative to visit an average of 7.5 prescribers per day. In April 2010, staff reported that they were falling short. During Q1 2010, representatives had averaged only 7.0

149 [redacted]

150 [redacted]

visits per day.[151] Staff promised to try harder. Purdue continued to set a target for daily sales visits for every sales representative, and the Sacklers tracked the results, quarter by quarter, for at least the next four years, in marketing plans and updates to the Board.[152] The results were always close to 7 visits per day.

195. Purdue also set targets for the total number of sales visits by the entire sales force per quarter—huge numbers that were always more than a hundred thousand visits. Meeting those targets was a top priority for the entire company. For Q1 2010, the target was to visit prescribers 127,376 times. Staff told the Sacklers that Purdue employed 489 sales representatives and that, during Q1 2010, they achieved the goal.[153] The Sacklers tracked the total number of sales visits per quarter, every quarter, for at least the next four years.

196. [redacted]

197. The Sacklers also tracked the cost of the sales visits. In April 2010, staff reported to the Sacklers that each visit to a prescriber cost Purdue $219, and they were working to lower the cost to a target of $201.[154]

198. **June 2010:** Purdue staff completed an updated 10-year plan for growing Purdue's opioid sales. On information and belief, based on distribution of other 10-year plans, this plan was presented to the Sacklers. According to the plan, the Sacklers were to receive at least $700,000,000 each year from 2010 through 2020. Beginning on page one, staff emphasized that selling this

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[151] 2010-04-21 Board report, PWG004330952 at 4.

[152] 2010-04-21 Board report, PWG004330952 at -956-957; 2012-7-27 Board report, PWG004344648 at -652-653; 2014-2-4 Board report, PWG004333873 at -880-881.

[153] 2010-04-21 Board report, PWG004330952 at 4, 20. They exceeded the goal and visited prescribers 133,561 times.

[154] 2010-04-21 Board report, PWG004330952 at 4.

volume of opioids "will require significant salesforce support" so the plan detailed the "optimization" of sales visits and the number of representatives they would require. Sales VP Gasdia wrote that they planned for each representative to visit prescribers 1,540 times per year, so that 500 representatives could make 770,000 visits at a cost of $212 per visit. He proposed to grow the sales force to 1,050 sales representatives by 2015. To reach the Sacklers' expectations, the plan projected that Purdue would convince doctors to switch patients from short-acting opioid combination drugs (*e.g.*, Vicodin and Percocet) and other short-acting opioids (*e.g.*, tramadol, tapentadol) to Purdue's soon-to-be-released Butrans opioid, and that Butrans would become a billion-dollar drug.[155]

199. **July 2010:** Richard Sackler emailed staff just before the July 4th holiday weekend to demand more details about sales and marketing. Richard Sackler directed them to send to the Board plans for "the marketing program" and "the sales program," with instructions to "[redacted] get this out before the weekend."[156] A staff member wrote to the CEO: "Are you expecting us to provide the marketing plan by tomorrow?"[157] Richard wrote again, stating: [redacted] Staff promised to provide full details about sales and marketing at the July Board meeting.[158] Kathe Sackler then asked staff to circulate the materials before the meeting.[159]

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[155] 2010-06-24 Purdue Pharma 2010 10-Year Plan, pgs. 1-15, Key Assumptions, PWG004415002 at 2-18, 65.

[156] 2010-07-01 email from Richard Sackler to multiple staff members, PWG004335504.

[157] 2010-07-01 email from Russell Gasdia, PWG004335504.

[158] 2010-07-06 email from John Stewart, PWG004335529.

[159] 2010-07-09 email from Kathe Sackler, PWG004333208.

200. At the Board meeting, the Sacklers focused on sales tactics again. Staff presented plans for selling Purdue's new Butrans opioid. Staff told the Sacklers that they had identified [redacted] prescribers to target with the Butrans sales campaign. Staff reported that they planned to add 125 sales representatives and increase the number of prescriber visits by more than 30%.[160]

201. The Board (the Sacklers and, at that point, three other directors) responded with numerous questions and orders about the sales campaign. The Board asked staff to determine whether sales would increase if they gave doctors free samples of opioids,[161] even though Purdue had expressly agreed in the 2007 Judgment to stop distributing samples of OxyContin. The Board requested details about tactics Purdue sales staff used to influence doctors that Purdue viewed as "key opinion leaders," who could influence other doctors to prescribe more opioids: "Provide the Board with more information on the strategy/tactics with respect to KOL's, how they are identified, how do we plan to interact with them, how do we see them helping build appropriate utilization of Butrans - and any other relevant information that will/could influence the prescribing of the product."[162]

202. The Board pushed staff on whether they were describing the benefits of opioids aggressively enough. Purdue was not legally allowed to claim that Butrans was effective for 7 days because the evidence did not support that claim. Nevertheless, the Board wanted to know why Purdue didn't claim 7 days of effectiveness in its marketing.[163]

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[160] 2010-07-22 Butrans Commercial Strategy Plan Board Presentation, PWG004349737 at slides 17, 46, 49, 66, 81; 2010-06-01 email from William Mallin, PWG004465215.

[161] 2010-07-22 questions during Board meeting, PWG004333515.

[162] 2010-07-22 questions during Board meeting, PWG004333515.

[163] 2010-07-22 questions during Board meeting, PWG004333515 at 5 ("Why is there no reference to efficacy data in the marketing materials? ... a specific reference or statement to Butrans providing efficacy for 7 days seems to be the desired statement ... we may not have data that supports efficacy at that specific time point.").

203. Purdue was not legally allowed to claim that Butrans was effective for osteoarthritis ("OA") because the clinical trials testing Butrans for patients with osteoarthritis had failed. Despite this, the Board wanted to know if sales representatives could remain silent about the failed trial: "What can be said in response to a prescriber who asks directly or indirectly, 'can this product be prescribed for my patient with OA?' In responding are we required to specifically mention the failed trials in OA, [redacted]?"[164]

204. At the July 2010 Board meeting, the Sacklers and other Board members asked staff about opioid sales generated by doctors who were suspected of diversion and abuse, which Purdue had collected on a list code-named *Region Zero*. Staff assured the Board that Purdue tracked prescriptions by *Region Zero* doctors, including the exact prescriptions, units, and dollars from each prescriber.[165] Staff then sent the detailed data on those prescriptions written by problem prescribers to the Board.[166]

205. Also at the same July 2010 Board meeting, the Sacklers voted to [redacted]

[164] 2010-07-22 questions during Board meeting, PWG004333515 at 5.

[165] 2010-07-22 questions during Board meeting, PWG004333515 at 7.

[166] 2010-08-16 email from William Mallin, PWG004510920, at -927-928; 2010-08-11 *Region Zero* prescribers, PWG004510933.

[167] [redacted]

206. Later in July 2010, staff told the Sacklers that Purdue employed 491 sales representatives and that, during Q2 2010, they visited prescribers 135,824 times.[168] [redacted] Meanwhile, staff told the Sacklers that Purdue had paid their family $389,000,000 in the first six months of 2010.[169]

207. **August 2010:** The Sacklers continued to focus on the sales force. That month, Purdue decided not to acquire a new insomnia drug because of the risk that promoting it could distract sales representatives from selling Purdue's opioids. Richard Sackler concluded that "loss of focus" in sales representatives' meetings with prescribers was too great a risk, and Purdue decided not to go through with the deal.[170]

208. A few days later, the Sacklers received information regarding the abuse of OxyContin. Staff told them that the most common way of abusing oxycodone, by far, was swallowing it—which a crush-proof coating on OxyContin did not affect. Staff also reported to the Sacklers that data from one state's prescription monitoring program showed far higher rates of "doctor-shopping" for OxyContin prescriptions than for other long-acting opioids.[171] "Doctor-shopping" was identified as referring to a circumstance in which a patient gets opioids from multiple prescribers—an indication that the patient is at risk of addiction, overdose, and death.

209. **September 2010:** Staff discussed the Board's July 2010 decision to hire more sales representatives. Staff said they were working to implement the decision, adding 125 sales

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[168] 2010-07-27 Board report, PWG004330924 at 5, 27. Staff told the Board that the target for visits was 142,657; that representatives visited 7.0 prescribers per day, on average, compared to the target of 7.5; that the average cost of a visit was $219; and that they were still working to lower the cost to $201.

[169] 2010-07-27 Board report, PWG004330924 at 18.

[170] 2010-08-14 email from Richard Sackler, PWG004333232 at 2.

[171] 2010-08-16 email from Stuart Baker, PWG004460588; 2010-08-19 presentation by Paul Coplan, PWG004460589 at slides 7, 31.

territories.[172] The Vice President of Sales & Marketing, Russell Gasdia, also [redacted] that 82% of prescriptions for OxyContin were to "continuing" patients who were already taking the drug, [redacted].[173] The same month, the Sacklers voted to pay their family $240,000,000.

210. **October 2010:** Staff told the Sacklers that Purdue employed 506 sales representatives and, during Q3 2010, they visited prescribers 141,116 times.[174] [redacted]

211. Meanwhile, staff told the Sacklers that Purdue had paid their family $629,000,000 in the first nine months of 2010.[175]

212. **November 2010:** Staff warned the Sacklers that doctors were not prescribing Purdue's highest dose and most profitable opioids as much as the company had expected, so it might be necessary to cut the family's quarter-end payout from $320,000,000 to $260,000,000 and distribute it in two parts: one in early December and one closer to the end of the month.[176] Mortimer Sackler objected to the decrease and the division into two payments, and he demanded answers from staff: "Why are you BOTH reducing the amount of the distribution and delaying it

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[172] 2010-09-15 Executive Committee notes, PWG004414538.

[173] 2010-09-15 presentation by Russell Gasdia, PWG004414543 (minutes); PWG004414543 (slides) at slide 10. As discussed in Section D(4), Purdue focused much of its unfair and deceptive marketing efforts on promoting continuing, long-term use of its opioids.

[174] 2010-10-25 Board report, PWG004330897 at 3, 26. Staff told the Sacklers the target was 144,414; representatives visited 6.8 prescribers per day, on average, compared to the target of 7.5; each sales representative visit to a prescriber cost Purdue $219; and they were working to lower the cost to $201.

[175] 2010-10-25 Board report, PWG004330897 at pg. 15.

[176] 2010-11-23 email from Edward Mahony, PWG004335499.

and splitting it in two?" "Just a few weeks ago you agreed to distribute the full 320 [million dollars] in November."[177]

213. Staff also reported that the expansion of the sales force that the Sacklers had ordered was being implemented, including 125 new sales territories.[178] The Sacklers voted to spend $158,086,000 to employ sales representatives in 2011.

214. Staff also reported to the Sacklers that drug company leaders can be punished for breaking the law and "owners, officers, and managers will especially face even more serious scrutiny in the future."[179]

215. **December 2010:** The Sacklers voted to pay their family $260,000,000.

216. In 2011, the Sacklers continued to direct Purdue's deceptive sales tactics and receive multi-million-dollar payouts. In January, the Sacklers voted to pay the legal expenses of specific individuals if they were defendants or witnesses in investigations of Purdue, including several sales executives and John Crowley, Executive Director of Controlled Substances Act Compliance. In September 2009, a Purdue sales manager had emailed Crowley that Purdue was promoting opioids to an illegal pill mill: "I feel very certain this is an organized drug ring," and "Shouldn't the DEA be contacted about this?" Purdue sat on the information and did not report it to the authorities for more than two years, until after the pill mill doctor had already been arrested, and the Sacklers had arranged for lawyers in case Crowley was questioned.[180]

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[177] 2010-11-23 and 2010-11-24 emails from Mortimer Sackler, PWG004335506.

[178] 2010-11-10 Executive Committee notes, PWG004414520.

[179] 2010-11-10 Executive Committee notes, PWG004463002; 2010-11-10 Slideshow presentation by Bert Weinstein, PWG004463016 at slide 7.

[180] 2016-07-10 "More than 1 Million OxyContin Pills Ended up in the Hands of Criminals and Addicts. What the Drugmaker Knew," by Harriet Ryan, Lisa Girion, and Scott Glover, *Los Angeles Times*.

217. **January 2011:** Staff reported to the Sacklers that a key initiative in Q4 2010 had been the expansion of the sales force. Staff told the Sacklers that Purdue employed 590 sales representatives and, during Q4 2010, they visited prescribers 125,712 times.[181] [redacted]

[redacted]

218. Staff told the Sacklers that Purdue paid their family $889,000,000 in 2010. But staff reported that Purdue's revenue was still hundreds of millions of dollars less than expected because doctors were prescribing less of Purdue's highest dose opioids.[182] Staff told the Sacklers that sales of the highest doses continued to fall below expectations, and the gap had cost the company $120,000,000 in the month of December 2010 alone.[183] The Sacklers faced the prospect of shrinking payouts if doctors did not prescribe more of the highest doses.

219. Also in January 2011, Richard Sackler met with sales representatives for several days at the Butrans Launch Meeting and discussed how they would promote Purdue's newest opioid. Richard Sackler quickly followed up with sales management to demand a briefing on how the sales visits were going in the field:

> I'd like a briefing on the field experience and intelligence regarding Butrans. How are we doing, are we encountering the resistance that we expected and how well are we overcoming it, and are the responses similar to, better, or worse than when we marketed OxyContin® tablets?[184]

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[181] 2011-01-24 Board report, pgs. 4, 5, 35, PWG0004330861, -865, -866, 896. Staff told the Sacklers that, at the Board's direction, Purdue had hired 74 more sales representatives and planned to hire 51 more. Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 125,553 visits; and that representatives visited 6.2 prescribers per day, on average, compared to a target of 7.5; and that each visit cost Purdue $219. They were still working to lower the cost to $201.

[182] 2011-01-24 Board report, pg. 22, PWG0004330883.

[183] 2011-01-21 email from Sharon Salwan, PWG004332955.

[184] 2011-01-30 email from Richard Sackler to Russell Gasdia, PWG004334486.

220. Richard Sackler's interventions into sales tactics made employees nervous. Two hours after sending his request, Richard Sackler asked Sales VP Russell Gasdia to call him, on a Sunday morning, on his cell phone. When [redacted], CEO John Stewart tried to slow things down, warning staff that such requests would be "never-ending."[185]

221. Richard Sackler kept pushing for more sales. After one week of prescriptions doubled Purdue's forecast, Richard Sackler wrote to Gasdia: "I had hoped for better results."[186] In a follow-up message, Richard Sackler asked staff to tell him the ratio of prescriptions per sales representative visit to a prescriber, divided out by the prescribers' specialties. He asked for a Board discussion of the barriers that sales representatives were encountering during promotion. After trying to answer Richard Sackler's questions and getting another dissatisfied response, [redacted] wrote to the CEO asking him to intervene. In a later message, Richard Sackler wrote to the staff again: "What do I have to do to get a weekly report on Butrans sales without having to ask for it?"[187] One staff member asked [redacted] to respond. The CEO announced that, from then on, staff would send a sales report to the Sacklers every week. When staff sent the first weekly report, Richard Sackler responded immediately: "What else more can we do to energize the sales and grow at a faster rate?"[188]

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[185] 2011-01-31 email from John Stewart to Russell Gasdia and David Rosen, PWG004334486.

[186] 2011-02-15 email from Richard Sackler, PWG004335267.

[187] 2011-03-08 email from Richard Sackler, PWG004335139 at 1.

[188] 2011-03-16 email from Richard Sackler, PWG004334969 at 1.

222. Mortimer Sackler also pressed staff for more information about sales. When two days passed without an answer to Richard and Mortimer Sackler's inquiry, Mortimer inquired: "Any answer to this yet?"[189] Staff rushed to prepare answers to share with all the Sacklers.[190]

223. The people who worked for the Sacklers knew their appetite for sales was extreme. Although the launch of Purdue's Butrans opioid was on track to beat every drug in its class, Richard Sackler asked the CEO and Sales VP: "Do you share my disappointment [regarding the trajectory of Butrans prescriptions]?"[191] Sales VP Russell Gasdia replied privately to the CEO: "as far as his disappointment, I do not share that."[192]

224. **February 2011:** Staff reported to the Sacklers that law enforcement was increasingly concerned about lawbreaking by drug companies and the resulting "danger to public safety."[193] Staff also told the Sacklers that Purdue was receiving a rising volume of hotline calls and other compliance matters, reaching an all-time high during Q4 2010. Staff informed the Sacklers that sales representatives had engaged in improper promotion of Purdue opioids, but the company had decided not to report the violations to the government. Staff also reported to the Sacklers about the risks of OxyContin, including that 83% of patients in substance abuse treatment centers began abusing opioids by swallowing pills, and that it took, on average, 20 months for a patient to get treatment. Staff reported to the Sacklers that Purdue tracked to individual zip codes

[189] 2011-04-05 and 2011-04-08 emails from Mortimer Sackler, PWG004334431 at 2-3.

[190] 2011-04-08 email from Russell Gasdia, PWG004334431 at 1-2.

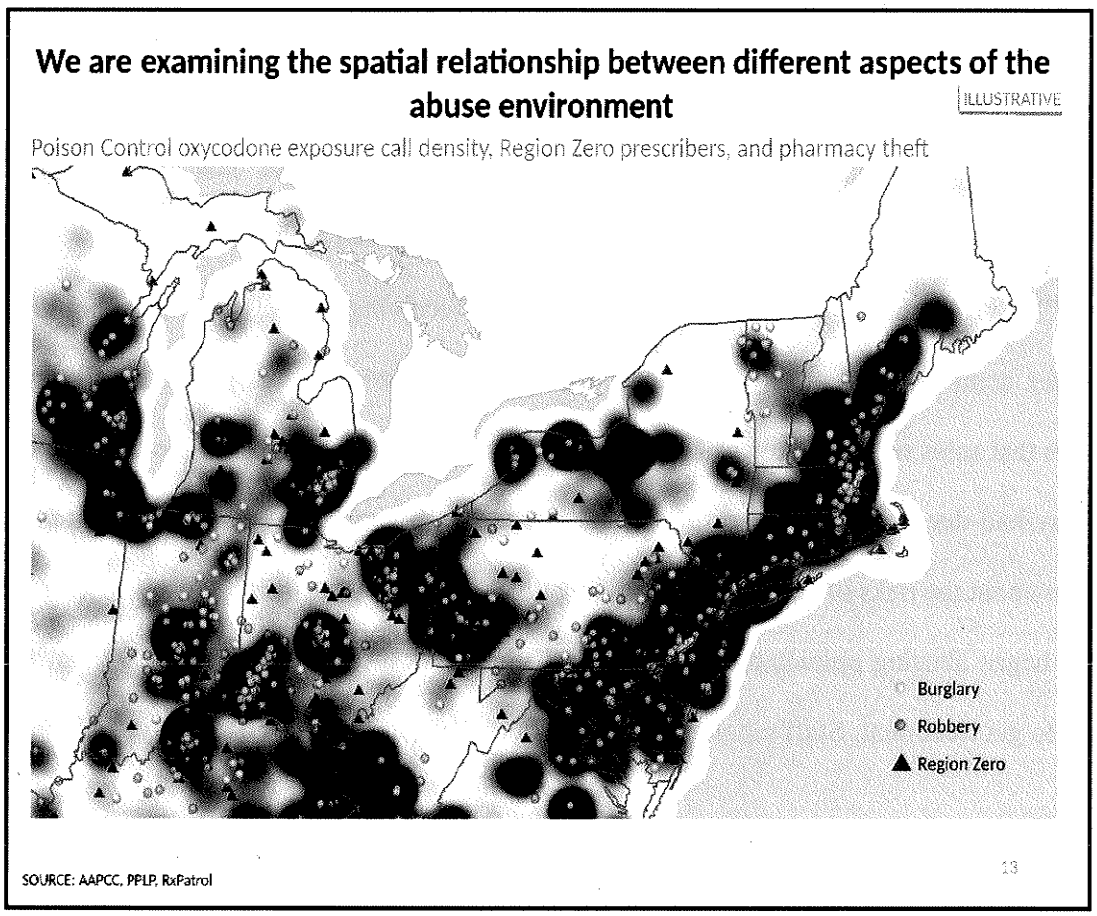
[191] 2011-03-09 email from Richard Sackler, PWG004335290 at 1.

[192] 2001-03-10 email from Russell Gasdia, PWG004335290 at 1.

[193] 2001-02-03 Board meeting materials, slide 48, PWG004343068.

the correlation between poison control calls for OxyContin overdose, pharmacy thefts, and *Region Zero* prescribers Purdue suspected of abuse and diversion.[194]

225. Staff even gave the Sacklers a map correlating dangerous prescribers in several states with reports of oxycodone poisonings, burglaries, and robberies.[195] Numerous *Region Zero* prescribers were located in New York and Massachusetts near the borders those states share with Vermont.



Map presented to the Purdue Board in 2011

[194] 2011-02-03 presentation by Bert Weinstein, slides 22-24, 86, 94-95, PWG004343068, 89-91, 161-162.

[195] 2011-02-03 presentation by Bert Weinstein, slide 95, PWG 004343161.

226. **March 2011:** Staff reported to the Sacklers on OxyContin sales and again focused on revenue from doctors in *Region Zero*—prescribers that Purdue suspected of improper prescribing but that Purdue had not reported to the authorities. Staff told the Sacklers that if *Region Zero* doctors stopped prescribing opioids, Purdue would lose almost 10% of its sales.[196]

227. **April 2011:** The Sacklers met with Sales VP Russell Gasdia to talk about sales. He told them that OxyContin was the best-selling painkiller in America, with more than three billion dollars in annual sales—almost double the second-place drug.[197] The Sacklers voted to pay their family $189,700,000.

228. **May 2011:** In response to the Sacklers' repeated requests, staff sent Richard, Jonathan, Kathe, Mortimer, and Theresa Sackler a report on the sales tactics representatives were using to push Butrans. The first tactic reported to these Sacklers was focusing on a select "core" of physicians that Purdue calculated would be most susceptible to sales representatives lobbying to prescribe more opioids.[198] [redacted]

[196] 2011-03-01 2011 OxyContin Tablets Sales Trends and Projections, PWG004337144, at 156-169.

[197] 2011-04-14 Board presentation, PWG004337213, -236.

[198] 2011-05-25 email from Russell Gasdia, PWG004332980.

[redacted]

229. The second tactic staff reported to Richard, Jonathan, Kathe, Mortimer, and Theresa Sackler in the May 25, 2011 email was "positioning of Butrans for specific patient types."[199] In Vermont, promotion for "specific patient types" meant pushing opioids for elderly patients with arthritis. [redacted]

230. A third tactic reported to these five Sacklers was getting prescribers to commit to put specific patients on opioids.[200] [redacted]

231. Jonathan Sackler was not satisfied that these tactics would be enough to boost sales. [redacted], he wrote to John Stewart: "this is starting to look ugly. Let's talk."[201] Stewart and the sales team scrambled to put together a response and set up a meeting with Jonathan for the following week.

232. That same month, staff reported to the Sacklers that Purdue had hired 47 more sales representatives according to the Sacklers' orders. Staff told the Sacklers that Purdue employed 639

[199] 2011-05-25 email from Russell Gasdia, PWG004332980.

[200] 2011-05-25 email from Russell Gasdia, PWG004332980.

[201] 2011-05-25 email from Jonathan Sackler, PWG004335076, -78.

sales representatives and, during Q1 2011, they visited prescribers 173,647 times.[202] [redacted]

[redacted]

233. Meanwhile, the Sacklers voted to pay $10,000,000 to try to settle a lawsuit by the Attorney General of Kentucky regarding Purdue's marketing of OxyContin.[203] Staff also told the Sacklers that they had received another 88 calls to Purdue's compliance hotline, but had not reported any of them to the authorities.[204]

234. **June 2011:** Staff reported to the Sacklers that Purdue's opioid sales were hundreds of millions of dollars less than expected and that a prime reason was that doctors were not prescribing enough of the highest doses.[205] The headline presented at the Board meeting read: "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." Staff told the Sacklers: "As a result of the change in prescriptions by strength, OxyContin brand Kgs dispensed are below mid 2010 levels." Staff reported to the Sacklers that Purdue would rely on sales representative visits and paid physician spokespersons to maintain demand. For a "Super Core" of "Very High Potential" opioid prescribers, Purdue would order its sales representatives to make sales visits every week.[206]

235. The Sacklers immediately pushed to find ways to increase sales. Richard Sackler asked Sales VP Russell Gasdia to include him in a meeting with District Managers who were the

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[202] 2011-05-02 Board report, pgs. 5, 6, 36, PWG004415402, -406, 407, -4437. Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 168,210 visits; and that representatives visited 6.66 prescribers per day, on average, compared to a target of 7.0.

[203] 2011-05-20 Board minutes, PWG004409681, -910PKY183212910.

[204] 2011-05-20 compliance report, PWG004337345, -388.

[205] 2011-05-12 Executive Committee notes, PWG004332957.

[206] 2011-06-21 Mid-Year Update, PWG004337450, -457-478.

day-to-day supervisors of the sales representatives. Then, having missed the meeting, he engaged Gasdia again by email, [redacted][207] Gasdia told Richard that Purdue had hired 147 new sales representatives at the Board's direction. Gasdia told Richard that Purdue instructed the sales representatives to focus on converting patients who had never been on opioids or patients taking "low dose Vicodin, Percocet, or tramadol"—all patients for whom Purdue's opioids posed an increase in risk.[208]

236. [redacted]

237. In an email message, Gasdia told Richard Sackler that Purdue instructed sales representatives to focus on the few highest-prescribing doctors in their territory and visit them over and over. According to a district manager of the territory including Vermont, "If a rep went to see somebody who was not writing a lot of opioids, even if the doctor was new or they may be seen to have the potential to write opioids, those reps were called into question. Some of them were given warnings; others were put on probation."

238. Gasdia also told Richard Sackler that staff had initiated performance enhancement plans for sales representatives who were not generating enough opioid prescriptions. [redacted]

[207] [redacted]

[208] 2011-06-16 email from Russell Gasdia, PWG004335072.

[redacted]

239. In response to Gasdia's message about the sales representatives, Richard Sackler wrote back six minutes later and asked to meet with Gasdia without delay. Gasdia scrambled to schedule a meeting about sales tactics with him for first thing the next morning. Richard Sackler would not wait until the morning and instructed Gasdia to call him that same day.

240. Richard Sackler continued the correspondence that day, criticizing Purdue's managers for allowing sales representatives to target "non-high potential prescribers." "How can our managers have allowed this to happen?"[209] He insisted that sales representatives push the doctors who prescribed the most drugs.

241. To make sure his orders were followed, Richard Sackler demanded to be sent into the field with the sales representatives. He wanted a week shadowing Purdue sales representatives, two representatives per day. Gasdia appealed to Purdue's Chief Compliance Officer, warning that Richard Sackler promoting opioids was "a potential compliance risk."[210] Compliance replied: "LOL."[211] Staff instructed: "Richard needs to be mum and be anonymous." Excerpts from the staff emails regarding Richard Sackler's request to shadow sales representatives in the field appear below.

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[209] 2011-06-16 email from Richard Sackler, PWG004334785.

[210] 2011-06-16 email from Russell Gasdia, PWG004335333 ("Based on our discussions, perhaps you could sit down with JS on your thoughts. Also, I haven't spoken to him about RS going to field with reps. Perhaps you could also say something to JS and indicate I came to you for counsel as I saw this as a potential compliance risk?").

[211] 2011-06-16 email from Bert Weinstein, PWG004335245.

To: Gasdia, Russell[Russell.Gasdia@pharma.com]
From: Weinstein, Bert
Sent: Thur 6/16/2011 7:47:14 PM
Subject: Re: Feedback from District Manager Advisory Council - FYI

LOL - I told him you raised concerns with me. We agreed Richard needs to be mum and be anonymous

From: Gasdia, Russell
To: Weinstein, Bert
Sent: Thu Jun 16 17:08:15 2011
Subject: Fw: Feedback from District Manager Advisory Council - FYI

I spoke to John and he said Stuart cleared Dr Richard observing calls with reps. I told him I spoke with you and you have concerns..he said he'd speak with you.

From: Sackler, Dr Richard
To: Gasdia, Russell
Cc: JHS (US)
Sent: Thu Jun 16 16:45:56 2011
Subject: Re: Feedback from District Manager Advisory Council - FYI

Russ,
One more thing. Who have you chosen for me to go to the field with the week after the budget meetings? Where are they? Can we conveniently do two reps each day especially if I travel to get to the right place as I probably should do.

Purdue internal emails

242. A number of executives, including the CEO, got involved in planning Richard Sackler's sales visits. All of them were worried. One wrote:

> About 5 last night, John [Stewart, the CEO] was walking by my office – I yelled out to stop him – and said that you had mentioned to me that Richard wanted to go into the field, and that you had raised concerns with me. John seemed angry, and asked if I had concerns. I told him could be issues and Richard could be out on a limb if he spoke about product at all or got into conversations with HCPs [health care providers], or identified himself, especially with FDA Bad Ad possibilities. John agreed Richard would have to be mum throughout, and not identify himself other than as a home office person.[212]

[212] 2011-07-17 email from Bert Weinstein, PWG004335262.

243. Richard Sackler indeed went into the field to promote opioids to doctors alongside a sales representative. In a conversation about his field contact, Richard Sackler argued to the Vice President of Sales that a legally-required warning about Purdue's opioids was not needed. He asserted that the warning "implies a danger of untoward reactions and hazards that simply aren't there." He insisted there should be "less threatening" ways to describe Purdue opioids.[213]

244. Meanwhile, the Sacklers voted to pay their family $200,000,000.

245. A few days later, sales and marketing staff scrambled to prepare responses to questions from the Sacklers. Mortimer Sackler asked about launching a generic version of OxyContin to "capture more cost sensitive patients." Kathe Sackler recommended looking at the characteristics of patients who had switched to OxyContin to see if Purdue could identify more patients to convert. Jonathan Sackler wanted to study changes in market share for opioids, focusing on dose strength.[214]

246. At the same time, sales staff were organizing more ways for Richard Sackler to oversee their work in the field. Gasdia proposed to Richard Sackler:

> In addition to field contacts with representatives, you may want to consider attending one of the upcoming conventions where we will be attending. At each of the ones listed below, we will have a promotional booth for OxyContin & Butrans. In addition, we are sponsoring educational programs for Butrans and OxyContin in the form of a 'Product Theater.'
>
> This would provide you the opportunity to be on the convention floor, observing numerous presentations being provided by our representatives and see a wide range of interactions over the course of a day. In addition, we can arrange for one-on-one meetings with key opinion leaders who are attending, many of them are approved consultants/advisors for us and you can have some open conversations regarding the market, perceptions around Butrans and

[213] 2011-07-20 email from Richard Sackler, PWG004415795, -797.

[214] PWG004335281.

OxyContin. Finally, you could observe the Product Theaters we are implementing.[215]

247. **August 2011:** Staff told the Sacklers that Purdue employed 640 sales representatives and, during Q2 2011, they visited prescribers 189,650 times.[216] [redacted]

248. Meanwhile, staff reported to the Sacklers that, in the first seven months of 2011, Purdue paid the family $211,000,000.[217]

249. **September 2011:** Richard Sackler directed staff to study a savings card program for a widely used cholesterol medication (not an addictive narcotic) to learn how Purdue could use it for opioids.[218] That same month, the Sacklers voted to pay their family $140,800,000 more.

250. **November 2011:** Staff told the Sacklers that Purdue still employed 640 sales representatives and, during Q3 2011, they visited prescribers 189,698 times.[219] [redacted] Looking ahead, the Sacklers voted to spend $162,682,000 to employ sales representatives in 2012.

251. Meanwhile, staff told the Sacklers that, in the first nine months of 2011, Purdue paid their family $551,000,000.[220]

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[215] 2011-07-26 email from Russell Gasdia, PWG004335243.

[216] 2011-08-03 Board report, pgs. 6, 42, PWG004330818, -823, -859. Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 187,950 visits; and that representatives visited 7.2 prescribers per day, on average, compared to a target of 7.0.

[217] 2011-08-03 Board report, pg. 29, PWG004330818.

[218] 2011-09-28 email from Richard Sackler to John Stewart, PWG004334870.

[219] 2011-11-09 Board report, pgs. 5, 41, PWG004330776, -781, -817. Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 189,525 visits; and that representatives visited 7.2 prescribers per day, on average, compared to a target of 7.0.

[220] 2011-11-09 Board report, pg. 26, PWG004330776, -802.

252. **January 2012:** Jonathan Sackler started the year pressing Sales VP Russell Gasdia for weekly updates on sales. A few days later, Richard Sackler interjected himself further into the details surrounding Purdue's advertising with the sales staff. He had noticed that online advertisements appeared indiscriminately on webpages with content associated with the advertisement—regardless of whether the association was positive or negative. Staff assured Richard Sackler that, when Purdue bought online advertising for opioids, it specified that the advertisements appear only on pages expressing positive views toward opioids, and would not appear with articles "about how useless or damaging or dangerous is our product that we are trying to promote."[221]

253. That same month, staff told the Sacklers that Purdue employed 632 sales representatives and, during Q4 2011, they visited prescribers 165,994 times.[222] [redacted]

254. The Sacklers were not satisfied with the sales effort. **In February 2012**, staff reported to the Sacklers that prescriptions had dropped, and that a decrease in sales representative visits to prescribers was a major driver of the decline. Staff asked the Sacklers to be patient, because representatives had missed work for December holidays and the company's mandatory National Sales Meeting in January.[223] Mortimer Sackler was not pleased. He suggested that, "in future years we should not plan the national sales meeting so close following the winter break as it extends the period of time since the doctor last saw our rep." Mortimer Sackler wrote: "Wouldn't

[221] 2012-01-26 email from Russell Gasdia, PWG004335285.

[222] 2012-01-25 Board report, pgs. 7, 48, PWG004334921, -927. -968. Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 166,315 visits; and that representatives visited 7.03 prescribers per day, on average, achieving the target of 7.0.

[223] 2012-02-07 email from Russell Gasdia, PWG004334192.

it be better to have the reps get back to work for January and back in front of doctors."[224] Mortimer Sackler was agitated by the thought of doctors going too many days without a sales representative visiting to promote Purdue opioids. If Purdue rescheduled its meeting, "[a]t least then the doctors will have gotten at least one reminder visit from our reps in the last month whereas now they might go two months without seeing one of our reps??" Staff replied to Mortimer Sackler, arguing for "balance."[225] Richard Sackler replied within minutes that, since the National Sales Meeting prevented sales representatives from visiting doctors, "[m]aybe the thing to have done was not have the meeting at all."[226] Purdue's compliance officer forwarded the exchange to his staff, commenting: "Oh dear."[227]

255. Meanwhile, Richard Sackler interrupted sales staff many times a day, often in a hurry: "I had hoped you would have updated this," "Will I have it by noon?" "get to this ASAP."[228] Staff advised each other: "avoid as much e mail with dr. r as you can."[229] Sales VP Gasdia wrote to the CEO in exasperation: "I'm not sure what we can do about Dr. Richard."[230]

256. Also in February, [redacted][231]

[224] 2012-02-07 email from Mortimer Sackler, PWG004334192.

[225] 2012-02-08 email from Russell Gasdia, PWG004334191.

[226] 2012-02-08 email from Richard Sackler, PWG004334191.

[227] 2012-02-08 email from Bert Weinstein, PWG004334191.

[228] 2012-02-02 and 2012-02-03 emails from Richard Sackler, PWG004521501; *see also* 2012-02-22 emails from Richard Sackler, PWG004334404.

[229] 2012-01-09 email from William Mallin, PWG004336654.

[230] 2012-02-01 email from Russell Gasdia, PWG004334724.

[231] [redacted]

257. Throughout the spring, the Sacklers pressed staff to promote Purdue's opioids more aggressively. In February, Gasdia wrote to sales staff that the Board of Directors ("BOD") was not satisfied with the money coming in: "Things are not good at the BOD level."[232] When sales dropped for one week on account of the Presidents' Day holiday, Richard Sackler wrote to sales management: "This is bad."[233] Gasdia forwarded Richard's message to his colleagues, asking how they could "create a greater sense of urgency at the regional management and district management level."[234]

258. Meanwhile, Gasdia urged the CEO to defend him [redacted] against Richard Sackler's micromanagement of sales: "Anything you can do to reduce the direct contact of Richard into the organization is appreciated."[235] A week later, Richard wrote to sales management again to criticize them for U.S. sales being "among the worst" in the world.[236]

259. **March 2012:** Staff sent the Sacklers a revised 2012 budget that cut the proposed payout to their family from $472,500,000 to $418,200,000.[237]

260. On one Saturday morning, Richard Sackler wrote to marketing staff, demanding monthly data for all extended release pain medications for the past twelve years and an immediate meeting that Monday night.[238] Gasdia [redacted] Do let us know how this

[232] 2012-02-07 email from Russell Gasdia, PWG004335301.

[233] 2012-02-07 email from Richard Sackler, PWG004335348.

[234] 2012-02-07 email from Russell Gasdia, PWG004335348.

[235] 2012-02-07 email from Russell Gasdia, PWG004335349.

[236] 2012-02-10 email from Richard Sackler, PWG004334401.

[237] 2012-03-05 email from Edward Mahony, PWG004333513.

[238] 2012-03-17 email from Richard Sackler to David Rosen, PWG004334669.

goes."[239] Later that month, staff created for Richard Sackler a historical summary of key events determining OxyContin sales.[240] Eleven of the key events in sales history were changes in the size of the Purdue sales force—all known to Richard Sackler because the Sacklers had ordered them.

261. A few days later, staff sent Richard Sackler an assessment of recently improved opioid sales. Staff told Richard that the increase in prescriptions was caused by tactics that Purdue taught sales representatives: pushing opioids for elderly patients with arthritis ("proper patient selection") and encouraging doctors to use higher doses of opioids ("quick titration").[241] In the coming months, Purdue would study, document, and expand the use of higher doses to increase sales.

262. Richard Sackler wrote that he was not satisfied with a report on sales and instructed Gasdia to discuss it with him within a day. Gasdia scrambled to schedule the meeting. Then Richard Sackler asked Gasdia to address both Butrans sales tactics and a decline in OxyContin sales and propose corrective actions. John Stewart suggested that Richard Sackler's frustrations could be linked to dosing. He encouraged Gasdia to tell Richard Sackler that patients on lower doses seemed to stop taking opioids sooner, and that much of the profit that Purdue had lost had been from doctors backing off the highest dose of OxyContin (80mg).

263. Richard Sackler was not satisfied. Days later, after sales did not increase, staff told him that they were starting quantitative research to determine why patients stay on opioids, so they could find ways to sell more opioids at higher doses for longer.[242]

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[239] 2012-03-18 email from Russell Gasdia, PWG004334669.

[240] 2012-03-28 presentation, PWG004334222.

[241] 2012-03-28 email from David Rosen, PWG004334209.

[242] 2012-04-20 email from David Rosen, PWG004334403.

264. **April 2012:** Staff told the Sacklers that Purdue employed 630 sales representatives and, during Q1 2012, they visited prescribers 179,554 times.[243] [redacted]

265. Meanwhile, Richard Sackler kept pushing the staff to increase sales. When the mandatory weekly report to the Sacklers showed that sales representatives achieved 9,021 prescriptions in a week, Richard Sackler asked Sales VP Russell Gasdia for a commitment that the representatives would get weekly prescriptions to 10,000: "Are you committed to breaking 10K/wk Rx's this month?"[244] A colleague replied incredulously to Gasdia: "Is there any question of your commitment?"[245]

266. Gasdia tried to assure Richard Sackler that they were selling opioids aggressively: "Windell and the sales force, as well as Mike and the marketing team (initiatives being implemented) are focused and committed to accelerating the growth trend ... everyone in the commercial organization is focused on exceeding the annual forecast."[246] Richard Sackler wanted more. He wanted to know what tactics sales staff would use to get more prescriptions, and he wanted to talk about it right away. First he wrote: "give me the table of weekly Rx plan and the actual. Then show how you plan to make up the current shortfall."[247] Then he asked for a meeting within 24 hours. Then Richard Sackler did not want to wait that long: "Can we meet in person today?"[248]

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[243] 2012-04-30 Board report, pgs. 6, 33, PWG004332587, -592, -619. Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 171,024 visits; and that representatives visited 7.0 prescribers per day, on average, compared to a target of 7.1.

[244] 2012-04-11 email from Richard Sackler, PWG004335340, -41.

[245] 2012-04-11 email from David Rosen, PWG004334387.

[246] 2012-04-12 email from Russell Gasdia, PWG004335341.

[247] 2012-04-12 email from Richard Sackler, PWG004335340-41.

[248] 2012-04-12 email from Richard Sackler, PWG004335340-41.

267. **May 2012:** Executives emphasized to managers overseeing sales representatives [redacted] that the Sacklers were tracking their efforts, and that Richard Sackler required weekly reports. Staff gave the only reply that was acceptable at Purdue: "All our efforts are focused on attaining the objective" of increased opioid prescriptions that the Sacklers set.[249]

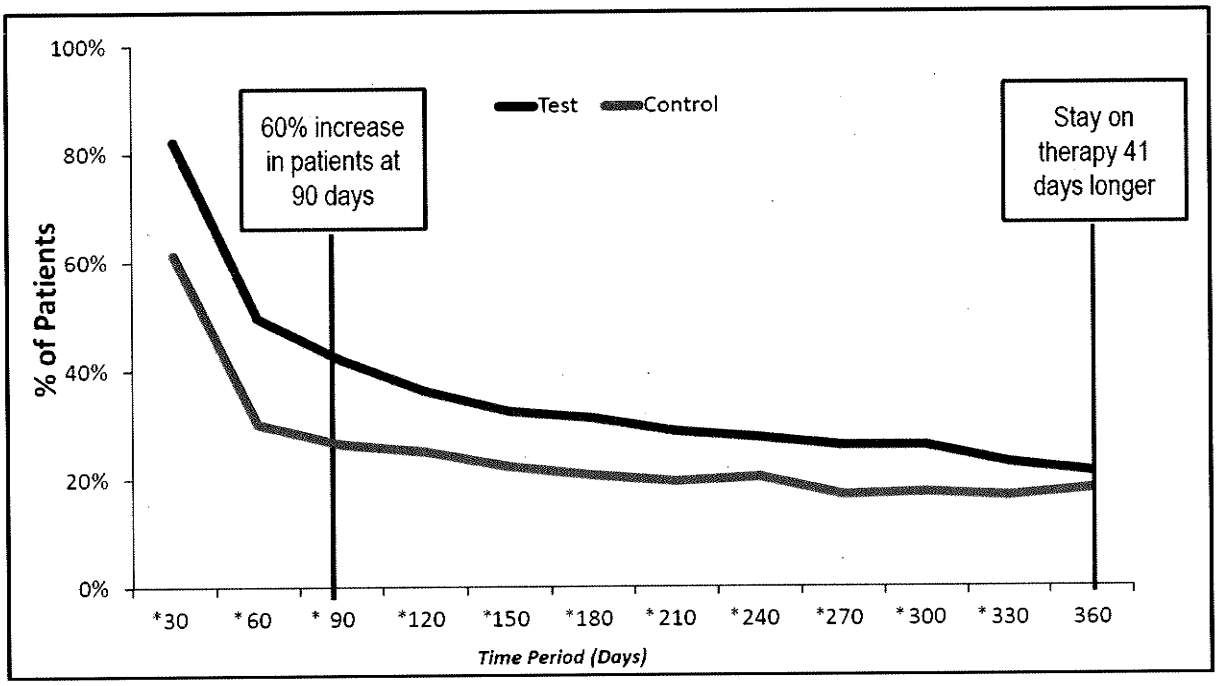
268. **June 2012:** The Sacklers discussed sales and marketing again. Staff reported to the Sacklers that they had added 120,000 sales visits to drive sales of OxyContin.[250]

269. Staff also told the Sacklers that they expanded the use of opioid savings cards, because Purdue's latest data showed opioid savings cards led to 60% more patients remaining on OxyContin longer than 90 days. The Sacklers reviewed the results of Purdue's confidential studies showing that opioid savings cards kept more patients on opioids for 90 days, 120 days, 150 days, 180 days, 210 days, 240 days—even an entire year.[251]

[249] 2012-05-15 email from Gary Lewandowski, PWG004336403.

[250] 2012-06-18 Mid Year Sales and Marketing Board Update, slide 10, PWG004335279.

[251] 2012-06-18 Mid Year Sales and Marketing Board Update, slides 11-12, PWG004335279.



Purdue internal analysis linking increased savings card utilization with increased duration of opioid use

As explained above, keeping patients on opioids for these lengths of time presented heightened risks of addiction and overdose.

270. **July 2012:** David Sackler (Richard Sackler's son) took a seat on the Board. For events after July 2012, this Complaint includes David in "the Sacklers."

271. Staff told the Sacklers that Purdue employed 633 sales representatives and, during Q2 2012, they visited prescribers 183,636 times.[252] [redacted]

272. **August 2012:** The Sacklers voted to direct Purdue to recruit an additional marketing executive and make candidates available to meet with members of the Board.

273. **November 2012:** Staff provided the Sacklers with the results of [redacted] study of 57,000 patients that Purdue performed explicitly to determine how opioid dose "influences

[252] 2012-07-23 Board report, PWG004344648 at -653, -690. Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 190,662 visits; and that representatives visited 7.0 prescribers per day, on average, compared to a target of 7.1.

patient length of therapy." The results showed that patients on the highest doses "are the most persistent." The "Recommended Actions" presented to the Sacklers included "additional workshops for the sales force" and "specific direction" to the sales representatives about using higher doses to keep patients on drugs longer. Staff told the Sacklers that encouraging higher doses "is a focal point of our promotion," and that sales representatives would "emphasize the importance" of increasing patients' opioid doses, as soon as three days after starting treatment.[253]

274. That same month, the Sacklers voted to set Purdue's budget for Sales and Promotion for 2013 at $312,563,000. Staff told the Sacklers that Purdue employed 622 sales representatives and, during Q3 2012, they visited prescribers 180,723 times.[254] [redacted]

[redacted]

275. **January 2013:** Richard Sackler questioned staff about the drop in opioid prescriptions caused by Purdue sales representatives taking time off for the holidays. Richard Sackler was not satisfied: "Really don't understand why this happens. What about refills last week? Was our share up or down?"[255] Staff assured him that doctors were "sensitive" to sales representative visits and, as soon as the representatives went back into the field, they would "boost" opioid prescriptions again.[256]

276. Staff told the Sacklers that they continued to reinforce the *Individualize The Dose* campaign, which the Sacklers knew and intended would promote higher doses. Staff also told the Sacklers that sales representatives would place greater emphasis on the opioid savings cards, which

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[253] 2012-11-01 Board report, pgs. 18, 30, PWG004415673, -690, -702.

[254] 2012-11-01 Board report, pgs. 15, 54, PWG004330717, -731. PWG000414901, -940. Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 199,466 visits; and that representatives visited 7.0 prescribers per day, on average, compared to a target of 7.1.

[255] 2013-01-07 email from Richard Sackler, PWG004334613.

[256] 2013-01-07 email from David Rosen, PWG004334613.

the Sacklers knew and intended would keep patients on opioids longer. Staff reported to the Sacklers that Purdue had conducted a sensitivity analysis on the opioid savings cards to maximize their impact and, as a result, had increased the dollar value and set the program period to be 15 months long. Staff also reported to the Sacklers that Purdue had created promotional materials to support these tactics and had distributed them to the sales force.

277. That same month, staff told the Sacklers that Purdue employed 609 sales representatives and, during Q4 2012, they visited prescribers 153,890 times.[257] [redacted]

278. **February 2013:** The Sacklers met with staff about tactics for promoting Purdue's opioids. They discussed research on what influences prescriptions, how doctors had responded to Purdue's increased promotion, and sales force promotion themes. On the same day, the Sacklers voted to award bonuses and salary increases to executives, including those involved in marketing Purdue's opioids.

279. **March 2013:** Staff reported to the Sacklers on the devastation caused by prescription opioids. [redacted] staff told the Sacklers that drug overdose deaths had more than tripled since 1990—the period during which Purdue had made OxyContin the best-selling painkiller. Staff told the Sacklers that tens of thousands of deaths were only the "tip of the iceberg." Staff reported that, for every death, there were more than a hundred people suffering from prescription opioid dependence or abuse.[258] For the Sacklers, however, the opioid epidemic was simply another opportunity to sell more opioids: [redacted]

[257] 2013-01-28 Board report, pgs. 10, 56, PWG004415259 at 268, 314. Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 191,264 visits; and that representatives visited 7.0 prescribers per day, on average, compared to a target of 7.1.

[258] 2013-03-21 Board presentation, PWG004337710 at 746-48.

[redacted][259]

280. **May 2013:** Staff reported to the Sacklers again that they were successfully using opioid savings cards to get patients to "remain on therapy longer." Staff told the Sacklers that they were using direct mail and email, as well as sales visits, to push the opioid savings cards.[260]

281. Staff reported to the Sacklers that, despite these sales efforts, they were not achieving the goals of getting enough patients on higher doses of opioids and getting doctors to prescribe more pills in each prescription. Staff told them that "there is an unfavorable 'mix' of prescriptions across strengths," and Purdue was losing tens of millions of dollars in revenue because sales of the highest doses (60mg and 80mg) were too low. Staff told the Sacklers that there was also a second problem: "lower average tablet counts per prescription." Because doctors were not prescribing enough pills during each patient visit, Purdue was losing tens of millions of dollars in revenue. Staff promised the Sacklers: "A deeper analysis is underway to determine the cause of the decline in the 30mg, 60mg, and 80mg tablet strengths, as well as the lower than budgeted average tablets per prescription. Once the analysis is complete, we will have a better sense of what tactics to implement to address both issues."[261]

282. The Sacklers met with Sales VP Russell Gasdia about the strategy for selling high doses. Gasdia told the Sacklers that "[t]itration up to higher strengths, especially the 40mg and 80mg strengths is declining." He analyzed the "Causes of OxyContin's Decline in Higher

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[259] [redacted]

[260] 2013-05-13 Board report, pg. 18, PWG004334509 at 526.

[261] 2013-05-13 Board report, pg. 8, PWG004334509 at 516.

Strengths," and how Purdue would reverse that decline. He told the Sacklers that Purdue's #1 tactic to sell higher doses was sending sales representatives to visit prescribers. The #2 tactic was a marketing campaign designed to promote high doses—Purdue's *Individualize The Dose* campaign. After that, Gasdia told the Sacklers, came opioid savings cards. After that came special focus on the most prolific opioid prescribers.[262]

283. Gasdia told the Sacklers that the staff would develop even more tactics to sell higher doses. They were using Purdue's data on thousands of doctors and patients to learn what made people willing to use high doses of opioids. They had started a study of physician characteristics and a "patient level analysis to determine what patient characteristics" were associated with "higher dose volume."[263]

284. That same month, staff told the Sacklers that Purdue employed 637 sales representatives and, during Q1 2013, they visited prescribers 155,354 times.[264] [redacted]

285. **July 2013:** Purdue staff discussed "threats" to their business from data on long-term opioid use, as public health authorities reacted to the danger of keeping patients on opioids for longer periods of time.[265] On information and belief, this issue was presented to the Sacklers at a Board meeting. Meanwhile, staff sent the Sacklers a "Flash Report" that OxyContin sales had dropped $96,400,000 from the year before. Staff explained to the Sacklers that insufficient volume

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[262] 2013-05 Board presentation by Russell Gasdia, PWG004337835 at 854-55.

[263] 2013-05 Board presentation by Russell Gasdia, PWG004337835 at 856.

[264] 2013-05-13 Board report, pgs. 12, 62, PWG004334509 at 520. Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 172,788 visits; and that representatives visited 6.8 prescribers per day, on average, compared to a target of 7.1. Staff assured the Sacklers that "call productivity is expected to increase towards the targeted goal throughout 2013."

[265] 2013-07-24 Communications and External Affairs Committee minutes, PWG004329632 at -635.

of sales representative visits to promote OxyContin to prescribers was an important reason for the dropping sales. Staff told the Sacklers that they would increase the number of sales visits and had retained McKinsey & Company to study how to get doctors to prescribe more OxyContin.[266]

286. Staff also reported to the Sacklers that key priorities were to reverse "the decline in higher strengths" of Purdue opioids, and the decline in "tablets per Rx," which were reducing Purdue's profit. They told the Sacklers that Purdue staff were studying ways to fight these trends, and McKinsey would analyze the data down to the level of individual physicians.[267]

287. Mortimer Sackler asked for more detail on what was being done to increase sales. Staff told the Sacklers that McKinsey would analyze whether sales representatives were targeting the prescribers who were most susceptible to increasing opioid use. Staff told the Sacklers that McKinsey would study whether Purdue could use incentive compensation to push representatives to generate more prescriptions. Making the sales representatives' income depend on increasing prescriptions could be a powerful lever. Staff told the Sacklers that McKinsey would study using "patient pushback" to get doctors to prescribe more opioids: when doctors hesitated to prescribe Purdue opioids, Purdue could get patients to lobby for the drugs. Staff told the Sacklers that McKinsey would also study techniques for keeping patients on opioids longer, including the need for sales representatives "to make a lot of calls on physicians with a high number of continuing patients."[268]

288. Staff also reported to the Sacklers that they had trained Purdue's sales representatives to use new sales materials designed to get patients on higher doses of opioids for

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[266] 2013-07-05 email from Edward Mahony, PWG004334598 at 600-02.

[267] 2013-07-23 Board report, pg. 25, PWG004414544 at 568.

[268] 2013-07-07 email from John Stewart, PWG004334492; attachment PWG004334496-508.

longer periods. Staff told the Sacklers that Purdue employed 634 sales representatives and, during Q2 2013, they visited prescribers 177,773 times.[269] Staff assured the Sacklers that they were trying to achieve even more sales visits by monitoring the representatives.[270]

289. Before the month ended, the Sacklers met to discuss a report on sales tactics that McKinsey had prepared for them: *Identifying Granular Growth Opportunities for OxyContin: First Board Update*. McKinsey confirmed that Purdue's sales visits generated opioid prescriptions. They urged the Sacklers to demand more sales visits from sales representatives, increasing each representative's annual quota from 1,400 towards 1,700. McKinsey also advised the Sacklers to control the sales representatives' target lists more strictly, to make representatives visit doctors who give the biggest payoff. Based on a review of data, McKinsey also suggested that the Sacklers should have staff emphasize opioid savings cards in neighborhoods with high concentration of Walgreens pharmacies. To allow even more targeted promotion of high doses, McKinsey asked Purdue to obtain "prescriber level milligram dosing data" so they could analyze the doses prescribed by individual doctors.[271]

290. Days later, staff told the Sacklers that Purdue paid their family $42,000,000.[272]

291. **August 2013:** The Sacklers met to discuss an update to the McKinsey report on sales tactics: *Identifying Granular Growth Opportunities for OxyContin: Addendum to July 18th and August 5th Updates*. McKinsey recommended that the Sacklers immediately order a series of

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[269] 2013-07-23 Board report, pgs. 11, 12, 59, PWG004414544 at 554, 556, 602. Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 191,184 visits; and that representatives visited 6.9 prescribers per day, on average, compared to a target of 7.1.

[270] 2013-07-23 Board report, pgs. 10-11, PWG004414544 at 553-54.

[271] 2013-07-18 Identifying Granular Growth Opportunities for OxyContin: First Board Update, PWG004337901 at 7991-8009.

[272] 2013-08-06 email from Edward Mahony, PWG004333602.

actions to increase sales. McKinsey urged the Sacklers to direct sales representatives to visit the most prolific opioid prescribers. McKinsey told the Sacklers that prescribers in the more prolific group write "25 times as many OxyContin scripts" as less prolific prescribers. They also reported to the Sacklers that sales representative visits to these prolific prescribers cause them to prescribe even more opioids: if Purdue ordered representatives to focus on the most prolific prescribers, it could increase sales.[273]

292. Second, McKinsey recommended that the Sacklers fight back against steps that the DEA, the U.S. Department of Justice, and others were taking to stop illegal drug sales. Two months earlier, the Walgreens pharmacy company admitted that it broke the law by filling illegitimate prescriptions, and it agreed to new safeguards to stop illegal prescribing. McKinsey told the Sacklers that "deep examination of Purdue's available pharmacy purchasing data shows that Walgreens has reduced its units by 18%." Even worse for the Sacklers, the new safeguards were hurting sales of the highest doses: "the Walgreens data also shows a significant impact on higher OxyContin dosages"—specifically the 80mg dose. McKinsey urged the Sacklers to lobby Walgreens' leaders to loosen up. For the longer term, McKinsey advised the Sacklers to develop a "direct-to-patient mail order" business for Purdue opioids, so they could sell the high doses without pharmacies getting in the way.[274]

293. Third, McKinsey advised the Sacklers that they should use their power on the Board to insist on increasing sales, with monthly accountability: "Establish a revenue growth goal (*e.g.*, $150M incremental stretch goal by July 2014) and set monthly progress reviews with CEO and

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[273] 2013-08-08 Identifying Granular Growth Opportunities for OxyContin: Addendum to July 18th and August 5th Updates, PWG004338010.

[274] 2013-08-08 Identifying Granular Growth Opportunities for OxyContin: Addendum to July 18th and August 5th Updates, PWG004338010 at 15-17.

Board." McKinsey knew what the Sacklers were looking for: they reported that "the value at stake is significant—hundreds of millions, not tens of millions." McKinsey urged the Sacklers to make "a clear go-no go decision to 'Turbocharge the Sales Engine.'"[275]

294. **October 2013:** The Sacklers met again to discuss implementation of the sales tactics McKinsey had recommended. The Sacklers discussed DEA efforts to stop illegal dispensing of opioids at CVS and Walgreens and how Purdue could get around the new safeguards by shifting to mail-order pharmacies, specialty pharmacies, or Purdue distributing opioids to patients directly.

295. Meanwhile, McKinsey kept reporting to Purdue on tactics to get more patients on higher doses of opioids. McKinsey found that Purdue could drive opioid prescriptions higher by targeting the highest-prescribing doctors and sending sales representatives to visit each prolific prescriber dozens of times per year. McKinsey pointed to a "true physician example" who wrote 167 more OxyContin prescriptions after Purdue sales representatives visited him.[276]

296. **October 2013:** Mortimer Sackler pressed for more information on dosing and "the breakdown of OxyContin market share by strength."[277] Staff told the Sacklers that "the high dose prescriptions are declining," and "there are fewer patients titrating to the higher strengths from the lower ones."[278] In response to the Sacklers' questions, staff explained that sales of the highest doses were not keeping up with the Sacklers' expectations because some pharmacies had implemented "good faith dispensing" policies to double-check prescriptions that looked illegal and some prescribers were under pressure from the DEA.[279] Staff promised to increase the budget for

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[275] 2013-08-08 Identifying Granular Growth Opportunities for OxyContin: Addendum to July 18th and August 5th Updates, PWG004338010 at 17-18.

[276] 2013-08-22 McKinsey presentation, slide 10, PWG004335592.

[277] 2013-10-28 email from Mortimer Sackler, PWG004334213.

[278] 2013-10-28 email from David Rosen, PWG004334210-011.

[279] 2013-10-28 email from David Rosen, PWG004334211.

promoting OxyContin by $50,000,000, and get sales representatives to generate more prescriptions with a new initiative to be presented to the Sacklers the following week.[280]

297. At the end of the month, the Sacklers met to discuss Purdue's budget for sales and marketing for 2014. Staff again told the Sacklers that Purdue's opioid savings cards kept patients on opioids longer.[281] Looking ahead at 2014, staff reported to the Sacklers that doctors shifting away from high doses and towards fewer pills per prescription could cost Purdue hundreds of millions of dollars in lost sales.[282] To fight against that threat, staff told the Sacklers that they would increase the sales visits by each representative to 7.3 visits per day and visit prescribers a total of 758,164 times.[283]

298. **November 2013:** Richard Sackler complained that he was getting too much information about the dangers of Purdue opioids. He had set up a Google alert to send him news about OxyContin, and he objected to a Purdue Vice President: "Why are all the alerts about negatives and not one about the positives of OxyContin tablets?"[284] Staff immediately offered to replace Richard Sackler's alert with a service that provided more flattering stories.[285]

299. Staff reported to the Sacklers that a key initiative during Q3 2013 was for sales representatives to encourage doctors to prescribe OxyContin to elderly patients on Medicare.[286] [redacted]

[redacted]

[280] 2013-10-23 email from Edward Mahony, PWG004334218.

[281] 2013-10-29 OxyContin 2014 Budget Proposal to the Board, PWG004338136.

[282] 2013-10-29 Sales & Marketing presentation to the Board, PWG004338063.

[283] 2013-10-29 Sales Force 2014 Objectives presented to the Board, PWG004338073.

[284] 2013-11-18 email from Richard Sackler, PWG004336630.

[285] 2013-11-18 email from Raul Damas, PWG004336630.

[286] 2013-11-01 Board report, pg. 15, PWG004334067.

[redacted]

300. Staff also reported to the Sacklers that another key initiative during Q3 2013 was for sales representatives to promote OxyContin for patients who had never taken opioids before.[287] [redacted]

301. Staff also told the Sacklers that analysis conducted in July 2013 showed that opioid savings cards earned the Sacklers more money by keeping patients on opioids longer; specifically, more patients stayed on OxyContin longer than 60 days. Staff reported to the Sacklers that Purdue was pushing opioid savings cards in sales representative visits, through email to tens of thousands of health care providers, and online.[288] [redacted]

302. Staff reported to the Sacklers that Purdue paid their family $399,920,000 during January-September 2013. But staff told the Sacklers that, during the same period, Purdue lost hundreds of millions of dollars in potential profits because some prescribers were shifting away from higher doses of Purdue opioids.[289]

[287] 2013-11-01 Board report, pg. 14, PWG004334066.

[288] 2013-11-01 Board report, pgs. 15-16, 23-24, PWG004334067-068, -075-076.

[289] 2013-11-01 Board report, pgs. 3, 6, PWG004334055, -058.

303. Staff also reported to the Sacklers that a key initiative in 2013 was to train sales representatives to keep patients on Butrans opioids longer. They told the Sacklers that, at the same time as the initiative to keep patients on opioids longer, Purdue launched a new high dose of its Butrans opioid; sales representatives began promoting the new high dose to physicians using new sales materials; and initial orders were double the company's forecasts. Staff reported to the Sacklers that marketing and sales activities generated 266,842 additional prescriptions and highlighted that opioid savings cards generate especially "high returns" by keeping patients on opioids longer.[290]

304. Staff reported to the Sacklers that Purdue had sent more than 880,000 emails to health care professionals to promote its Butrans opioid, and posted online advertising seen more than 5 million times for Butrans and nearly 4 million times for OxyContin. They told the Sacklers that hundreds of thousands of communications to prescribers nationwide presented the same "key selling messages" designed to get more patients on OxyContin at higher doses for longer periods of time, and specifically promoted Purdue's opioid savings cards.[291] On information and belief, these communications were disseminated to Vermont prescribers.

305. Staff reported to the Sacklers that they were working with McKinsey to study ways to sell even more OxyContin. Staff also reported that they had direct access to physician-level data to analyze prescriptions by individual doctors. Staff gave the Sacklers the latest results regarding how opioid savings cards led to patients staying on OxyContin longer.[292]

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[290] 2013-11-01 Board report, pgs. 11-13, 27, PWG004334063-065, -079.

[291] 2013-11-01 Board report, pgs. 14, 16, PWG004334066, -68.

[292] 2013-11-01 Board report, pgs. 20-23, PWG004334072-75.

306. Staff also told the Sacklers that they would begin reviews of sales representatives according to their sales ranking, with a focus on the bottom ten percent. Staff reported to the Sacklers that Purdue employed 637 sales representatives and, during Q3 2013, they visited prescribers 179,640 times,[293] [redacted]

307. **December 2013:** Staff told Richard Sackler that Butrans sales were increasing, and they suspected the increase was caused by Purdue's improved targeting, in which sales representatives visited the most susceptible prolific prescribers.[294]

308. Meanwhile, staff contacted Richard Sackler because they were concerned that the company's "internal documents" could cause problems if investigations of the opioid crisis expanded.[295] Early the next year, staff told Jonathan Sackler about the same concern. Jonathan studied collections of news reports and asked staff to assure him that journalists covering the opioid epidemic were not focused on the Sacklers.[296]

309. **January 2014:** Staff reported to the Sacklers on how Purdue's program for complying with state and federal law compared to recent agreements between other drug companies and the government. Other companies had agreed that sales representatives should not be paid bonuses based on increasing doctors' prescriptions, but Purdue still paid representatives for generating sales. Other companies disclosed to the public the money they spent to influence continuing medical education, but Purdue did not. Other companies had adopted "claw-back"

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[293] 2013-11-01 Board report, pgs. 11, 52, 55, PWG004334063, -104, -107. Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 196,845 visits; and that representatives visited 6.9 prescribers per day, on average, compared to a target of 7.1.

[294] 2013-12-04 email from David Rosen, PWG004334232.

[295] 2014-01-03 email from Burt Rosen, PWG004332488 ("I spoke to Richard just before the year end and raised concerns over our internal documents.").

[296] 2014-01-02 email from Jonathan Sackler, PWG004332488.

policies so that executives would forfeit bonuses they earned from misconduct, but Purdue had not. The boards of other companies passed resolutions each quarter certifying their oversight of the companies' compliance with the law, but the Sacklers did not.[297]

310. **February 2014:** Staff sent the Sacklers the final results from 2013.[298] Staff told the Sacklers that net sales were hundreds of millions of dollars below budget because doctors were not prescribing enough of the highest doses of opioids, doctors were including too few pills with each prescription, and sales representatives were not visiting doctors enough.[299] Sales VP Russell Gasdia wrote privately to a friend: "Our myopic focus on extended release opioids with abuse deterrent properties has not yielded the results people thought it would in the market. It's been hard to convince colleagues and the board that our success in this market is over."[300]

311. To get higher sales, staff told the Sacklers that they had tightened the requirements for sales representatives' pay: from now on, sales representatives would lose bonus pay if they did not visit "high value" prescribers often enough.[301] [redacted]

[297] 2014-01-16 quarterly compliance report to the Board, PWG004338834.

[298] 2014-02-03 email from Edward Mahony, PWG004332207.

[299] 2014-01-30 memo from Edward Mahony, PWG004332208.

[300] 2014-02-27 email from Russell Gasdia, PWG004335682.

[301] 2014-01-30 memo from Edward Mahony, PWG004332209.

[302] [redacted]

[redacted]

312. Also in February 2014, staff told the Sacklers that Purdue's marketing had an immense effect in driving opioid prescriptions: according to Purdue's analysis, its sales and marketing tactics generated an additional 560,036 prescriptions of OxyContin in 2012 and 2013. Nevertheless, staff reported to the Sacklers that net sales for 2013 had been $377,000,000 less than budgeted. Staff again reported that Purdue was losing hundreds of millions of dollars in expected profits because prescribers were shifting away from higher doses of Purdue opioids and including fewer pills per prescription. Staff told the Sacklers that a "Key Initiative" was to get patients to "stay on therapy longer."[303]

313. Staff also told the Sacklers that key sales priorities were again to encourage doctors to prescribe Purdue opioids for elderly patients and patients who had not taken opioids before. Staff reported to Sacklers again that sales representatives were continuing the *Individualize The Dose* campaign.[304] As the Sacklers knew, Purdue designed that campaign to encourage higher doses. Staff also told the Sacklers that Purdue's "eMarketing" campaign for OxyContin reached 84,250 health care providers during Q4 2013. Staff told the Sacklers that they found increasing

[303] 2014-02-04 Board report, pgs. 3, 5, 9, 22, PWG004333875, -877, -881, 894.

[304] 2014-02-04 Board report pgs. 13-14, PWG004333885-886.

compliance concerns with Purdue's speaker programs, in which the company paid doctors to promote Purdue opioids to other doctors.[305]

314. [redacted]

315. Staff told the Sacklers that Purdue employed 632 sales representatives and, during Q4 2013, they visited prescribers 176,227 times,[307] [redacted]

316. That February report was the last of its kind. After Q4 2013, Purdue discontinued the detailed Quarterly Reports that had created a paper trail of targets for sales visits and been emailed among the Board and staff. In 2013, the City of Chicago served Purdue with a subpoena seeking internal documents about Purdue's marketing of opioids. Purdue fought the subpoena, and it was withdrawn. For 2014, Purdue decided to limit many of its official Board reports to numbers and graphs, and relay other information orally. But the Sacklers continued to demand information about sales tactics, and their control of Purdue's deceptive marketing did not change.

317. **March and April 2014:** Staff told the Sacklers that Purdue was achieving its goals of selling higher doses of OxyContin and more pills of OxyContin per prescription, but weekly prescriptions of Purdue's Butrans opioid were below expectations because of a reduced number of

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[305] 2014-02-04 Board report pgs. 15, 39-40, PWG004333887, -911-912.

[306] [redacted]

[307] 2014-02-04 Board report, pgs. 9, 47, PWG004333881, -919. Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 183,960 visits; and that representatives hit the target of visiting 7.1 prescribers per day, because managers reduced the target for visiting pharmacies to allow more visits to prescribers.

sales representative visits promoting that opioid.[308] The Sacklers had assumed prescriptions would fall, but staff were concerned that the effect could be greater than anticipated.

318. **May 2014:** Richard and Jonathan Sackler's father, Raymond Sackler, sent David, Jonathan, and Richard Sackler a confidential memo about Purdue's strategy [redacted] The memo recounted that some physicians had argued that patients should not be given high doses of Purdue opioids, or kept on Purdue opioids for long periods of time, but Purdue had defeated efforts to impose a maximum dose limit or a maximum duration of use. Raymond Sackler asked David, Jonathan, and Richard Sackler to talk with him about the memo.

319. **June 2014:** The Sacklers removed Russell Gasdia as Vice President of Sales and Marketing and began pushing his replacement to sell more opioids faster. Gasdia warned his replacement that Richard Sackler managed the sales operation intensely—"there are times this becomes a tennis match with Dr. Richard."[309] Sure enough, Richard Sackler told Gasdia's replacement that he would be given little time to show that he could increase opioid sales: "it is very late in the day to rescue the failed launch" of Butrans, which was not making as much money as Richard Sackler desired.[310] CEO Mark Timney tried to caution Richard that it was "a little early" to be attacking the new sales leader, since he'd been at Purdue only two weeks.[311]

[308] 2014-03-07 email from Edward Mahony, PWG004524096-097; 2014-04-06 email from Edward Mahony, PWG004335566.

[309] 2014-06-10 email from Russell Gasdia, PWG004335670.

[310] 2014-06-10 email from Richard Sackler, PWG004335674.

[311] 2014-06-10 email from Mark Timney, PWG004335674.

320. That same month, staff sent the Sacklers an "Update on L.A. Times mitigation effort" about tactics to discourage scrutiny of Purdue's misconduct.[312] Staff wrote to the Sacklers:

> As you may recall, one of our efforts to mitigate the impact of a potential negative *Los Angeles Times* (LAT) story involved assisting a competing outlet in marginalizing the LAT's unbalanced coverage by reporting the facts before the LAT story ran. The following *Orange County Register* story, developed in close coordination with Purdue, achieved this goal. This fact-based narrative robs the LAT account of its newsworthiness and contradicts many of the claims we expected that paper to make.[313]

In 2012, the *Los Angeles Times* had studied coroner's records and revealed that overdoses killed thousands of patients who were taking opioids prescribed by their doctors, refuting the Sacklers' lie that patients who are prescribed opioids don't get addicted and die.[314] The next year, the *Los Angeles Times* revealed that Purdue tracked suspicious prescribing of OxyContin with a secret list of 1,800 doctors code-named *Region Zero*, but did not report them to the authorities.[315]

321. **July 2014:** Richard Sackler called staff to complain about studies that the FDA required for opioids and how they might undermine Purdue's sales. He emphasized that Purdue Board members felt the requirements to conduct studies were unfair. Staff tried to reassure Richard that the studies would take "several years to complete, thereby keeping our critics somewhat at-bay during this time."[316]

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[312] 2014-06-30 email from Raul Damas, PWG004336634. A few weeks after receiving the mitigation update, Richard Sackler demanded that the *L.A. Times* send him all the paper's correspondence with Purdue. 2014-08-14 email from Scott Glover, PWG004332246.

[313] 2014-06-30 email from Raul Damas, PWG004336634. Years earlier, the Sacklers had tried to influence the *New York Times* to be "less focused on OxyContin/Purdue." 2011-04-22 email from John Stewart, PWG004332542.

[314] 2012-11-11 "Legal drugs, deadly outcomes," by Scott Glover and Lisa Girion.

[315] 2013-08-11 "OxyContin maker closely guards its list of suspect doctors," by Scott Glover and Lisa Girion.

[316] 2014-07-22 email from Todd Baumgartner, PWG004334051-052.

322. **In July** and again in **August, September**, and **October 2014:** Staff warned the Sacklers that two of the greatest risks to Purdue's business were "Continued pressure against higher doses of opioids," and "Continued pressure against long term use of opioids."[317]

RISKS

i. Continued pressure against higher doses of opioids,

ii. Continued pressure against long term use of opioids,

Staff report to the Board on risks facing Purdue's business

Staff told the Sacklers that Purdue's #1 opportunity to resist that pressure was by sending sales representatives to visit prescribers; and, specifically, by targeting the most susceptible doctors, who could be convinced to be prolific prescribers, and visiting them many times.[318]

323. **In August,** [redacted][319]

324. **September 2014:** Kathe Sackler dialed in to a confidential call about *Project Tango*. *Project Tango* was a secret plan for Purdue to expand into the business of selling drugs to treat opioid addiction. In internal documents, Purdue staff wrote down what it had publicly denied for decades: that addictive opioids and opioid addiction are "naturally linked." Staff proposed that Purdue should expand across "the pain and addiction spectrum," to become "an end-to-end pain

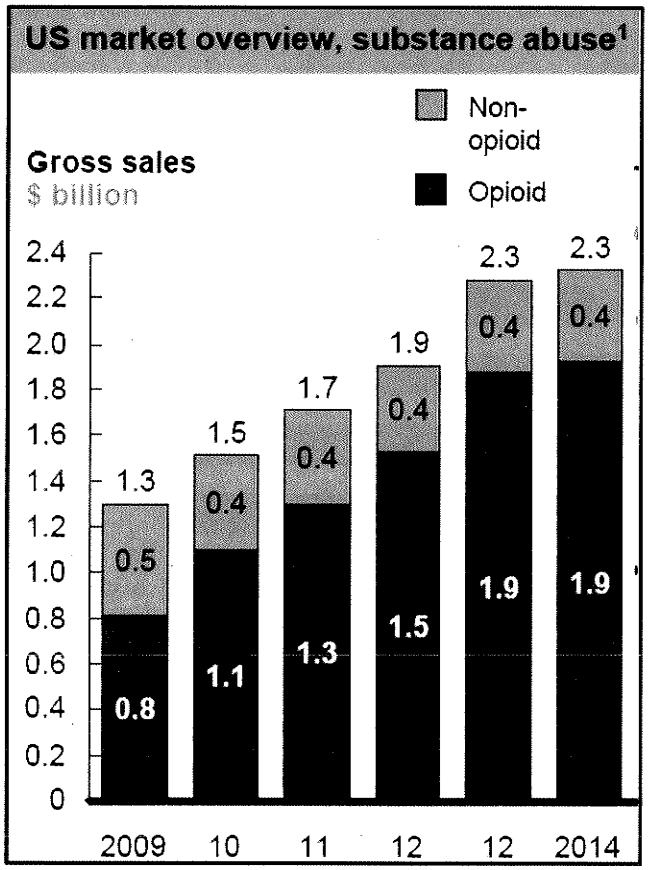
[317] 2014-07-01 Board Flash Report, slide 5, PWG004336412; 2014-08-05 Board Flash Report, slide 6, PWG004334424; 2014-09-05 Board Flash Report, slide 6, PWG004334661; 2014-10-15 Board Flash Report, slide 7, PWG004334293.

[318] 2014-07-01 Board Flash Report, slide 5, PWG004336412; 2014-08-05 Board Flash Report, slide 6, PWG004334424; 2014-09-05 Board Flash Report, slide 6, PWG004334661.

[319] [redacted]

provider." Purdue illustrated the end-to-end business model with a picture of a dark hole labeled "Pain treatment" that a patient could fall into—and "[o]pioid addiction treatment" waiting at the bottom.[320]

325. Kathe Sackler and the *Project Tango* team reviewed their findings that the "market" of people addicted to opioids—measured in billions of dollars, rather than human lives—had doubled from 2009 to 2014.



Purdue's Measure of the Opioid Addiction "Market"

[320] 2014-09-10 email from Brian Meltzer, PWG004490064; 2014-09-12 presentation, PWG004415180.

The presentation reviewed by Kathe Sackler and the staff showed that the catastrophic trend of addiction rates provided an excellent compound annual growth rate ("CAGR"): "Opioid addiction (other than heroin) has grown by ~20% CAGR from 2000 to 2010."[321]

326. The presentation made clear that Purdue's tactic of blaming addiction on untrustworthy patients was a lie. Instead, the truth is that opioid addiction can happen to anyone who is prescribed opioids:

> ▪ *"This can happen to any-one – from a 50 year old woman with chronic lower back pain to a 18 year old boy with a sports injury, from the very wealthy to the very poor"*

Purdue's "Project Tango" patient and clinical rationale

The presentation concluded that the millions of people who became addicted to opioids were the Sacklers' next business opportunity. Staff wrote: "It is an attractive market. Large unmet need for vulnerable, underserved and stigmatized patient population suffering from substance abuse, dependence and addiction." The team identified eight ways that Purdue's experience getting patients *on* opioids could now be used to sell treatment for opioid addiction.[322]

327. Kathe Sackler instructed staff to look into reports of children requiring hospitalization after swallowing buprenorphine—the active ingredient in both Purdue's Butrans opioid and the opioid addiction treatment that the Sacklers considered selling, through *Project*

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[321] 2014-09-10 presentation, slide 4, PWG004415175. The Board discussed *Project Tango* in October 2014. 2014-10-01 Board meeting materials, PWG004338853.

[322] 2014-09-10 presentation, slides 2, 4, PWG4415175.

Tango, in a film that melts in a patient's mouth.[323] Staff assured Kathe Sackler that children were overdosing on pills, not films, "which is a positive for *Tango*."[324]

328. [redacted]

329. [redacted] The *Tango* team mapped how patients could get addicted to opioids through prescription opioid analgesics (such as Purdue's OxyContin) or heroin, and then become consumers of the new company's Suboxone. The team noted the opportunity to capture repeat customers: even after patients were done buying Suboxone the first time, between 40-60% would relapse and need it again.[326]

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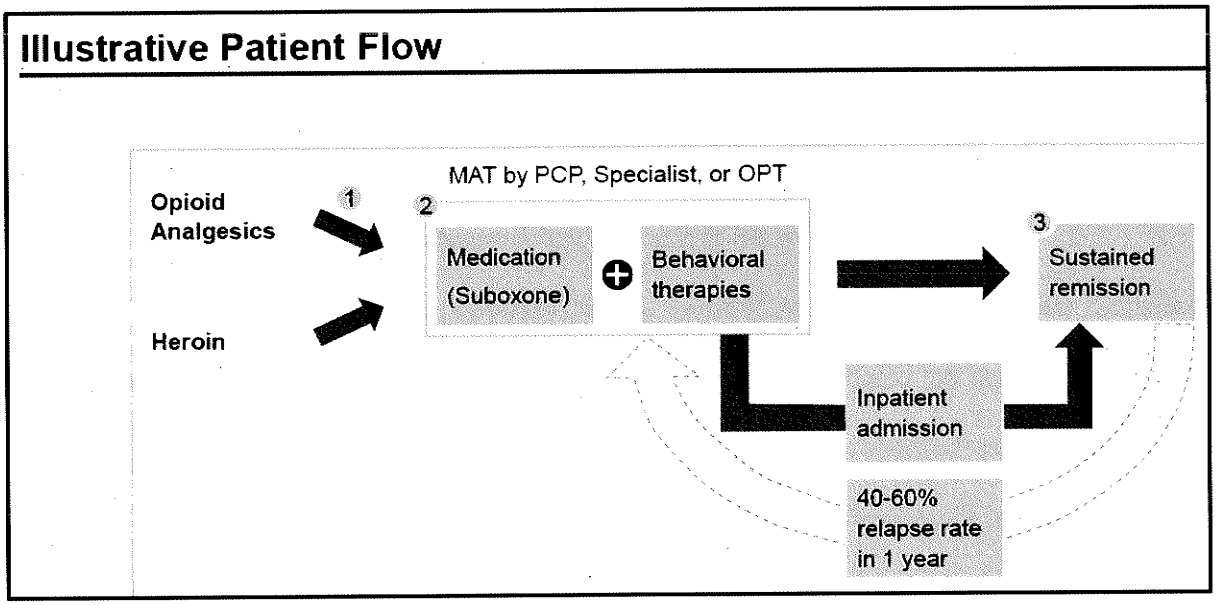
[323] 2014-09-16 email from Kathe Sackler, PWG004331682.

[324] 2014-09-17 email from Mark Timney, PWG004331681-682.

[325] [redacted]

[326] 2015-02-24 *Project Tango* presentation, PWG004334111.



Purdue presentation explaining "Project Tango" patient flow

330. The next month, *Project Tango* came to an end. Kathe, David, Jonathan, and Mortimer Sackler discussed the discontinuation of the project at their Business Development Committee meeting. But the Sacklers' efforts to sell addictive opioids continued.

331. **October 2014:** Staff sent the Sacklers a Proposed Operating Plan and Budget to be approved by the Board for 2015.[327] Staff told the Sacklers that a key tactic for 2015 would be to convert patients from short-acting opioids to OxyContin. Staff warned the Sacklers that prescribers were shifting away from the highest doses of Purdue's opioids, and toward fewer pills per prescription, and those shifts would cost Purdue $99,000,000 a year. Staff told the Sacklers that a key tactic to increase Butrans sales in 2015 would be for Purdue sales representatives to push doctors to "titrate up" to higher doses. Staff likewise told the Sacklers that visits to doctors by sales representatives would be a key tactic to launch Purdue's new Hysingla opioid: the company would "[l]everage Purdue's existing, experienced sales force to drive uptake with target HCPs" and

[327] 2014-10-24 email from Edward Mahoney, PWG004336423.

"[a]dd additional contract sales force capacity at launch to drive uptake."[328] Staff proposed that Purdue employ 519 sales representatives, paid an average salary of $81,300 plus a bonus of up to an additional $124,600 based on sales.[329]

332. Meanwhile, sales staff exchanged news reports of a lawsuit accusing Purdue of deceptive marketing in Kentucky.[330] They quoted Purdue's own attorney and Chief Financial Officer stating that the company faced claims of more than a billion dollars that "would have a crippling effect on Purdue's operations and jeopardize Purdue's long-term viability."[331] Purdue's Vice President of Corporate Affairs was delighted by the article, because it did not reveal the Sacklers' role in the misconduct. "I'm quite pleased with where we ended up. There's almost nothing on the Sacklers and what is there is minimal and buried in the back."[332] [redacted][333]

[328] 2015 Commercial Budget Review, slides 19, 26, 31, 38, 51, 67, PWG004336456, -463, -468, , -475, -488, -504.

[329] 2015 Budget Submission, slides 13, 56, PWG004336544, -587.

[330] 2014-10-20 email from John Axelson, PWG004336379.

[331] 2014-10-20 Bloomberg Businessweek report, PWG004336386.

[332] 2014-10-20 email from Raul Damas, PWG004415329.

[333] [redacted]

333. **November 2014:** Staff reported to the Sacklers that their sales tactics were working, and the shift away from higher doses of OxyContin had slowed.[334]

334. **December 2014:** Staff told the Sacklers that Purdue would pay their family $163,000,000 in 2014 and projected $350,000,000 in 2015.[335]

335. **New Year's Eve 2014:** Richard Sackler told staff that he was starting a confidential sales and marketing project on opioid prices and instructed them to meet with him about it on January 2.[336]

336. Early in the morning of **January 2, 2015**, staff started collecting sales data for Richard Sackler.[337] They didn't move quickly enough. Days later, Richard Sackler demanded a meeting with sales staff to go over plans for selling the highest doses. He asked for an exhaustive examination to be completed within 5 days, including:

> [U]nit projections by strength, mg by strength ... pricing expectations by strength ... individual strength's market totals and our share going back[w]ard to 2011 or 12 and then forward to 2019 or 2020 ... the same information for Hysingla ... [and] the history of OxyContin tablets from launch to the present.[338]

The CEO stepped in to say the work would have to wait three weeks [redacted]. Richard let him know that wasn't a great response—"That's longer than I had hoped for"—and directed marketing staff to start sending him materials immediately.[339]

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[334] 2014-11 OxyContin Brand Strategy and Forecast for 2015, PWG004338984 ("Strength mix shifting toward lower strengths has slowed with 40-80mg share going from 29% in the 10 Year Plan to 33% in the Budget").

[335] November 2014 report slide 8, PWG004334630.

[336] 2014-12-31 email from Richard Sackler, PWG004334464-465.

[337] 2015-01-02 email from Saeed Motahari, PWG004334463.

[338] 2015-01-07 email from Richard Sackler, PWG004334459-460.

[339] 2015-01-08 email from Richard Sackler, PWG004334459. Mark Timney had started as CEO a year earlier with the idea that he could "separate Board interaction from the organization" so the

337. That same month, the Sacklers voted to evaluate employees' 2014 performance on a scorecard that assigned the greatest value to the volume of Purdue opioid sales. Employees were expected to generate more than one-and-a-half billion dollars. The Sacklers also voted to establish the company's scorecard for 2015: once again, the biggest factor determining employees' payout would be the total amount of Purdue opioid sales.

338. **April 2015:** Staff told the Sacklers that sales of Purdue's highest dose 80mg OxyContin were down 20% and that the average prescription had declined by eight pills since 2011.

339. The Sacklers voted to expand the sales force by adding another 122 representatives.[340] As with every reference to "the Sacklers" after July 2012, that includes Beverly, David, Ilene, Jonathan, Kathe, Mortimer, Richard, and Theresa Sackler.

340. Staff told the Sacklers the additional representatives would increase net sales of opioids by $59 million.[341]

341. **June 2015**: After the City of Chicago sued Purdue Pharma for deceptive advertising, [redacted][342] [redacted]

Sacklers would stop directing sales staff. 2014-01-29 email from Mark Timney, PWG004334456. That effort failed.

[340] 2015-04-21 Board materials, PWG004330062 ("It was decided to move forward with an expansion of the sales force by 122 reps"); 2015-05-04 Strategic Plan Update, slide 5, PWG004332262; 2015-04-21 Board decision, PWG004340515.

[341] 2015-04-21 Board materials, PWG004330058.

[342] [redacted]

[redacted] as discussed in Section A.

342. **October 2015:** Purdue executives identified avoiding investigations of Purdue's opioid marketing as a "Key Activity" in the company's Operational Plan.[343]

343. **November 2015:** The Sacklers voted on the budget for Purdue for 2016. Staff warned the Sacklers that public concern about opioids could get in the way of Purdue's plans. Staff again told the Sacklers that two of the most significant challenges to Purdue's plans were doctors not prescribing enough of the highest strength opioids and including too few pills in each prescription. Staff told the Sacklers that declining prescriptions of the highest doses and fewer pills per prescription would cost Purdue $77 million.[344]

344. Staff proposed to the Sacklers that, for 2016, Purdue would plan for prescribers to average 60 pills of Purdue opioids per prescription. They told the Sacklers that they would aim to make enough of those pills be high doses to make the average per pill 33 milligrams of oxycodone.[345] That way, Purdue could hit its target for the total kilograms of oxycodone it wanted to sell.

345. To make sure Purdue hit the targets, staff told the Sacklers that sales representatives were visiting prescribers 21% more often than before. Staff told the Sacklers that they had aggressively reviewed and terminated representatives who failed to generate prescriptions. Staff

[343] 2015-10-27 Executive Operating Committee presentation, slide 16, PWG004329881.

[344] 2015-11 budget for 2016, slides 16, 28, 44, PWG004336046, -058, -074.

[345] 2015-11 budget for 2016, slide 41, PWG004336071.

reported to the Sacklers that, in 2015 alone, Purdue replaced 14% of its sales representatives and 20% of its district managers for failing to create enough opioid sales.[346]

346. Looking ahead, staff told the Sacklers that "the 2016 investment strategy focuses on expanding the Sales Force." They reported that the proposed budget for sales and promotion was $11,600,000 higher than 2015, "primarily due to the Sales Force expansion." The top priority for the sales representatives would be to visit the highest-prescribing doctors again and again. Staff proposed to the Sacklers that the #1 overall priority for 2016 would be to sell OxyContin through "disproportionate focus on key customers." They told the Sacklers that sales representatives would also target prescribers with the lowest levels of training, physician's assistants and nurse practitioners, because they were "the only growing segment" in the opioid market.[347] Purdue executives expected that, each quarter, the sales representatives would visit prescribers more than 200,000 times and would get 40,000 new patients onto Purdue opioids.[348]

347. **December 2015:** Staff prepared to address wide-ranging concerns raised by the Sacklers. Kathe and Mortimer Sackler wanted staff to break out productivity data by indication versus prescriber specialty for each drug. Richard Sackler sought details on how staff were calculating 2016 mg/tablet trends. Jonathan Sackler sought a follow-up briefing on how public health efforts to prevent opioid addiction would affect OxyContin sales.

348. **2016:** The Sacklers participated in regular meetings with the rest of the Board throughout 2016: in January, March, April, June, August, October, November, and December.

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[346] 2015-11 budget for 2016, slides 7, 39, PWG004336037, -069. Purdue fired 107 sales representatives in 2015.

[347] 2015-11 budget for 2016, slides 24, 26, 49, PWG004336054, -056, -079.

[348] 2015-11-03 email from Zach Perlman, Executive Committee materials, slide 36, PWG004335977.

349. **April 2016:** The Sacklers considered exactly how much money was riding on their strategy of pushing higher doses of opioids. The month before, the CDC announced guidelines to try to slow the epidemic of opioid overdose and death. The CDC urged prescribers to avoid doses higher than 30mg of Purdue's OxyContin twice per day. The CDC discouraged twice-a-day prescriptions of all three of Purdue's most profitable strengths—40mg, 60mg, and 80mg. Staff studied how much money Purdue was making from its high dose strategy and told the Sacklers the amount at risk on a state-by-state basis. In Vermont, [redacted].[349]

350. **May 2016:** Richard Sackler told staff to circulate a *New York Times* story reporting that opioid prescriptions were dropping for the first time since Purdue launched OxyContin twenty years earlier. The *Times* wrote: "Experts say the drop is an important early signal that the long-running prescription opioid epidemic may be peaking, that doctors have begun heeding a drumbeat of warnings about the highly addictive nature of the drugs." The only person quoted in favor of *more* opioid prescribing was a professor whose program at his university was funded by the Sacklers.[350]

351. **June 2016:** The Sacklers met to discuss a revised version of *Project Tango*—another attempt to profit from the opioid crisis. This time, they considered a scheme to sell the overdose antidote NARCAN. The need for NARCAN to reverse overdoses was rising so fast that the Sacklers calculated it could provide a growing source of revenue, tripling from 2016 to 2018.

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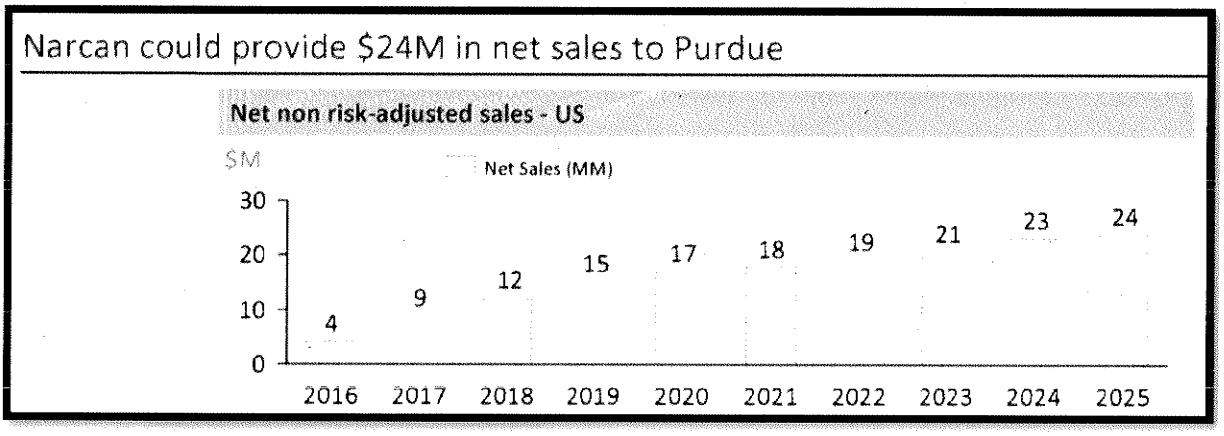
[349] PWG003976914.

[350] 2016-05-21 email from Richard Sackler, PWG004527906; 2016-05-20 "Opioid Prescriptions Drop for First Time in Two Decades," by Abby Goodnough and Sabrina Tavernise. The opioid advocate was Dr. Daniel B. Carr, director of Tufts Medical School's program on pain research education and policy.



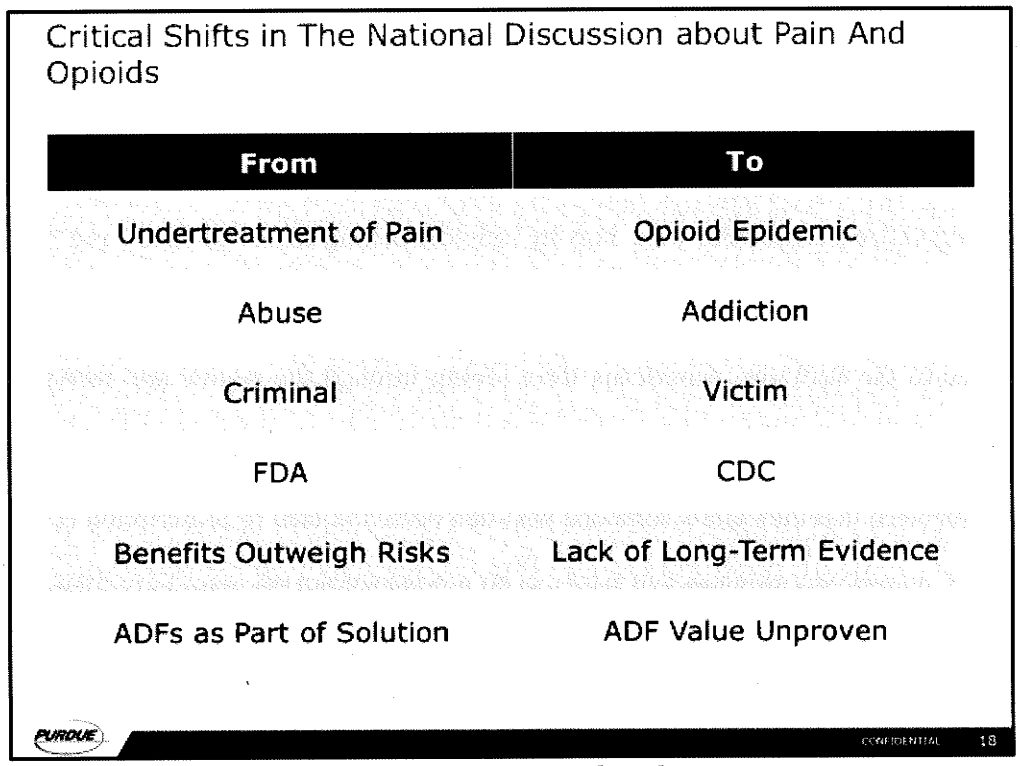
Board presentation showing potential sales from acquiring NARCAN

Like *Tango*, Purdue's analysis of the market for NARCAN confirmed that they saw the opioid epidemic as a money-making opportunity and that the Sacklers understood how Purdue's opioids put patients at risk. Staff presented NARCAN to the Sacklers as a "strategic fit" because NARCAN is a "complementary" product to Purdue opioids. The presentation specifically identified patients on Purdue's prescription opioids as the target market for NARCAN. The plan called for studying "*long-term script users*" to "better understand target end-patients" for NARCAN. Likewise, the plan identified the same doctors who prescribed the most Purdue opioids as the best market for selling the overdose antidote; Purdue planned to "leverage the current Purdue sales force" to "drive direct promotion to targeted opioid prescribers." Finally, staff's presentation to the Sacklers noted that Purdue could profit from government efforts to use NARCAN to save lives, [redacted].[351]

352. That same month, staff presented the 2016 Mid-Year Update. They warned the Sacklers that shifts in the national discussion of opioids threatened their plans. The deception that

[351] 2016-06 Board Book slides 46-49, 114, PWG004335773-776, -841. They planned to "Segment opioid patients to better understand target end-patients (e.g., long-term script users)."

Purdue had used to conceal the risks of opioids was being exposed. Staff summarized the problems on a slide:[352]



2016 Mid-Year Board Update

353. First, to convince doctors to prescribe dangerous opioids, Purdue had promoted its drugs as the solution to "undertreatment of pain." Richard Sackler had made sure that Purdue bought the internet address 5thvitalsign.com so it could promote pain as the "fifth vital sign" (along with temperature, blood pressure, pulse, and breathing rate) to expand the market for opioids. But now, staff reported to the Sacklers, doctors and patients were starting to worry more about the epidemic of opioid addiction.[353]

[352] 2016-06-08 Mid-Year Update, slide 18, PWG004335859. "ADF" on the slide refers to abuse-deterrent formulations of opioids, such as Purdue's crush-resistant OxyContin, which do not prevent addiction.

[353] 2016-06-08 Mid-Year Update, slide 18, PWG004335859.

354. Second, to conceal the danger of addiction, Purdue had falsely blamed the terrible consequences of opioids on drug abuse. One of Purdue's key messages argued: "It's not addiction, it's abuse."[354] But now, staff reported to the Sacklers, doctors and patients were realizing that addiction was a true danger.[355]

355. Third, to avoid responsibility for Purdue's dangerous drugs, the Sacklers had chosen to stigmatize people who were hurt by opioids, calling them "junkies" and "criminals." Richard Sackler had written that Purdue should "hammer" them in every way possible.[356] But now, staff reported to the Sacklers, Americans were seeing through the stigma and recognizing that millions of families were victims of addictive drugs. Staff told the Sacklers that nearly half of Americans reported that they knew someone who had been addicted to prescription opioids.[357]

356. Fourth, the Sacklers had long sought to hide behind the approval of Purdue's drugs by the FDA. But FDA approval could not protect the Sacklers when their deceptive marketing led thousands of patients to become addicted and die. The CDC reported that opioids were, indeed, killing people. The CDC Director said: "We know of no other medication that's routinely used for a nonfatal condition that kills patients so frequently."[358] The 2016 Mid-Year Update warned that the truth was threatening Purdue.

357. [redacted]

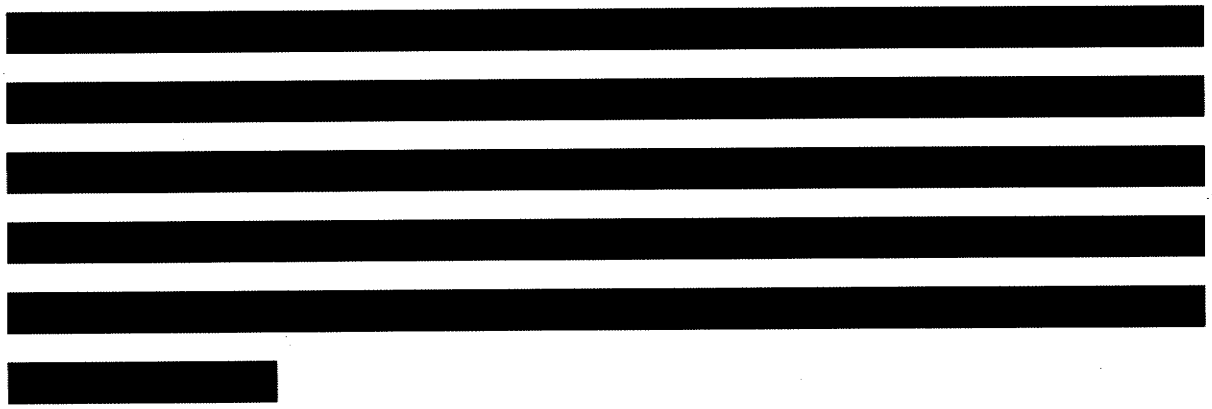
[354] 2008-05-16 email from Pamela Taylor, PWG004445356; 2008-04-16 Executive Committee notes, PWG004332813; 2008-04-16 presentation by Luntz, Maslansky Strategic Research, slide 28, PWG004414396.

[355] 2016-06-08 Mid-Year Update, slide 18, PWG004335859.

[356] 2001-02-01 email from Richard Sackler, PWG004342047 ("we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals.").

[357] 2016-06-08 Mid-Year Update, slides 18, 20, PWG004335859, -861.

[358] 2016-03-15 briefing by CDC Director Tom Frieden.



358. **November 2016:** Staff prepared draft statements to the press denying the Sacklers' involvement in Purdue. Their draft claimed: "Sackler family members hold no leadership roles in the companies owned by the family trust."[359] That was a lie. Sackler family members held the controlling majority of seats on the Board and, in fact, controlled the company. A staff member reviewing the draft commented: "Love the … statement."[360] Staff eventually told the press: "Sackler family members hold no management positions."[361]

359. **December 2016:** Richard, Jonathan and Mortimer Sackler had a call with staff about another revised version of *Project Tango*. The new idea was to buy a company that treated opioid addiction with implantable drug pumps. The business was a "strategic fit," because Purdue sold opioids and the new business treated the "strategically adjacent indication of opioid dependence."[362] The Sacklers kept searching for a way to expand their business by selling both addictive opioids and treatment for opioid addiction.

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[359] 2016-11-03 email from Robert Josephson, PWG004336632.

[360] 2016-11-03 email from Raul Damas, PWG004336632 ("Love the second statement" – it was the second of two statements in the draft).

[361] 2016-11-28 email from Robert Josephson, PWG004331703.

[362] 2016-12-22 Braeburn Pharmaceuticals: Structuring Analysis, slide 3, PWG004336600.

360. **In April 2017,** [redacted][363]

361. **May 2017:** Staff told the Sacklers that the independent nonprofit's final report had concluded that Purdue's reformulation of OxyContin was not a cost-effective way to prevent opioid abuse.[364] Theresa Sackler asked staff what they were doing to fight back to convince doctors and patients to keep using the drug.[365]

362. That same month, the Sacklers were looking for a new CEO. Long-time employee Craig Landau wanted the job and prepared a business plan titled "SACKLER PHARMA ENTERPRISE." Landau was careful to acknowledge their power: he recognized that Purdue operated with "the Board of Directors serving as the 'de facto' CEO." He proposed that Purdue should take advantage of other companies' concerns about the opioid epidemic through an "opioid consolidation strategy" and become an even more dominant opioid seller "as other companies abandon the space."[366] The Sacklers made him CEO a few weeks later.

363. **June 2017:** Staff told the Sacklers that getting doctors to prescribe high doses of opioids and many pills per prescription were still key "drivers" of Purdue's profit. Purdue's

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[363] [redacted]

[364] 2017-05-06 email from Gail Cawkwell, PWG004333152.

[365] 2017-05-06 email from Theresa Sackler, PWG004333152.

[366] 2017-05-02 Landau presentation, PWG004415342.

management was concerned that the CDC's efforts to save lives by reducing doses and pill counts would force the company "to adjust down our revenue expectations."[367]

364. Staff told the Sacklers that Purdue's opioid sales were being hurt by cultural trends such as the HBO documentary, "*Warning: This Drug May Kill You.*"[368] HBO's film was a problem for Purdue because it showed actual footage from Purdue's misleading advertisements next to video of people who overdosed and died.

365. Staff felt the pressure of the opioid epidemic, even if the Sacklers did not. In one presentation, staff told the Sacklers: "Purdue Needs a New Approach." Their suggestion for a new direction was: "A New Narrative: Appropriate Use."

The Sacklers led Purdue so far off course that employees proposed appropriate use of drugs as a "new narrative" to reinvent the company. Staff also suggested that the Sacklers create a family foundation to help solve the opioid crisis.[369]

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[367] 2017-06 Board of Directors: Purdue Mid-Year Pre-Read, slides 2, 152, PWG004333346, -496.

[368] 2017-06 Board of Directors: Purdue Mid-Year Pre-Read, slide 6, PWG004333350.

[369] 2017-06 Board of Directors: Purdue Mid-Year Pre-Read, slides 36-38, PWG004333380-382.

366. The Sacklers did not redirect the company toward appropriate use or create the suggested family foundation. Instead, they approved a 2018 target of [redacted]—more than the number of sales visits they had ordered for OxyContin in 2010.

367. **October 2017:** Richard Sackler learned that insurance company Cigna had cut OxyContin from its list of covered drugs and replaced it with a drug from Purdue's competitor, Collegium. Richard read that Collegium had agreed to encourage doctors to prescribe lower doses of opioids, and Collegium's contract with Cigna was designed so Collegium would earn *less* money if doctors prescribed high doses. Cigna announced that opioid companies influence dosing: "While drug companies don't control prescriptions, they can help influence patient and doctor conversations by educating people about their medications." Richard Sackler's first thought was to counterpunch. He immediately suggested that Purdue drop Cigna as the insurance provider for the company health plan.

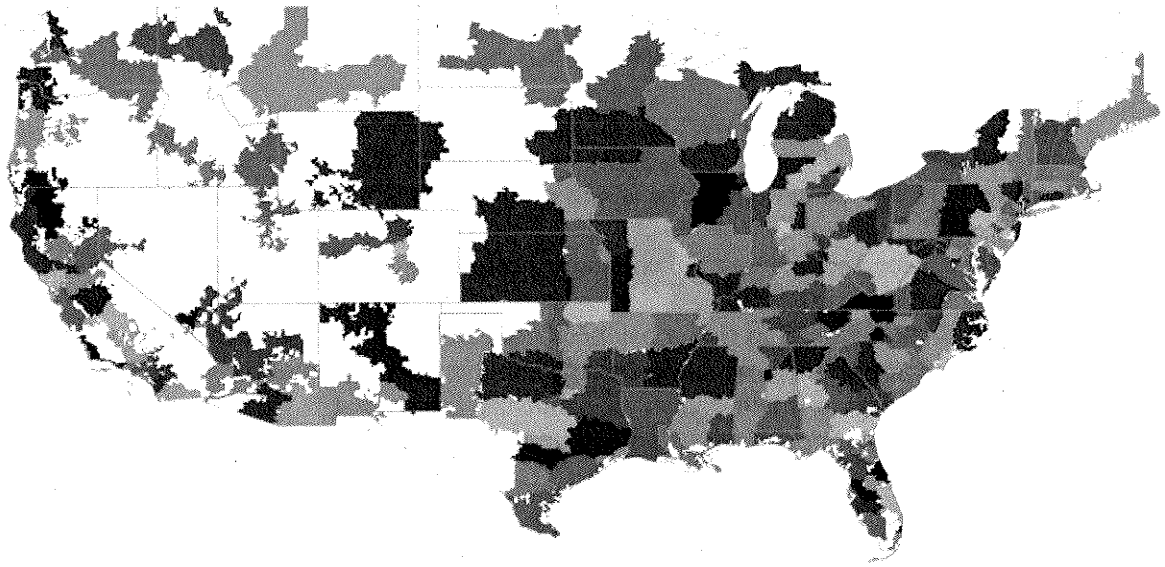
368. On October 17, Beverly Sackler served her last day on the Board. A week later, the *New Yorker* published an article entitled "The Family That Built an Empire of Pain." The story quoted a former FDA Commissioner: "the goal should have been to sell the least dose of the drug to the smallest number of patients." The reporter concluded: "Purdue set out to do exactly the opposite."[370]

369. **November 2017:** Jonathan Sackler suggested that Purdue launch yet another opioid. Staff promised to present a plan for additional opioids at the next meeting of the Board.[371] At the Board meeting that month, the remaining Sackler Board members (Richard, David, Ilene,

[370] 2017-10-23 email from Robert Josephson, PWG004332511.

[371] 2017-11-21 email from Craig Landau, PWG004333245.

Jonathan, Kathe, Mortimer, and Theresa Sackler) voted to cut the sales force from 582 representatives to 302 representatives. They knew sales representatives would continue to promote opioids in Vermont. Staff even gave Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler a map of where the remaining sales representatives worked, with Vermont shaded to show that Purdue would keep visiting prescribers here.[372]



Purdue internal map of planned sales representative territories for 2018

370. **January 2018:** Richard Sackler received a patent for a drug to treat opioid addiction—his own version of *Project Tango*. Richard had applied for the patent in 2007. He assigned it to a different company controlled by the Sackler family, instead of Purdue. Richard's patent application says opioids *are* addictive. The application calls the people who become addicted to opioids "junkies" and asks for a monopoly on a method of treating addiction.[373]

[372] 2017-11 Board budget, slides 47, 51, PWG004333838, -842.

[373] 2018-01-09, U.S. Patent No. 9,861,628 ("a method of medication-assisted treatment for opioid addiction"); 2007-08-29, international patent publication no. WO 2008/025791 Al.

371. In January, [redacted][374] Richard Sackler also met with Purdue staff about the sales force again. They discussed plans to cut the force to 275 representatives. In February, Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler decided to lay off 300 sales representatives.

372. **By April 2018**, staff were scared. Richard Sackler was again asking questions about sales. Staff prepared a presentation for the Board of Directors ("BoD"). One employee suggested that they add more information about the company's problems. Another cautioned against that:

> "I think we need to find a balance between being clear about what reality looks like – which I certainly support in [this] situation – and just giving so much bad news about the future that it just makes things look hopeless. Let's not give the BoD a reason to just walk away."[375]

373. **On May 3** and again on **June 6 and 8, 2018:** all seven remaining Sacklers attended meetings of the Board: Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler. But just as their employees predicted, the Sacklers attempted to walk away. Richard Sackler was the first to go; he resigned from the Board in July 2018. By April 2019, the other six had left, too, leaving no Sackler family members on the Board – for the first time in Purdue Pharma history.

D. In Carrying Out the Sacklers' Instructions, Purdue's Sales Force Misrepresented the Risks and Benefits of Opioids and Deployed Unfair Tactics to Maximize Profits.

374. In 2007, Purdue entered into consent decrees with the federal government and numerous states, including Vermont, to resolve investigations into its marketing of OxyContin.

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[374] [redacted]

[375] 2018-04-10 email from Paul Medeiros, PWG004335698.

As reported by USDOJ, those investigations centered on misrepresentations that OxyContin was less addictive and had less abuse potential than IR opioids, and that patients taking OxyContin could discontinue the drug without withdrawal symptoms. Prospectively, the decrees required Purdue more generally to discontinue all deceptive marketing, including any misrepresentations regarding OxyContin's potential for abuse, addiction, or physical dependence, and to provide a fair balance of risk and benefit information as required by FDA regulations. Specifically, the Vermont Consent Judgment required that all material used in promoting OxyContin be "not inconsistent with the Package Insert, contain only information that is truthful, balanced, accurately communicated, and not minimize the risk of abuse, addiction or physical dependence associated with the use of OxyContin." The Vermont Consent Judgment also required Purdue to disseminate "written, non-branded educational information related to detecting and preventing abuse and diversion of opioid analgesics," the intended purpose of which was to enlist Purdue's considerable financial resources to set the record straight on the abuse and diversion potential of opioids. Instead, Purdue seized a new opportunity to continue deceiving the public regarding the broader risks of dependence and addiction.

375. As part of Purdue's agreement with the United States, the Sacklers, as members of the Board of Directors, were required to undergo training to understand the terms of the corporate integrity agreement and to verify their agreement to comply with its terms.[376] This training was to include "the proper methods of promoting, marketing, selling, and disseminating information about Purdue's products in accordance with ... FDA requirements."[377]

[376] Purdue Corporate Integrity Agreement § III.C.1.

[377] Purdue Corporate Integrity Agreement § III.C.1.

376. Notwithstanding its legal commitments to the State of Vermont, Purdue failed to correct its misrepresentations or actually reform its conduct. Instead, Purdue—at the direction of the Sacklers (as described in Sections B and C herein)—built upon its decades-long foundation of deceptive messaging that had established chronic opioid therapy as commonplace and generated billions of dollars in profit for Purdue. Purdue has continued to omit discussion of the serious risks of opioids and lack of evidence supporting long-term opioid use—thereby failing to correct its prior deceptions—and to affirmatively under-represent the serious risks and over-represent the benefits of opioids for the treatment of chronic pain. Purdue also pursued new, unfair marketing tactics to expand and preserve its customer base—and therefore the Sacklers' profits.

377. Purdue did so under orders from the Sacklers to implement several specific campaigns and under intense pressure to increase sales and revenues. The Sacklers outlined particular objectives—to build a market of new initiates to opioid therapy, to boost the duration of opioid treatment, and to increase the dosages of opioids prescribed. The Sacklers helped to create or were aware of and sanctioned marketing messages that Purdue sales representatives were trained to convey: that pain was undertreated, that opioids were preferable to over-the-counter and milder combination drugs, that the benefits of opioids greatly outweighed the risks, and that the risks of addiction and death were minimal and attached to very particular types of undesirable persons and behavior.

378. Purdue accomplished much of this through its sales force: the messages they verbally conveyed to healthcare providers, and the materials they showed or distributed to prescribers, or directed prescribers to review online. Since the launch of OxyContin, Purdue relied heavily on its sales representatives to market its opioids directly to prescribers, and that practice continued into 2018. For example, of the $167 million Purdue spent on promoting opioids

nationwide in 2016, $156 million—93.4%—was spent on detailing. By establishing personal relationships with doctors, Purdue's sales representatives were able to disseminate their misrepresentations in targeted, one-on-one settings.

379. As described in Section C, the Sacklers constantly directed Purdue to be more aggressive with its sales force. Between 2008 and 2016, the Sacklers directed significant expansions of the sales force, with the express purpose of increasing revenues. The Sacklers also pushed Purdue to increase the intensity of detailers' activities—requiring more visits per day and more visits to higher volume prescribers. Between 2008 and 2017, Purdue repeatedly approved increases in the number of sale representatives and the budget for marketing. At the same time, the Sacklers were setting and approving sales goals—in terms of dollars, prescriptions written, and milligrams purchased.

380. The Sacklers were obsessed with results, down to the most granular details. As Board directors, they did not simply approve budgets and top-line sales goals. As described in Section C, they regularly sought and received a host of data, including quarterly and yearly sales representative visits; sales trends and projections by product, pill strength, and number of prescriptions; prescriptions of competitor pain medications; new patient starts and existing patient retentions; pharmacy inventory; the relationships between sales representative visits and prescribing, patient dose and length of therapy, and various marketing tactics and sales; and more.

381. At least 26 different Purdue sales representatives have detailed Vermont prescribers since 2006. Each of those representatives was expected to make seven to eight in-person sales calls to prescribers per day. Purdue's own records indicate that its representatives detailed at least 645 Vermont prescribers (a very significant percentage of the several thousand physicians, nurse practitioners, and physician's assistants practicing in the State) between 2006 and 2017. Many of

these prescribers were visited repeatedly. Indeed, in that same period, Purdue sales representatives made in excess of 11,000 unique sales visits in Vermont. Purdue assessed sales representatives' performance based on their ability to drive prescribing of its opioids; for example, one former Purdue detailer in Vermont had a sales goal of 1,100 OxyContin prescriptions per month.

382. The content of these sales calls was documented in "call notes," which Purdue expected to be detailed, thorough, and accurate. According to internal sales training documents, sales representatives were instructed to "[p]repare a concise call note that captures the key points of the dialogue between the Representative and the Customer," "ensure that call reporting clearly reflects the sales presentation," "[r]e-read every word of your call report to make sure that it is clear and accurate," "[a]lways review a call note before saving the record to ensure that it accurately reflects the important events that took place during the call," and complete the call note shortly after the sales call to ensure accuracy.

383. Purdue developed sophisticated plans to select prescribers for sales visits based on their prescribing habits. It purchased and closely analyzed prescription sales data that allowed the company to track prescribing of its opioids and those of its competitors. According to a former Purdue employee who trained and supervised Vermont sales representatives, any prescribing of an opioid—whether Purdue's or a competitor's—could land a prescriber on a detailing target list.

384. Purdue employed the same marketing tactics and messages in Vermont as it did nationwide, using uniform marketing materials and national and regional sales training. Purdue carefully trained its sales representatives to deliver company-approved sales messages. The company exactingly directed and monitored its sales representatives—through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' "call notes" from each visit—to ensure that individual detailers actually delivered the company's

desired messages. Purdue likewise required its sales representatives to deploy sales aids reviewed, approved, and supplied by the company.

385. As set forth below, through its sales force and deceptive promotional materials, Purdue misrepresented the serious risk of addiction posed by its opioids and misleadingly promoted OxyContin as effective for 12 hours. Purdue also deceptively and unfairly promoted its opioids in news ways and to new groups, by (a) targeting the elderly and the opioid-naïve with false claims about the safety and efficacy of low doses; (b) pushing physicians to prescribe the highest strengths of Purdue's opioids without disclosing the risks attendant to higher dosing; and (c) scheming to keep patients on opioids for longer periods, including offering innocuous-seeming savings cards, even though Purdue knew both that there was no good science supporting the efficacy of long-term opioid therapy and that the serious risks of addiction, overdose, and death increased with duration of use. The Sacklers approved or sanctioned all of this conduct, both by (a) ordering certain strategies and (b) being fully apprised of others, then directing Purdue to implement those strategies with more sales representatives making more visits to more prescribers.

1. To Fulfill the Sacklers' Directions and With the Sacklers' Awareness and Approval, Purdue Falsely Minimized or Failed to Disclose the Known, Serious Risk of Addiction

386. As explained above, the Sacklers directed Purdue employees to minimize the risk of addiction by promoting a narrative in which opioid deaths and disability were attributed to abuse and abusers, not to prescribed use and foreseeable addiction. This messaging was implemented through several sales pitches: (1) baldly understating addiction risk; (2) re-casting "addiction" as benign condition, like tolerance or pseudo-addiction; (3) convincing prescribers that addiction could be prevented by screening likely abusers from treatment.

387. To convince Vermont prescribers and patients that opioids were safe, Purdue built upon its extensive and effective foundation of deceptive marketing and deceptively minimized and

failed to disclose the risks of long-term opioid use, particularly the risk of addiction. Purdue trained its sales representatives to deflect questions about addiction into discussions of how to identify "appropriate patients," and to draw distinctions between "physical dependence" and "addiction" to allay prescribers' concerns about addiction risks. This strategy has been crucial to Purdue's business model, because the vast majority of Purdue's OxyContin sales are for patients who are continuing users of the drug (as opposed to new prescriptions). Deceptively minimizing the risk of addiction also was critical to Purdue's efforts to encourage new prescriptions, as prescribers and consumers have become more aware of the opioid epidemic over the last ten years.

388. These misrepresentations and omissions, described further below, reinforced each other to create the dangerously misleading impressions that:

(a) Purdue's ER/LA opioids present a reduced risk of addiction, and even patients who present symptoms of addiction may simply be physically dependent on the drug or have undertreated pain that should be treated with more opioids;

(b) patients at greatest risk of addiction can be identified and vetted out, allowing doctors to confidently prescribe opioids to all other patients and even prescribe to high-risk patients, provided they are closely managed;

(c) the abuse-deterrent formulations of Purdue's opioids both prevent abuse and are inherently less addictive; and

(d) physicians can prescribe steadily higher doses of opioids without added risk.

These deceptive messages often were delivered in combination and had a cumulative impact. Each of them has now been debunked by FDA and the CDC.

389. These core messages on addiction risk flowed directly from the strategy devised by Dr. Richard Sackler, who had previously served as Purdue's President and CEO from 1999 to 2003. Dr. Sackler directed Purdue to characterize the growing opioid problem as one of "abuse" rather than "addiction." Thus, according to Purdue's misrepresentations, doctors had no reason to fear that legitimate pain patients would become addicted, and screening tools and abuse-deterrent

formulations could keep the abusers at bay. As described in Section C, in 2016, when the tide of public opinion regarding opioids had turned, the staff reported to the Sacklers that the concepts of undertreatment and abuse—which had long been successful parts of Purdue's marketing—were no longer accepted as plausible explanations for an epidemic of addiction linked tightly to overprescribing.

390. Purdue's marketing strategy to increase opioid prescriptions focused on two distinct patient groups: keeping existing patients with "continuing" opioid prescriptions, which constituted over 80% of Purdue's sales, and identifying and gaining new patients who were not yet on opioid therapy or were new to the Purdue brand. To maintain and expand "continuing" prescription patients, Purdue built on its prior deceptions and persisted in misleading prescribers and the public about the benefits of opioids and of its specific opioid products, especially for long-term use, while minimizing the serious risks associated with these drugs, including addiction and overdose. To expand its reach and generate new prescriptions, Purdue took additional steps to expand the market for its opioids.

391. Overall, Purdue's marketing strategy created the impression that opioids were an ordinary and appropriate treatment for many kinds of people, that opioids generally (and OxyContin, specifically) provided meaningful benefits that justified their use, and that the risks of these drugs were minimal (and outweighed by the benefits).

a. Omitting, trivializing, and mischaracterizing addiction risk

392. In furtherance of the strategic narrative set by the Sacklers—to deny addiction risk or deflect addiction concerns—Purdue's sales representatives regularly omitted from their visits to Vermont prescribers any discussion of the addiction risks that are plainly associated with long-term use of opioids. Given that Purdue admitted that it had made misrepresentations between 1996 and 2007, these material omissions were particularly damaging. Purdue did not train its sales force

to correct the company's historic, deeply misleading—but highly profitable—message that patients who receive chronic opioid therapy for legitimate pain conditions face only a very small risk of becoming addicted.

393. These omissions, where were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading, especially in light of Purdue's prior misrepresentations regarding the risk of addition. In addition, by failing to correct this earlier misinformation, Purdue's representatives let stand the dangerous impression that patients who receive chronic opioid therapy for legitimate pain conditions are unlikely to become addicted.

394. The messages delivered in Vermont by detailers to prescribers were, as Purdue intended, passed on to patients. Patients receiving substance abuse treatment and whose addiction began with prescriptions for chronic pain often report that they were not warned of the risk they might become addicted to opioids. This is confirmed by national research: A 2015 survey of more than 1,000 opioid patients found that 40% were not told opioids were potentially addictive.[378]

"Pseudoaddiction"

395. In furtherance of the strategic narrative set by the Sacklers to deny addiction risk or deflect addiction concerns, Purdue represented to Vermont prescribers that red-flag signs of addiction may simply be indicators of medically undertreated pain that should be treated with higher doses. This concept was dubbed "pseudoaddiction" in earlier marketing, and the term persisted in marketing to Vermont prescribers until at least 2014. Even after Purdue stopped calling it "pseudoaddiction," Purdue continued to advance this unsubstantiated and misleading concept. Purdue consistently used this concept to suggest to prescribers that they should prescribe

[378] Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities* (Jan. 27, 2016), http://www.hazeldenbettyford.org/about-us/news-and-media/press-release/doctors-missing-questions-that-could-prevent-opioid-addiction.

higher doses of opioids when presented with patients who quite clearly exhibit drug-seeking behaviors.

396. As discussed above, the concept of "pseudoaddiction" was developed by Dr. Haddox, a paid Purdue speaker in the 1990s who went on to become a high-level Purdue executive. Purdue ensured that the term and concept of "pseudoaddiction" appeared in *Responsible Opioid Prescribing*, a reference book that was distributed through the Vermont Board of Medical Practice to prescribers in Vermont. The concept has since been discredited. Nonetheless, Vermont prescribers interviewed during the State's investigation of Purdue's deceptive marketing scheme stated that they currently have in their possession, continue to reference, and rely upon copies of this book.

397. Purdue promoted the fallacy of pseudoaddiction in "*Providing Relief, Preventing Abuse*." This pamphlet was distributed for the purpose of fulfilling Purdue's obligation under the 2007 Vermont Consent Judgment to provide "written, non-branded educational information related to detecting and preventing abuse and diversion of opioid analgesics," and it was broadly disseminated in Vermont. But rather than provide accurate, non-deceptive information about the risk of abuse and diversion, this pamphlet reinforced the misleading message that drug-seeking behaviors—commonly understood to be symptoms of addiction—are instead signs of benign "pseudoaddiction."

398. Purdue promoted the concept of "pseudoaddiction" through other extensive, unbranded marketing that it funded or controlled. *Partners Against Pain* is a Purdue marketing imprint consisting of both medical education resources, distributed to prescribers (including Vermont prescribers) by the sales force, and a now-defunct website that, before Purdue shut it down in 2016, was styled as an "advocacy community" for better pain care. *Partners Against Pain*

existed since at least the early 2000s and served as a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. Through at least 2013, the *Partners Against Pain* website relied on and directed users to the 2001 Guideline from American Academy of Pain Medicine and American Pain Society, which endorsed the concept of "pseudoaddiction."

399. A *Partners Against Pain* "Pain Management Kit" that debuted in 2009 likewise advocated the "pseudoaddiction" concept, referring prescribers to the 2001 AAPM/APS "Definitions Related to the Use of Opioids for the Treatment of Pain." The kit also introduced another resource—a set of drug abuse screening tools (discussed in Section D(1)(b))—by stating that "[b]ehaviors that are suggestive of drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior." Purdue sales representatives have regularly directed Vermont prescribers to the *Partners Against Pain* website and distributed the Pain Management Kit to Vermont prescribers, and Vermont prescribers have used the *Partners Against Pain* website as a prescribing resource.

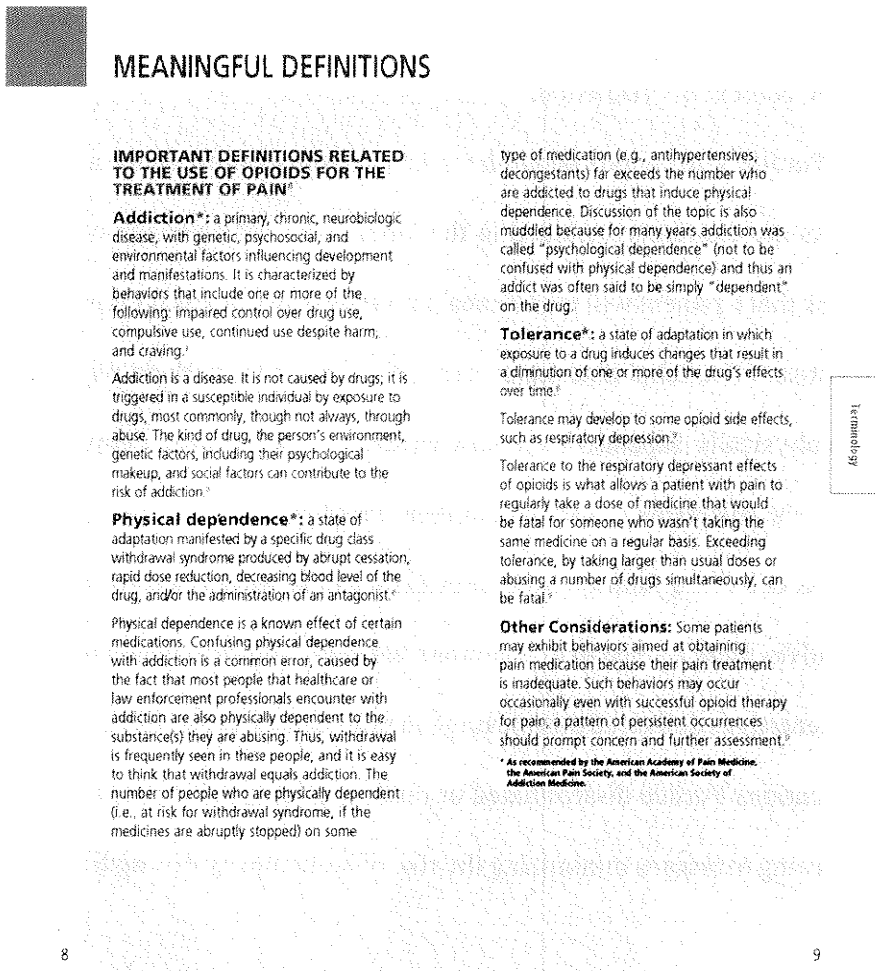
Distinction between "Physical Dependence" and Addiction

400. In furtherance of the strategic narrative set by the Sackler Defendants to deny addiction risk or deflect addiction concerns, Purdue also attempted to assuage prescribers' concerns about its products by distinguishing between "addiction" (dependence that results in compulsive drug use despite harmful consequences) and "physical dependence" (the body's need for higher doses of the opioid over time and withdrawal symptoms if opioids are discontinued). Purdue described "physical dependence" as a normal consequence of extended opioid use, but failed to disclose the serious risks and problems associated with physical dependence. Purdue misled prescribers when it drew a distinction between "physical dependence" and "addiction" without fully explaining the risks associated with both conditions—deliberately creating the

impression that the negative consequences prescribers (and patients) were worried about would only occur in the context of "addiction."

401. Purdue's omissions about the risks of physical dependence are all the more glaring because the risks are expressly included in the label. The 2013 version of the OxyContin label describes the risk that a patient will experience withdrawal symptoms if OxyContin is discontinued or reduced in dose. The label also states that infants born to mothers physically dependent on opioids will be physically dependent and may experience withdrawal themselves.

402. This misleading and incomplete message minimizing the risks of "physical dependence" was delivered through both sales calls and in written advertising materials. Purdue sales representatives were trained to differentiate between "physical dependence" and "addiction," and sales representatives delivered this message in sales calls to prescribers. Promotional materials and other publications Purdue disseminated or made available in Vermont have included similar, mutually reinforcing messages minimizing the risk of addiction by distinguishing it from "physical dependence."



MEANINGFUL DEFINITIONS

IMPORTANT DEFINITIONS RELATED TO THE USE OF OPIOIDS FOR THE TREATMENT OF PAIN*

Addiction*: a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.†

Addiction is a disease. It is not caused by drugs; it is triggered in a susceptible individual by exposure to drugs, most commonly, though not always, through abuse. The kind of drug, the person's environment, genetic factors, including their psychological makeup, and social factors can contribute to the risk of addiction.†

Physical dependence*: a state of adaptation manifested by a specific drug class withdrawal syndrome produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or the administration of an antagonist.†

Physical dependence is a known effect of certain medications. Confusing physical dependence with addiction is a common error, caused by the fact that most people that healthcare or law enforcement professionals encounter with addiction are also physically dependent to the substance(s) they are abusing. Thus, withdrawal is frequently seen in these people, and it is easy to think that withdrawal equals addiction. The number of people who are physically dependent (i.e., at risk for withdrawal syndrome, if the medicines are abruptly stopped) on some type of medication (e.g., antihypertensives, decongestants) far exceeds the number who are addicted to drugs that induce physical dependence. Discussion of the topic is also muddled because for many years addiction was called "psychological dependence" (not to be confused with physical dependence) and thus an addict was often said to be simply "dependent" on the drug.

Tolerance*: a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.†

Tolerance may develop to some opioid side effects, such as respiratory depression.†

Tolerance to the respiratory depressant effects of opioids is what allows a patient with pain to regularly take a dose of medicine that would be fatal for someone who wasn't taking the same medicine on a regular basis. Exceeding tolerance, by taking larger than usual doses or abusing a number of drugs simultaneously, can be fatal.†

Other Considerations: Some patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate. Such behaviors may occur occasionally even with successful opioid therapy for pain; a pattern of persistent occurrences should prompt concern and further assessment.†

* As recommended by the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine.

Terminology

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403. The *Providing Relief, Preventing Abuse* pamphlet included similar deceptions. It downplayed "physical dependence" as "a known effect of certain medications," citing benign blood pressure medications and decongestants as analogous examples. It also asserted that "physical dependence" and "addiction" are commonly confused.

404. Purdue's distinction between "physical dependence" and "addiction" was especially deceptive in the context of increasing public awareness of the risks of opioid addiction, because it implied that "physical dependence" was less harmful than "addiction." These messages also implied that physical dependence on OxyContin was no more problematic than physical

dependence on blood pressure medication. *Providing Relief, Preventing Abuse* also showed graphic pictures of the stigmata of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—to illustrate "potential signs consistent with drug abuse." In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients becoming addicted through oral use. These depictions deceptively reassured doctors that, as long as they do not observe physical signs of snorting or injecting, they need not worry that their patients are abusing or addicted to opioids.

405. Purdue's *Partners Against Pain* website likewise offered misleading and deceptively reassuring distinctions between addiction and physical dependence, presenting addiction as a neurobiological disease and physical dependence as a benign "state of adaptation."

406. In disseminating such messages, Purdue was attempting to avoid associations with addiction. This failed to acknowledge the very serious reality that Vermont consumers faced: that no matter what definitions and labels are applied, patients taking opioids are at serious risk of becoming "hooked," needing ever-increasing doses to avoid withdrawal symptoms, and being unable to stop taking opioids.

Other Unbranded Marketing Minimizing the Risk of Addiction

407. In furtherance of the strategic narrative set by the Sackler Defendants to deny addiction risk or deflect addiction concerns, Purdue disseminated or supported the dissemination of unbranded marketing materials that also minimized the risk of addiction associated with opioids generally.

408. Purdue maintained an online "interactive toolkit" for patients, caregivers, and prescribers—*In the Face of Pain* (www.inthefaceofpain.com)—that deceptively downplayed the risks of chronic opioid therapy. *In the Face of Pain*, which Purdue deactivated in October 2015 following an investigation by the New York Attorney General, was another example of

"unbranded" marketing. Although it featured the Purdue copyright at the bottom of each page, the site did not refer to Purdue products in particular and cultivated the impression that it was neutral and unbiased.[379] As of 2010, the "In the Face of Pain Toolkit" was also available on the *Partners Against Pain* website, which detailers frequently referenced during Vermont sales calls.

409. *In the Face of Pain* asserted that policies limiting access to opioids are "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. As of 2015, while a document linked from the *In the Face of Pain* website briefly mentioned opioid abuse, the site itself did not—even once—mention the risk of addiction, a risk so significant that it requires a black box warning on all opioid drug labels. At the same time, the website contained testimonials from several dozen physician "advocates" speaking positively about opioids. The website failed to disclose that, from 2008 to 2013, Purdue paid 11 of these advocates a total of $231,000.[380]

410. Purdue also continued working closely with allies, such as the American Pain Foundation ("APF")—a group that, as discussed above, was heavily dependent on funding from Purdue and other pharmaceutical companies—to disseminate misleading, unbranded messages about the risks of opioids.

411. APF's *Exit Wounds* described opioids as the "'gold standard' of pain medications" and minimized the risk of addiction. It emphasized that physical dependence often is mistaken for addiction and claimed that "[l]ong experience with opioids shows that . . . people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."

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[379] *In the Matter of Purdue Pharma L.P.*, Assurance No. 15-151, Assurance of Discontinuance (signed August 19, 2015).

[380] *Id.*

412. APF's *A Policymaker's Guide to Understanding Pain & Its Management* claimed pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction" and asserted, without basis, that "less than 1 percent of children treated with opioids become addicted." In addition to mischaracterizing the risk of addiction, *A Policymaker's Guide* perpetuated the misleading concept of pseudoaddiction, stating that "[p]seudo-addiction describes patient behaviors that may occur when pain is undertreated" and that "[p]seudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated"—*i.e.*, with more opioids.

The True Risks of Opioids

413. Purdue's claims regarding addiction are contrary to longstanding scientific evidence, and its failures to address the risk of addiction when promoting the use of these drugs are material omissions, given both the magnitude of the risk and the grave consequences of addiction. As confirmed by the CDC in its 2016 Guideline, "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])" exists. The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder." (Emphasis added.)

414. Studies have shown that at least 8-12%, and as many as 30% or even 40%, of long-term users of opioids experience problems with addiction.[381] In requiring a new black-box warning on the labels of all IR opioids in March 2016, similar to the warning already required for ER/LA

[381] Joseph A. Boscarino *et al.*, *Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system*, 105(10) Addiction 1776-82 (Oct. 2010); Joseph A. Boscarino *et al.*, *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM5 vs. DSM-4 Diagnostic Criteria*, 30(3) J. of Addictive Diseases 185-94 (July-Sept. 2011); Vowles, Kevin E. *et al.*, *Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis*, Pain 156.4 (2015): 569-576.

opioids, FDA emphasized the known, "serious risks of misuse, abuse, [and] addiction . . . . across all prescription opioid products."[382] That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published its *Guideline for Prescribing Opioids for Chronic Pain.*[383] The CDC found that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder."[384] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[385]

b. Overstating the efficacy of screening tools

415. In furtherance of the strategic narrative set by the Sackler Defendants to deny addiction risk or deflect addiction concerns, Purdue deceptively promoted screening tools—such as drug testing, pill counts, and patient contracts—as reliable ways to prevent addiction and safely prescribe long-term opioids. While screening tools may help doctors identify the most susceptible patients and identify diversion, and patient contracts convey the gravity of risks and establish protocols to stop diversion, they cannot prevent dependence or addiction from occurring. These misrepresentations provided false assurances to healthcare providers and patients that addiction was avoidable and largely the result of other prescribers' failure to rigorously manage and weed out problem patients who could have been easily identified with screening tools.

416. Purdue conveyed these messages during in-person sales calls in Vermont. For example, when one prescriber discussed with the Purdue sales representative the increasingly

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[382] Food and Drug Administration, *FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death* (Mar. 22, 2016), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[383] CDC Guideline, *supra* n.26, at 2.

[384] CDC Guideline, *supra* n.26, at 2.

[385] CDC Guideline, *supra* n.26, at 25.

aggressive behavior of his opioid patients and his fears for his staff's safety, the representative emphasized the importance of continuing to prescribe OxyContin for "appropriate patients": *e.g.*, ones who attended scheduled appointments, signed and abided by patient contracts, and complied with urine screens and pill checks.

417. Purdue also promoted the "Opioid Risk Tool" created by opioid advocate Dr. Lynn Webster, who received research funding from Purdue, as part of its *Partners Against Pain* "Pain Management Kit." This "Opioid Risk Tool" is a five-question, one-minute screening tool that relies on honest patient self-reporting (particularly unlikely given the sensitive topic and the nature of addiction) to purportedly allow doctors to manage the risk that their patients will become addicted to or abuse opioids. Sales representatives distributed the kit in CD ROM format to prescribers in Vermont, and frequently directed prescribers to the *Partners Against Pain* site throughout recent years.

418. Purdue promoted screening tools as a reliable means to manage addiction risk in CME and scientific conferences available to Vermont prescribers. In 2011, Purdue sponsored a CME taught by Dr. Lynn Webster via webinar titled "Managing Patient's Opioid Use: Balancing the Need and Risk." This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths." Purdue also funded a 2012 symposium called "Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes," which taught doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addictive behavior could be safely treated with opioids.

419. The 2016 CDC *Guideline for Prescribing Opioids for Chronic Pain—United States* ("CDC Guideline") confirms the lack of substantial scientific evidence to support Purdue's claims

regarding the utility of screening tools and patient management strategies in managing addiction risk. There are no studies assessing the effectiveness of screening tools, patient contracts, urine drug testing, or pill counts—all which were widely promoted by Purdue and believed by doctors in Vermont—"for improving outcomes related to overdose, addiction, abuse, or misuse."[386] In fact, the CDC Guideline recognizes that risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy." (Emphasis added.)[387]

c. Overstating the efficacy of "abuse-deterrent" properties

420. In furtherance of the strategic narrative set by the Sacklers to deny addiction risk or deflect addiction concerns, Purdue deceptively marketed its abuse-deterrent opioids—a reformulated version of OxyContin and Hysingla ER—to Vermont prescribers in a manner that falsely implies that these abuse-deterrent drugs can curb abuse and even addiction. As explained above, the Sacklers were advised, even before the abuse-deterrent formulation was brought to market in 2010, that Purdue's reformulation would not prevent addiction—or even abuse. In truth, all these reformulations do is make it harder to crush the pill. This does nothing to protect against the most common form of abuse, which is via oral ingestion.

421. Oral abuse of prescription opioids includes not only taking the drugs without a prescription, but also taking higher or more frequent doses than prescribed. Rather than focus on the oral abuse associated with the widespread prescribing of OxyContin for chronic pain, Purdue

[386] 2016 CDC Guideline, *supra* n.26, at 11.

[387] 2016 CDC Guideline, *supra* n.26, at 18. These screening tools may serve different purposes: they can assist doctors in identifying diversion, and they can convey to patients the gravity of the risks of opioid use.

tied abuse and addiction to less common illegal product diversion and abuse via snorting or injecting the drug. Purdue's proffered solution—introduced as an abuse-deterrent formulation in 2010—was a new pill coating and other elements to make its opioids more difficult to crush or inject (*i.e.*, making it tamper-resistant). Purdue misleadingly assured prescribers that they could prescribe Purdue's opioids without contributing to the epidemic of misuse and abuse.

422. FDA approved the reformulated OxyContin in 2010.[388] In its medical review of Purdue's application, however, FDA found that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)" and that "[w]hile the reformulation is harder to crush or chew, possibly mitigating some accidental misuse, oxycodone HCI is still relatively easily extracted."[389] (Emphasis added.)

423. Purdue regularly cited its introduction of abuse-deterrent opioids as evidence of its commitment to addressing the opioid crisis, as described in Section F. In fact, the tamper-resistant reformulation, and the change in labeling, made Purdue richer by solving an inconvenient business problem: how to keep the money flowing after April 2013, when OxyContin's patent was set to expire. Generic versions of OxyContin had become available in February 2011, threatening to erode Purdue's share of the long-acting opioid market and decrease the price Purdue could charge. However, Purdue convinced FDA in April 2013 that original OxyContin—which Purdue had designed and promoted for years—should be removed from the market as unsafe because it lacked abuse-deterrent properties. The impact was that generic equivalents of the old formulation could not be sold, once again securing brand exclusivity for OxyContin and Purdue through at least 2017.

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[388] Center for Drug Evaluation and Research Approval Package for NDA 22-272, Apr. 5, 2010, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/ 022272s000Approv.pdf.

[389] Center for Drug Evaluation and Research, NDA 22-272, *Summary Review for Regulatory Action* (Dec. 30, 2009), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000MedR.pdf, at 7.

424. Purdue also used the abuse-deterrent properties of its opioids as a primary selling point to differentiate its products from its competitors, including generic short-acting opioids. As recently as 2015, internal sales training documents characterize the "abuse-deterrence labeling" as one of four "Strategic Pillars" for achieving OxyContin sales goals, directing Purdue employees to "[e]levate the importance of abuse deterrence as a key driver for [extended-release opioid] prescribing."

425. However, Purdue knew or should have known that its abuse-deterrent drugs were regularly tampered with and abused. In online forums such as bluelight.org and Reddit, drug abusers discuss a variety of ways to tamper with OxyContin and Hysingla ER, including by grinding the pills, microwaving then freezing them, or dissolving them in soda or lemon juice. A 2015 study by researchers at Washington University in St. Louis found that many addicts continued to abuse reformulated OxyContin. Of the survey respondents who continued to abuse the drug, most either continued with or switched to oral abuse, while roughly one-third found various methods to continue snorting or injecting it.[390]

426. As discussed in Section C, it appears from contemporaneous correspondence that [redacted]. And yet, abuse deterrence because a point of product differentiation and a key marketing message as soon as OxyContin was re-formulated. [redacted]

[390] Theodore J. Cicero & Matthew J. Ellis, *Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States: Lessons Learned from OxyContin*, 72(5) JAMA Psychiatry 424-430 (May 2015).

427. There remains no substantial scientific evidence that Purdue's abuse-deterrent opioids actually reduce opioid abuse. As the CDC Guideline states, "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," and the technologies—even when they work—"do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."

428. Because of their questionable benefits, any discussion of abuse-deterrent technologies has a high potential to mislead practitioners and patients and create a false sense of security about prescribing opioids, particularly for long-term use. In a 2014 survey of 1,000 primary care physicians, nearly 50% reported that they believed abuse-deterrent formulations of opioids are inherently less addictive.[391] One-third of the doctors in that same study had the mistaken impression that most prescription pill abuse is by means other than swallowing the pills.

429. Purdue's deceptive marketing of the benefits of its abuse-deterrent formulations was particularly dangerous because it persuaded doctors—who might otherwise have curtailed their opioid prescribing—to continue prescribing Purdue's opioids based on misleading assurances and deceptive implications that they are safer. It also allowed prescribers and patients to discount evidence of opioid addiction and attribute it to other opioids that don't have tamper-resistant properties—*i.e.*, to believe that while patients might abuse or overdose on non-abuse-deterrent opioids, Purdue's opioids do not carry that risk.

2. Purdue Misleadingly Promoted OxyContin as Supplying 12 Hours of Pain Relief.

430. As explained above, the Sacklers were keenly aware that Purdue's key point of differentiation between OxyContin and other opioid pain relievers on the market is its extended-

[391] Catherine S. Hwang *et al.*, *Primary Care Physicians' Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion*, 32(4) Clinical J. Pain 279-284 (Apr. 2016).

release formulation and "Q12"—or every 12 hour—dosing. The Sacklers were also aware that the OxyContin did not, in fact, deliver 12 hours of pain relief to a large number of users. Nevertheless, the Sacklers knew about and approved Purdue's efforts to promote the drug as a Q12/12 hour drug. Therefore, Purdue consistently overstated the efficacy of this dosing interval while omitting the serious risks associated with it, compared to other alternative pain relievers.

431. Purdue sought FDA approval for OxyContin's 12-hour dosing schedule to maintain a competitive business advantage over more-frequently dosed (*e.g.*, every 8 hours, or as needed) opioids, despite knowing that OxyContin does not provide pain relief for 12 hours in many patients, a phenomenon known as "end of dose failure." Internal Purdue marketing documents indicate that 12-hour dosing was considered key to differentiating the drug from the competition—generic, short-acting opioids that require patients to wake in the middle of the night to take the next dose.[392]

432. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. Purdue relied on labeling that it sought from FDA, and for which the company is legally responsible, directing 12-hour dosing. However, Purdue went well beyond the label's limited instructions to take OxyContin every 12 hours by affirmatively advertising that OxyContin lasts for 12 hours—and by failing to disclose that OxyContin does not provide 12 hours of pain relief to many patients.

433. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, around-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as

[392] Memo to OxyContin Launch Team (April 4, 1995), available at http://documents.latimes.com/oxycontin-launch-1995/.

providing "smooth and sustained pain control all day and all night."[393] But FDA has never approved such a marketing claim. To the contrary, FDA found in 2008, in response to a citizen petition by the Connecticut Attorney General, that a "substantial proportion" of chronic pain patients taking OxyContin experienced "end of dose failure."[394]

434. Sales representatives frequently referenced "Q12" dosing as a benefit of OxyContin during sales visits in Vermont. These misrepresentations continued into recent years in Vermont. Purdue trained its sales representatives to deliver the message of "[p]roven relief with Q12h dosing" to prescribers during sales calls.

435. Twelve-hour dosing is also featured in most OxyContin promotional pieces. A 2012 version of the *Conversion and Titration Guide*, for example, contains the tag line: "Because each patient's treatment is personal / Individualize the dose / Q12 OxyContin Tablets." And a 2014 visual aid used by sales representatives repeatedly refers not merely to OxyContin, but to *"[E]very 12-hour OxyContin"* and *"Every-12-Hour OxyContin Tablets."* None of these pieces discloses that the pain relief from each 12-hour dose will last well short of 12 hours for many patients, leaving prescribers and patients unprepared for end-of-dose failure and the craving for more opioids that the failure creates.

436. Purdue has known, since the launch of OxyContin, that the drug often wears off well short of 12 hours. According to a 2016 *Los Angeles Times* investigation, Purdue's own early studies showed many patients asking for more medication before their next scheduled dose. In

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[393] Purdue Pharma L.P., *New Hope for Millions of Americans Suffering from Persistent Pain*, PR Newswire (May 31, 1996), https://assets.documentcloud.org/documents/2815975/Pressreleaseversionone.pdf.

[394] FDA response letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation and Research, to Richard Blumenthal, Conn. Att'y Gen. (Sept. 8, 2008), http://www.purduepharma.com/wp-content/pdfs/fda_response_blumenthal_oxycontin.pdf, at 5.

one clinical trial, one-third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental short-acting opioids—"rescue medication"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once.[395] Prescribers, including prescribers in Vermont, likewise have observed and complained to Purdue sales representatives that OxyContin does not supply 12 hours of pain relief in a significant number of the prescribers' patients. And it was well-known to Purdue that OxyContin was routinely prescribed (including in Vermont) every 8 hours—rather than every 12 hours, as directed. One former Purdue employee, who trained and supervised sales representatives in Vermont, said Purdue knew providers frequently prescribed OxyContin for every 8 hours, tracked statistics on such prescribing, and sought to change it: "We talked about that in almost every meeting, how we were going to try and get people to buy [the 12-hour dosing]."

437. Purdue's solution to the end-of-dose failure experienced by many patients was to advise prescribers to maintain the 12-hour dosing schedule but to increase the dose of OxyContin. Purdue's sales representatives routinely told doctors in Vermont that, if the Q12 dose didn't last the full 12 hours, the doctor should increase—or "titrate"—the dose, rather than increasing the frequency of dosing. The OxyContin label and the *Conversion and Titration Guide* also advise prescribers that they can increase the dosage to achieve adequate pain relief "as clinical need dictates, while maintaining every 12-hour dosing." Increased opioid dosing poses greater risks, as discussed in Section D(3). However, Purdue's advice to "titrate up" when a patient experienced

[395] Harriet Ryan, Lisa Girion & Scott Glover, *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, Los Angeles Times (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/.

end-of-dose failure was not accompanied by appropriate warnings regarding the increased risk of addiction associated with higher doses.

438. Purdue's misrepresentations regarding 12-hour dosing—which Purdue has made since 1996 and continued to make at least until 2018, when it stopped promotion of opioids to prescribers through sales representatives—are particularly dangerous because the inadequate dosing helps fuel addiction. End-of-dose failure causes patients to experience the early stages of psychological and physical withdrawal symptoms on a daily basis, followed by a euphoric rush when they take their next dose—leading to a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[396]

439. The Sacklers [redacted]

440. Yet the Sacklers also had long known that OxyContin did not last 12 hours in some patients. Richard Sackler admitted in his 2015 deposition that Purdue's own clinical studies had shown that some patients complained they were "back in pain" after 8 or 9 hours.[397] On information and belief, based on the existential threat posed to Purdue by a 2004 citizens' petition submitted to the FDA by the Connecticut Attorney General, the other Sacklers knew about the end-of-dose failure problem as well. That petition complained that many patients were being

[396] Harriet Ryan, Lisa Girion & Scott Glover, *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, Los Angeles Times (May 5, 2016), http://www.latimes.com/ projects/oxycontin-partl.

[397] Richard Sackler Dep. Tr. 145:14-146:22, *Kentucky v. Purdue*, No. 07-CI-01303, Aug. 28, 2015.

prescribed unsafe amounts of OxyContin, in part because doctors were prescribing dosing more frequent than twice a day to compensate for the shorter duration of pain relief.[398] In response to the petition, the FDA in 2008 declined to change the label but found that a "substantial number" of chronic pain patients taking OxyContin experienced end-of-dose failure.[399]

3. Purdue Pushed Higher and Higher Doses of Opioids Without Disclosing the Risks

441. Although Purdue used the lowest strengths of OxyContin to expand its captive customer base, the Sacklers' ultimate goal was to move more and more patients up the dose "ladder" of its opioids, including to the 60mg and 80mg OxyContin pills—the most lucrative strengths for both the company and its owners. The Sacklers repeatedly, over the course of many years, directed Purdue executives to pursue and achieve this goal. As described in Section C, Purdue extensively tracked prescriptions of its highest-strength pills in particular. [redacted]

442. To sell more and more of the highest doses, Purdue falsely claimed to Vermont prescribers and consumers that opioids can be taken at ever-increasing doses for better pain relief, without disclosing that higher doses carry greater risk of addiction and overdose. They did so to fulfill the express expectations of the Sacklers, who viewed higher dosages as a clear pathway to increased sales and revenue.

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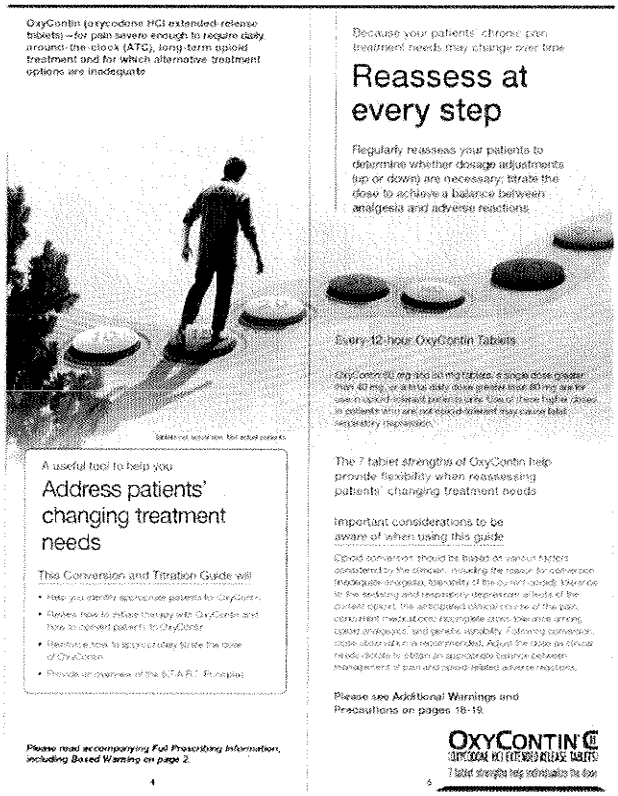
[398] Connecticut Attorney General Citizen Petition to FDA, Jan. 7, 2004, *available at* http://documents.latimes.com/fda-filing-2004/.

[399] FDA response letter from Janet Woodcock, Director, Center for Drug Evaluation and Research, to Richard Blumenthal, Connecticut Attorney General (Sept. 8, 2008), *supra* n.394. at 5.

443. The ability to escalate doses ("titrating up") was critical to Purdue's efforts to market opioids for long-term use to treat chronic pain. Unless doctors felt comfortable prescribing increasingly higher doses of opioids to counter tolerance to the drugs' effects, they may not have chosen to initiate opioid therapy at all. Numerous Purdue marketing materials depict the seven OxyContin tablet strengths—in a line or even a series of steps—and instruct prescribers that they can titrate, *i.e.*, increase the dose, "as clinical need dictates." These materials also conveyed the message that there was "no defined maximum daily dose" for OxyContin. The Sacklers, who were extensively briefed on these materials (from the *Options* and *Individualize the Dose* campaigns), were aware that the sales force would use them to promote higher doses and were responsible for that action.



444. Through at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a doctor did not prescribe, in the patient's opinion, a sufficiently high dose of opioids, the patient should find another doctor who would. This approach accords with advice provided to the Sacklers by McKinsey in 2013: to use "patient pushback" to influence hesitant prescribers.

445. *A Policymaker's Guide* asserted that dose escalations—even when unlimited—are "sometimes necessary." The publication did not disclose the risks from high doses of opioids.

446. Purdue also deceptively compared the risks of opioids to the risks of other pain relievers, like non-steroidal anti-inflammatory drugs ("NSAIDs" like Advil or Motrin) and acetaminophen (Tylenol). The company sponsored a 2013 CME titled "Overview of Management Options" that highlighted the evidence of adverse effects from high doses of NSAIDs but did not discuss the increased risk from using high doses of opioids. The CME was edited by Dr. Russell Portenoy, who received research support, honoraria, and consulting fees from Purdue. Issued by

the American Medical Association in 2013, the CME remains available from the American Medical Association ("AMA") online.[400] Purdue also sponsored a pain pamphlet for physician assistants that similarly emphasized the risk of liver damage from acetaminophen at higher doses, while omitting any comparable discussion of the risks of opioids at high doses.

447. Even where Purdue marketing materials acknowledged that certain serious risks rose with the dose, they failed to disclose the increased risk of addiction. For example, the *Conversion and Titration Guide* stated that "the ceiling to analgesic effectiveness is imposed only by side effects, the more serious of which may include somnolence and respiratory depression."

448. There is no valid scientific evidence that doses of opioids can be continuously titrated upward without significant added risk. On the contrary, the risk of addiction, overdose, and death are increased when patients are prescribed higher doses of prescription opioids.[401] Patients receiving high doses of opioids as part of long-term opioid therapy are 3x to 9x more likely to suffer overdose than those on low doses.[402] For example, in 2015 in Vermont, over 80% of individuals with opioid prescription histories who suffered opioid-related accidental fatalities had received high dose (at least 90 MME) analgesics in the five years prior to death.[403]

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[400] American Medical Association, *Pain Management – Overview of Management Options*, https://cme.ama-assn.org/activity/1296783/detail.aspx (last visited 8/3/18).

[401] National Institute on Drug Abuse, *Improving Opioid Prescribing*, last updated March 2017, https://www.drugabuse.gov/publications/improving-opioid-prescribing/improving-opioid-prescribing; Centers for Disease Control and Prevention, *Calculating Total Daily Dose of Opioids for Safer Dosage*, last visited Aug. 6, 2018, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.

[402] Kate M. Dunn *et al.*, *Opioid prescriptions for chronic pain and overdose: a cohort study*, 152(2) Annals of Internal Med. 85-92 (Jan. 19, 2010). Most overdoses were medically serious and 12% were fatal.

[403] Anne VanDonsel, Shayla Livingston, and John Searles (Vermont Department of Health), *Opioids in Vermont: Prevalence, Risk, and Impact* (October 27, 2016), http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Prevalence_Risk_Impact.pdf, at 31.

449. As compared to non-opioid pain remedies, patients develop a tolerance to opioids' analgesic effects more quickly than they develop a tolerance to opioids' depressive effects on respiration. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to accidental overdose even where opioids are taken as recommended.[404]

450. As confirmed by the CDC in its Guideline, research published over the past decade has consistently found that the "[b]enefits of high-dose opioids for chronic pain are not established," while the risks for serious harms are clear and dose-dependent. More specifically, the CDC explains—citing research dating back to 2010—that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid doses." The CDC also states that there are "increased risks for opioid use disorder, respiratory depression, and death at higher dosages."

451. The CDC Guideline reinforces earlier findings announced by FDA. In 2013, FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."[405]

452. Because of these risks, the CDC Guideline advises doctors to "avoid increasing doses" above 90 morphine milligram equivalents (MME) per day. Yet, many patients have received dangerously high doses of opioids, and every dosage of OxyContin available on the market imposes increased risks (compared to lower-dose analgesics) on patients. Of the seven

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[404] *See* Laxmaiah Manchikanti *et al.*, *Opioid Epidemic in the United States*, *supra* n.2 (60% of opioid overdoses prescribed were within guidelines).

[405] Letter from Janet Woodcock, M.D., Dir., FDA Ctr. for Drug Evaluation and Research, to Andrew Kolodny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013) https://www.regulations.gov/document?D=FDA-2012-P-0818-0793, at 13-14.

available OxyContin tablet strengths, the three strongest all exceed the CDC guideline limit when taken (as directed) twice daily: 40-mg (120 MME per day), 60-mg (180 MME per day), and 80-mg (240 MME per day). Patients on the twice-daily 80-mg dose receive nearly 3x the recommended ceiling of 90 MME. Even patients taking 30-mg of OxyContin twice daily reach the CDC daily maximum of 90 MME. Moreover, the CDC has made it clear that even much lower daily doses—exceeding just 20 MME per day—put patients at increased risk.[406] The lowest strength of OxyContin—the 10-mg tablet strength—exceeds this amount when taken twice daily as prescribed.[407] However, despite the known and growing body of research on the risks of these high-dose opioids, Purdue marketed OxyContin, and advocated for doctors to prescribe higher and higher doses to patients, without providing adequate disclosures of the risks these drugs posed.

4. Purdue Encouraged Long-term Use of Opioids—Including With Savings Cards—Despite the Known Risks and Absence of Benefits of Such Use.

453. In addition to convincing physicians to prescribe the highest doses of Purdue's opioids, the company also sought to keep patients on Purdue's opioids for longer periods of time—an explicit sales goal of the Sacklers. These two pursuits were complementary: as discussed in Section C, the Sacklers and Purdue knew that patients on opioids inevitably required higher and higher doses, and that patients on the highest doses tended to remain on opioid therapy the longest. The Sacklers aggressively sought to increase more long-term use—measured in months and years—despite the serious risks attendant to such use and the absence of scientific evidence supporting the efficacy of long-term opioid therapy.

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[406] Centers for Disease Control and Prevention, *Calculating Total Daily Dose of Opioids for Safer Dosage*, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.

[407] *Id.*

454. Purdue's deceptive marketing about the benefits of its products focused on a particular goal: reinforcing the supposed benefits of long-term opioid use, so that Purdue could derive revenue—and the Sacklers could derive profits—from long-term increased sales. Purdue's marketing messages lacked scientific support and were, in many cases, false.

455. To convince Vermont prescribers and patients that opioids should be used to treat chronic pain, despite the unavoidable risk of addiction, Purdue had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline made clear, there was "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." (Emphasis added.) In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials $\leq$ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[408] (Emphasis added.) FDA similarly recognized the lack of scientific support for long-term opioid use, stating in a 2013 letter to Dr. Kolodny that the FDA was "not aware of adequate and well-controlled studies of opioid use longer than 12 weeks."[409] Thus, Purdue's ongoing representations, to prescribers and consumers, regarding the benefits of long-term opioid therapy have continued to be misleading and deceptive.

456. It is well established that long-term opioid use harms, rather than helps, patient health and wellbeing. Purdue's marketing scheme ran contrary to the real science on the known risks and unproven benefits of long-term opioid use.

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[408] CDC Guideline, *supra* n.26, at 9, 15.

[409] Letter from Janet Woodcock, M.D., Dir., FDA Ctr. for Drug Evaluation and Research, to Andrew Kolodny, M.D., President, Physicians for Responsible Opioid Prescribing, *supra* n.405, at 10.

457. The available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health. As early as 2006, numerous peer-reviewed studies conducted by independent researchers have concluded that: (1) "[f]or functional outcomes, . . . other [non-addictive] analgesics were significantly more effective than were opioids,"[410] (2) increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater healthcare utilization,[411] and (3) "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[412] More recently, the CDC Guideline, approved by FDA, concluded that "there is no good evidence that opioids improve pain or function with long-term use."[413] (Emphasis added.) The CDC reinforced this conclusion throughout the CDC Guideline, finding that (a) "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later";[414] (b) "[a]lthough opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy";[415] and (c) "evidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for

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[410] Andrea D. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589-1594 (2006).

[411] Richard A. Deyo *et al.*, *Opioids for Back Pain Patients: Primary Care Prescribing Patterns and Use of Services*, 24 J. Am. Bd. Fam. Prac. 717-27 (2011).

[412] Andrea Rubenstein, *Are we making pain patients worse?* Sonoma Medicine (Fall 2009).

[413] CDC Guideline, *supra* n.26, at 20.

[414] *Id.* at 15.

[415] *Id.* at 18.

which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."[416] The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[417] As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life spent cycling through periods of addiction, abuse, and recovery do not improve their function and quality of life.

458. Purdue and the Sacklers who have served on its Board of Directors cannot have been unaware of the disconnection between the academic literature, which has never assessed efficacy beyond 12 weeks, and the prescribing reality—which Purdue was instrumental in shaping—that many patients use OxyContin and other opioids for many months or years. For example, a 2011 internal email among Purdue researchers discussed the need for "new research studies of not less than 12 months duration to determine the long-term effectiveness of opioids for chronic non-cancer pain"—an acknowledgement that such evidence did not exist.

a. Material Misrepresentations and Omissions Regarding Long-Term Use of Opioids

459. The FDA-approved labeling of Purdue's ER/LA opioids does not address long-term use (*i.e.*, beyond 12 weeks). Relied upon in the first OxyContin label—and still, to this day, the only clinical study Purdue has cited for OxyContin's efficacy in adults—is a two-week study of a scant 133 patients. Yet, Purdue marketed OxyContin with the expectation that health care providers—believing the drug to be appropriate for long-term use—would prescribe it to their chronic pain patients over periods of months or years. The State of Vermont did not uncover, in its review of call notes reflecting thousands of sales visits to prescribers, that detailers disclosed Purdue's lack of evidence supporting the use of opioids for more than 90 days.

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[416] *Id.* at 18-19.

[417] *Id.* at 20.

460. Routine, chronic pain conditions—like osteoarthritis and lower back pain—continued to be a focus of Purdue's marketing efforts for OxyContin and Butrans. In more recent years, sales representatives have used "patient vignettes" or "patient profiles"—brief summaries of the background and medical needs of fictional patients—to illustrate the kinds of patients who should be identified as "good" (according to Purdue) candidates for drugs like OxyContin and Butrans. These vignettes typically featured chronic, long-term health problems as indications appropriate for opioid use. For example, the "Carol" and "Maggie" patient profiles, used to market OxyContin, featured osteoarthritis of the hip and chronic low back pain. The "Scott" and "Pam" patient profiles, used to market Butrans, both featured chronic low back pain due to osteoarthritis. Purdue provided its sales representatives with these and other patient profiles, along with training on their use, and Vermont sales representatives used them in sales calls to Vermont healthcare providers.

461. In Vermont, Purdue sales representatives positioned Purdue's opioid products—namely OxyContin and Butrans—*specifically for* long-term pain relief, to encourage healthcare providers to convert patients from short-acting opioids or other pain relievers to Purdue's extended-release opioid products. For example, sales representatives asked prescribers how long they typically wait before transitioning patients from short-acting opioids to an extended-release product, like OxyContin. During one Vermont sales call, for example, the sales representative initiated this discussion, and the prescriber agreed that "he would think about some patients who have been on an IRO [immediate release opioid] way too long."

462. Upon information and belief, sales representatives in Vermont also delivered a national "insight message" crafted by Purdue specifically for use in sales calls—that "according to IMS, a 3rd party prescription data source, 41% of IR hydrocodone/APAP combination

prescriptions were associated with a length of therapy lasting 90 days or longer. Of these prescriptions lasting at least 90 days, the average number of days until a patient was converted to an extended- release opioid was 287." This message implied that long-term use was inappropriate for short-acting opioids, but not so for extended-release opioids, and that such patients should be transitioned to an extended-release opioid like OxyContin.

463. Purdue also reinforced the appropriateness of OxyContin for long-term use through written materials it distributed in Vermont. For example, Purdue's OxyContin *Conversion and Titration Guide*, which sales representatives widely referred to during sales visits and distributed in Vermont, implied that use could continue safely for years. A 2007 version of that guide recommended that "the need for around-the-clock opioid therapy should be reassessed periodically (*e.g.*, every 6 to 12 months) as appropriate for patients on chronic therapy," but did not disclose the absence of evidence supporting safety and efficacy of use for 6 to 12 months. Later versions of this *Guide* omit the parenthetical "(*e.g.*, every 6 to 12 months)" and simply state that prescribers should "periodically reassess the continued need for opioid analgesics." However, Purdue continued to train sales representatives to tell prescribers to periodically reassess "every 6 to 12 months," when prescribing OxyContin, even after this language had been removed from the printed marketing materials, but they did not train representatives to disclose that Purdue had no studies supporting efficacy of use beyond 12 weeks.

464. Purdue and Purdue-sponsored materials distributed nationally reinforced the message that opioids offer benefits to the patient with use that lasts months or even years. The APF-published *Exit Wounds*, a book written as a personal narrative of one veteran recovering from war injuries, asserted unequivocally that "[w]hen used correctly, opioid pain medications increase

[a person's] level of functioning" and that opioids "can really help improve your functioning in daily life." APF promoted this book until at least 2011.

465. Purdue also sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, a 2011 publication that falsely claimed that "multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving [d]aily function . . . [and] quality of life for people with chronic pain." *A Policymaker's Guide* cited a single study for this claim – which, upon examination, expressly noted the absence of long-term studies and actually found that "[f]or functional outcomes, . . . other analgesics were significantly more effective than were opioids."[418]

466. Purdue provided substantial funding to, and closely collaborated with, APF in creating *A Policymaker's Guide*. Purdue provided a grant for its development and distribution and kept abreast of the content of the guide as it was formulated. On information and belief, based on Purdue's close relationship with APF and the periodic reports APF provided to Purdue about the project, Purdue had editorial input into *A Policymaker's Guide*.

467. FDA has said for years that opioid manufacturers should not make claims regarding functional improvement and ability to perform daily activities, and FDA has warned Purdue competitors in public letters that such claims lacked substantial scientific evidence.[419]

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[418] Andrea D. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589-1594 (2006).

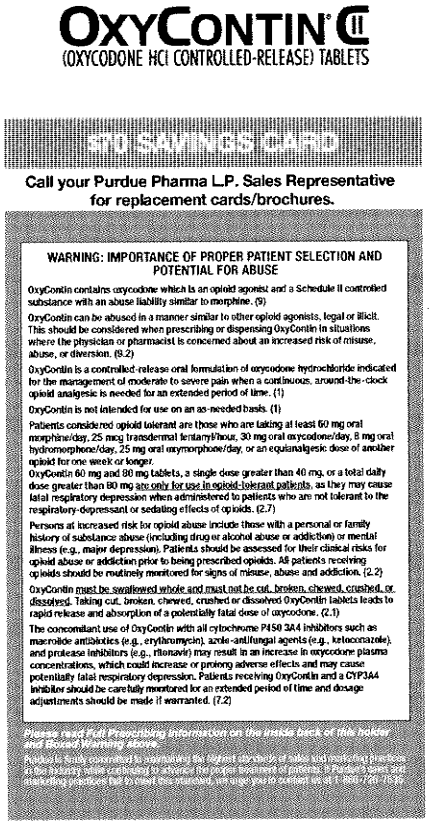
[419] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf; Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008).

468. These unsubstantiated and deceptive statements regarding the benefits of long-term opioid therapy misled prescribers and patients into believing that there were advantages to continuing opioid use over many months or even years.

b. Use of Savings Cards to Encourage Long-Term Use of Opioids

469. As a central component of the Sacklers' deliberate marketing strategy to encourage, initiate, and extend long-term use of these drugs, Purdue relied heavily on prescription discount "Savings Cards," which were known to boost so-called "continuing prescriptions." Purdue carried out this specific strategy at the direction of the Sacklers, who, as described in Section C, had studied the use of savings cards and instructed Purdue to optimize their use to meet long-term sales goals.

470. Purdue promoted "Savings Cards" in Vermont to provide patients with a Purdue-funded discount on their out-of-pocket cost for OxyContin and encourage long-term use of OxyContin:



471. Purdue trained sales representatives to discuss Savings Cards on every sales call. The company also carefully tracked redemption of Savings Cards and evaluated sales representatives on the number of Savings Cards redeemed in their districts.

472. The purpose behind Purdue's emphasis on Savings Cards was to boost the "continuing prescriptions" group of patients—which constituted 80% of its OxyContin sales—beyond 90 days of use. In a 2012 sales training document, Purdue explained that "market research has shown that ~60% more patients stay on therapy >90 days if a savings card is redeemed." Purdue had no research showing the benefits of OxyContin for these longer durations of treatment.

473. Purdue also used Savings Cards to encourage initiation of new patients on its opioids, lowering the barrier of entry by making the drugs cheaper to try. In a 2012 sales training

presentation, Purdue described its rationale for subsidizing a $0 (*i.e.*, free) copayment through Savings Cards for new Butrans patients: that a Savings Card was "effectively acting as a sample."

474. Sales representatives routinely distributed OxyContin Savings Cards during their sales visits to Vermont prescribers and pharmacies. Some Vermont healthcare providers declined Savings Cards, expressly referencing concerns about OxyContin use.

475. But Purdue continued to distribute the Savings Cards through marketing efforts in Vermont pharmacies, instructing pharmacists to inform opioid patients about available discounts for OxyContin that would bring the out-of-pocket price down significantly. In 2012, Purdue introduced what it described in internal documents as "new channels to broaden access to Patient Savings Card Program: "Relay Health," which provided automatic rebates at pharmacies, and downloadable savings cards on PurdueHCP.com. This training document identified the Savings Cards as being downloadable by "HCP"—or healthcare providers, but Purdue sales representatives seem to have encouraged pharmacists to tell *patients* to download the cards directly, as a workaround when prescribers chose not to offer them. In one 2012 sales call to a pharmacy, the Purdue detailer advised the pharmacy techs about how patients can go online to obtain savings cards "[s]ince the p[re]scribers in town are changing policies about cards."

476. Purdue has long been aware of the State of Vermont's concern that offering free or heavily subsidized opioids to consumers was an unfair business practice. In the 2007 Consent Judgment, Purdue expressly agreed to stop distributing samples of OxyContin in Vermont. Nonetheless, Purdue used the promotion of Savings Cards to eliminate or steeply discount patient co-payments—effectively making these drugs free to patients—as a way to drive long-term use.

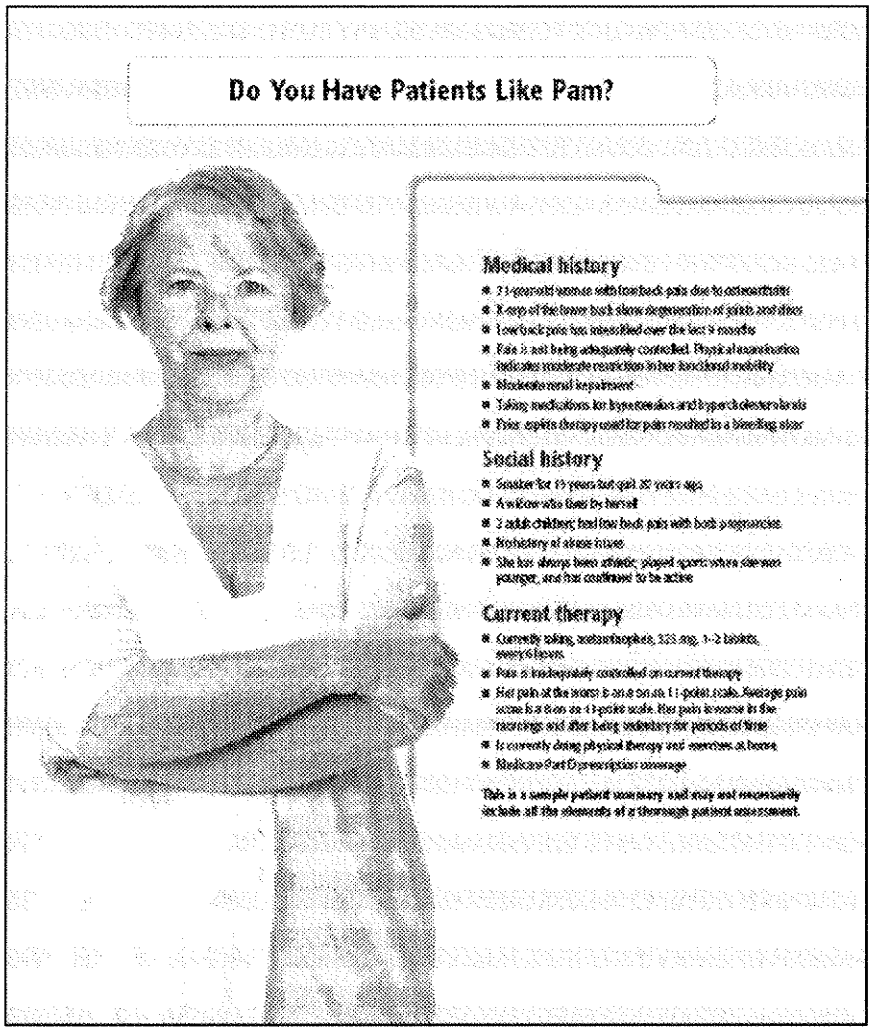
5. Purdue Targeted Elderly and Opioid-Naïve Patients

477. Part of Purdue's strategy to continue expanding its market share, and hence its revenue, has been to target two overlapping markets in particular: the elderly, a demographic that

has seen an explosion in opioid prescribing in recent years, and opioid-naïve patients—those who had not previously taken opioids. As discussed in greater detail above, Purdue staff purposefully targeted marketing efforts to increase opioid prescribing to elderly and opioid-naïve patients—and kept the Purdue Board and the Sacklers informed about these efforts—in their pursuit of the increased sales and market share the Sacklers directed staff to obtain.

478. Training materials, reviews of sales representatives, and Vermont detailer call notes include multiple references to Purdue's efforts to persuade doctors to start prescribing its ER/LA opioids to elderly patients.

479. Purdue also used its "patient vignettes" or "patient profiles" to subtly persuade doctors that OxyContin and Butrans were appropriate for their elderly patients, by featuring fictional patients who were older and/or who suffered from conditions like osteoarthritis that are common in older patients.



480. Purdue's unbranded marketing efforts also targeted elderly patients. For example, *In the Face of Pain*'s publication "The Handbook for People with Pain: A Resource Guide (5th Edition"), available through *In the Face of Pain*'s website, included a section entitled "Special Considerations for Seniors." This section identified "pain in the absence of disease" as a major problem affecting seniors "experienced daily by a majority of older adults in the United States." It goes on to list problems associated with pain, including "decreased mobility" and "increased risk for falls and weight loss." It highlights the fact that "most pain can improve with treatment," instructing seniors to speak to their healthcare providers and develop a treatment plan. These

unbranded marketing materials were intended to drive demand among elderly consumers for pharmacological pain treatment, including opioid therapy. However, they omit any reference to the risks and side effects of such treatments.

481. Purdue focused heavily on marketing its opioids in Vermont as medications that were covered by insurance plans, with a focus on educating physicians about Medicare Part D (prescription benefit) coverage for opioids, including OxyContin in particular. Sales representatives frequently wrote in call notes that they talked to prescribers about Medicare Part D coverage for OxyContin.

482. Purdue managers and sales representatives also focused detailing efforts on the nursing home market. For example, a call note from a visit to a Vermont pharmacy in May 2010 reflects the pharmacist's suggestion that the sales representative bring copies of the *Conversion and Titration Guide* to area nursing homes. In response text from the sales representative's supervisor, the supervisor stated "Good Call...you were given the names of two homes to focus on, lets [sic] talk about plans for these on our next work session." Other Vermont call notes from 2011 and 2012 discuss sales representatives' efforts to identify and gain access to providers at nursing homes and senior/assisted living facilities.

483. Purdue has targeted seniors for a reason: they have been an important growth sector for the opioid industry. In 2016, one-third of all enrollees in Medicare Part D—over 14.5 million beneficiaries, nationwide—received at least one opioid prescription.[420] And more than 500,000 enrollees nationwide were on a high dose of at least 120 MME—well above the CDC's

[420] U.S. Department of Health & Human Services Office of the Inspector General, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing*, HHS OIG Issue Brief (July 2017), https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf, at 1.

recommended maximum dosage of 90 MME.[421] These high doses underscore the eventuality that elderly patients will not simply remain on OxyContin 10-mg but will require escalating amounts—which come with escalating dangers and side effects that are particularly acute in the elderly.

484. Purdue's targeting of elderly patients overlapped with Purdue's broad marketing push to persuade doctors to prescribe OxyContin to opioid-naïve patients—even when faced with reluctant practitioners.

485. Sales representatives regularly suggested 10- and 15-mg OxyContin for elderly and opioid-naïve patients, without disclosing that Purdue had no evidence of efficacy at those doses. For example, during one sales call in April 2010 in Vermont, a sales representative wrote that she "[r]eviewed [OxyContin] newer strengths and IR to ER conversion guide, explained 10mg q12h is indicated for op[i]oid naive pts and well covered on part d. He will consider for his elderly." Another sales representative wrote in call notes in 2013 that he would ask providers about initiating opioid-naïve patients at the 10-mg dose: "Would it surprise you to know that an opioid naïve patient could be started on OxyContin 10 mg Q 12.?" None of these call notes indicate that sales representatives disclosed that OxyContin was no more effective than placebo at that dose.

486. Purdue's decisions to target the elderly and opioid-naïve patients reflect a business strategy that placed little value on the well-being and safety of consumers. For patients in these populations, opioid treatment generally—and especially OxyContin treatment—imposes significant risks and should be undertaken only if less-risky analgesics prove ineffective.

487. Elderly patients taking opioids are at greater risk for fracture and hospitalization, and they have increased vulnerability to adverse drug effects such as respiratory depression, which

[421] *Id.*

Purdue acknowledges in its opioids' labels (but not in its marketing).[422] Elderly patients who use opioids also have a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs.[423] The severity of these risks is increased with OxyContin treatment—which involves a higher opioid dose than as-needed opioids or opioid combination drugs—because the risks associated with opioids are dose-dependent. (*See* Section D(3).)

488. Purdue's specific focus on opioid-naïve patients was likewise unwarranted, in light of the steady stream of information over the past decade emphasizing (as the CDC summarized in 2016), that "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[424] Such risks are simply not warranted for most opioid-naïve patients. Other, less-risky analgesics are available on the market for opioid-naïve patients needing pain relief, including non-opioid pain relievers.

489. Nonetheless, through its marketing efforts, Purdue sought to capture elderly and opioid-naïve patients as a critical customer base that would grow Purdue's profits by continuing to require opioids as they became dependent on and/or addicted to these dangerous drugs.

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[422] OxyContin ER Full Prescribing Information (last revised 12/2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf; OxyContin & Hysingla labels; Hysingla ER Full Prescribing Information (revised 12/2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206627s004lbl.pdf; Kathleen W. Saunders, *et al., Relationship of opioid use and dosage levels to fractures in older chronic pain patients*, J Gen Intern Med 2010; 25:310-5 (April 2010).

[423] *Relationship of opioid use and dosage levels to fractures in older chronic pain patients, supra* n.422.

[424] Thomas R. Frieden & Debra Howry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501, 1503 (Apr. 21, 2016).

E. The Proliferation of Prescription Opioids Has Been Devastating to Vermont

Increased Opioid Abuse and Addiction

490. Purdue's deceptive marketing has reaped Purdue and the Sacklers massive profits but has been catastrophic for the State and its citizens. In 2010, 482,572 opioid prescriptions were dispensed in Vermont, a state with a population of just over 625,000.[425] That number continued to rise. In 2015, the number of opioid prescriptions increased to 498,973[426]—the equivalent of giving a prescription to every 1.3 people living in Vermont, including infants.

491. There is no question that this volume of opioids leads to increased incidence of dependence and addiction. In a 2014 survey by the U.S. Department of Health and Human Services, more than three percent of Vermonters—approximately 18,000 people—reported a dependence on a controlled substance.[427] Vermont ranks as the 8th-highest state for drug dependence nationwide,[428] despite other favorable health indicators like better access to health care and insurance coverage as compared to other states.[429]

492. Opioids are killing Vermont citizens at a skyrocketing rate, and a common origin is prescription opioids. Drug-related fatalities involving opioids nearly tripled between 2010 and

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[425] *Opioids in Vermont: Prevalence, Risk, and Impact*, *supra* n.403, at 30 ("Number of Prescriptions by Drug Type and Year"); Vermont Department of Health, *Special Report: Opioid Prescriptions and Benzodiazepines, 2014* (February 2016), http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Benzodiazepenes_Report.pdf, at 3.

[426] *Id.*

[427] amfAR Opioid & Health Indicators Database, *Percent of people 12+ Reporting Drug Dependence*, http://opioid.amfar.org/indicator/drugdep.

[428] *Id.*

[429] *See State Health Assessment Plan - Healthy Vermonters 2020* (December 2012), http://www.healthvermont.gov/sites/default/files/documents/2016/11/Healthy%20Vermonters%202020%20Report.pdf, at 13, 5, 27.

2018.[430] While the national average of opioid-related overdose deaths in 2017 was 14.6 per 100,000 persons, the rate in Vermont was 20.0 – 37% higher than the national average.[431] And these overdose deaths have a broad impact. In a state like Vermont, there are no anonymous deaths.

493. The link between prescription opioids and "street drugs" like heroin and fentanyl fuels the opioid crisis. Many addicts begin with a legal opioid prescription from their doctor or by taking a pill from a prescription bottle belonging to a family member or friend.[432] Prescription opioid users also are far likelier to use illegal opioids like heroin and fentanyl. CDC statistics show that people addicted to prescription opioids are 40x more likely also to be addicted to heroin. The same CDC report shows that nearly half (45%) of people who used heroin also were addicted to prescription opioid painkillers.[433] In 2017, the Vermont Department of Health reported that 80% of new heroin users also had a history of misusing prescription opioids.[434]

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[430] Vermont Department of Health, *Opioid-Related Fatalities Among Vermonters* (updated February 2019), http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Data_Brief_Opioid_Related_Fatalities.pdf.

[431] National Institute on Drug Abuse, *Vermont Opioid Summary* (revised March 2019), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/vermont-opioid-summary.

[432] Nora Volkow and Francis Collins, National Institute on Drug Abuse, *"All Scientific Hands On Deck" to End the Opioid Crisis*, May 31, 2017, https://www.drugabuse.gov/about-nida/noras-blog/2017/05/all-scientific-hands-deck-to-end-opioid-crisis ("While there were nearly 20,000 overdoses in 2015 due to heroin or fentanyl, the trajectory of opioid addiction usually begins with prescription opioid misuse. Some people with opioid addiction began by taking diverted pills from friends and family members, but others began with an opioid prescription of their own").

[433] Centers for Disease Control and Prevention, *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/.

[434] Vermont Department of Health, *Opioid Misuse, Abuse & Dependence in Vermont Data Brief, April 2017*, http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_data_brief_opiodmisuse.pdf.

494. The heroin/fentanyl problem in Vermont is acute—in 2018, fentanyl was involved in three-quarters of all opiate-related fatalities, and heroin was involved in over half of all opiate-related fatalities.[435] The number of fatal overdoses involving fentanyl, in particular, has skyrocketed in recent years—a fourteenfold increase from 6 fatalities in 2012 to 83 fatalities in 2018.[436]

495. Beyond just addiction, there are additional and serious health dangers associated with illicit heroin and fentanyl use, including collapsed veins, bacterial infections of the blood and heart, lung complications, and depression. When heroin is administered by injection, the sharing of needles or bodily fluids puts users at heightened risk for HIV and Hepatitis B and C—serious diseases that can be transmitted to sexual partners and children.[437] The concern about rising rates of HIV and Hepatitis C is very real in Vermont: in 2016, the CDC identified two Vermont counties—Essex and Windham—out of the more than 3,100 counties across the entire United States as among those in the 95th percentile (top 5% nationwide) at greatest risk for outbreaks of HIV and Hepatitis C.[438]

496. While heroin and fentanyl have contributed to the increasing number of opioid deaths in Vermont, the majority of opioid fatalities are causally linked to opioid prescriptions—which many heroin and fentanyl abusers have in their system at the time of their fatal overdose

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[435] *Opioid-Related Fatalities Among Vermonters*, *supra* n.430, at 1.

[436] *Id.* at 2.

[437] National Institute on Drug Abuse, *What are the medical complications of chronic heroin use?* (March 28, 2018) at 11, https://www.drugabuse.gov/publications/research-reports/heroin/what-are-medical-complications-chronic-heroin-use.

[438] Michelle M. Van Handel et al., *County-level Vulnerability Assessment for Rapid Dissemination of HIV or HCV Infects among Persons who Inject Drugs, United States*, Journal of Acquired Immune Deficiency Syndromes, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5479631/; American Foundation for AIDS Research, *Vermont Opioid Epidemic*, http://opioid.amfar.org/VT.

or have used at some point prior to their fatal overdose. A study by the Vermont Prescription Monitoring System found that 85% of opioid-related accidental fatalities in Vermont had received an opioid prescription within the last five years[439] and that 25% percent had received an opioid prescription within 30 days prior to their death.[440]

497. In Vermont, 90.6% of opioid-related fatalities in 2015 occurred in people who had controlled substance prescription histories. Of the decedents who had been given an opioid prescription during the year prior to their death, the average opioid prescription supply was 261 days.[441]

498. In the most recent years for which data from the Vermont Department of Health is available (2015, 2016, 2017, and 2018), prescription opioids have been involved in roughly one-third of opioid-related deaths in Vermont.[442]

499. The demand for opioid addiction treatment has risen dramatically. In 2008, 2,272 Vermonters were treated for opioid use in state-funded treatment facilities. By 2017, that number had tripled, to 6,605.[443]

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[439] Vermont Prescription Monitoring System, *Controlled Substance Prescription Histories for Opioid-Related Accidental Fatalities in 2015* at 3, http://www.healthvermont.gov/sites/default/files/documents/2017/01/HSRV_VPMS_10_28_16_opioid_related_accidental_fatality_brief.pdf.

[440] *Id.*

[441] *Opioids in Vermont: Prevalence, Risk, and Impact, supra* n.403, at 31 ("Prescription History of Individuals with Opioid-related Accidental Fatalities").

[442] *Opioid-Related Fatalities Among Vermonters, supra* n.430, at 1.

[443] Vermont Department of Health, *2017 Treatment Data*, http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Treatment_Data_by_Age_Gender_County_Total.pdf.

500. The effects of the opioid epidemic are widely felt in Vermont. In a 2016 poll commissioned by Vermont Public Radio, 53% of respondents said that they or someone they knew had been personally affected by opiate addiction.[444]

The devastating effects on infants and young children

501. Opioid use disorder in pregnant women has become prevalent in Vermont, as opioid use has proliferated more broadly, with potentially devastating health consequences for them and their infants. The number of women with diagnosed opioid use disorder at the time of delivery has increased dramatically over time in Vermont: from 0.5 per 1,000 deliveries in 2001 to 48.6 per 1,000 deliveries in 2014—over seven times the national average, and the highest among the 30 states that have compiled this data.[445] This widespread prevalence of opioid use disorder in pregnant Vermonters is a major public health concern, because of the serious potential adverse maternal and neonatal outcomes associated with opioid use during pregnancy: preterm labor, stillbirth, neonatal abstinence syndrome, and maternal mortality.[446]

502. The number of infants born in Vermont who are diagnosed with Neonatal Abstinence Syndrome ("NAS")—a condition in which a newborn baby suffers withdrawal symptoms—also far exceeds the national average. Based on available data from 2012, the Vermont Department of Health estimated that the rate of NAS in Vermont was five times higher than the national average, and the Vermont statistics have continued to rise.[447]

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[444] Vermont Public Radio, *The VPR Poll: The Issues, The Races and The Full Results* (July 27, 2016), http://digital.vpr.net/post/vpr-poll-issues-races-and-full-results#stream/0.

[445] *Opioid Use Disorder Documented at Delivery Hospitalization—United States, 1999-2014*, CDC Morbidity and Mortality Weekly Report (August 10, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6731a1.htm?s_cid=mm6731a1_e, at 847.

[446] *Id.* at 845.

[447] *Opioids in Vermont: Prevalence, Risk, and Impact*, *supra* n.403, at 44 ("Improved treatment and screening have helped to identify more infants exposed to opioids").

503. In 2008, there were 17.0 infants with NAS per 1,000 live births (to Vermont residents in Vermont hospitals). By comparison, in 2014, that number had more than doubled to 35.3 per 1,000 live births (to Vermont residents in Vermont hospitals).[448]

504. Infants exposed to opioids *in utero* also face serious health consequences. At least 60–80% of these babies will experience symptoms such as seizures, respiratory distress, diarrhea, hypertonia, feeding intolerance, tremors, and vomiting because of their exposure to opioids in the womb.[449]

505. Infants born with NAS require longer and costlier hospital stays than those who are born without exposure to opioids. In 2012, the average length of hospital stay for non-NAS infants born to Vermont residents in Vermont hospitals was 3.0 days, at a cost of $5,590. But Vermont infants with NAS faced hospital stays more than 2x longer and nearly 3x more expensive, averaging 7.4 days and $15,456 (respectively).[450]

506. More than 50% of Vermont children under the age of five who have been taken into the custody of the Vermont Department of Children and Families (DCF) have been removed from their homes because of opioid-related issues.[451] As reported in 2016, the reporting of incidences to DCF's Child Protection Line have increased by 30%—from 15,760 reports in 2012

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[448] Vermont Department of Health, *Neonates Exposed to Opioids in Vermont* (April 2017), http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Opioids_Neonate_Exposure.pdf, at 1.

[449] Stephen W. Patrick *et al.*, *Neonatal Abstinence Syndrome and Associated Health Care Expenditures*, Journal of the American Medical Association (2012), https://www.ncbi.nlm.nih.gov/pubmed/ 22546608.

[450] Vermont Department of Health, *Neonates Exposed to Opioids in Vermont*, *supra* n.448, at 2.

[451] Vermont Opioid Coordination Council, *Initial Report of Recommended Strategies*, *supra* n.6, at 3 n.1.

to 20,583 in 2016—and during those same years, approximately 30% of the calls related to substance abuse.[452]

The financial cost to our communities

507. Opioid overprescribing, misuse, and prescription diversion are draining Vermont's health care system. For example, one study estimated the 2007 total health care spending associated with opioid abuse in Vermont as exceeding $38 million.[453] From 2007 to 2018, opioid prescribing rose dramatically, as did the numbers of persons using, misusing, and abusing both prescription and illegal opioids.

508. The health care costs associated with opioid overprescribing, addiction, and abuse are crushing. Vermont consumers—individuals, employers, and private insurers—have paid millions for opioid prescriptions. Vermont's opioid treatment programs cost more than $70 million between 2012 and 2017 alone.[454] Vermont consumers have likewise borne substantial healthcare costs due to this epidemic of addiction.

509. It is well-established that health care costs for persons addicted to opioids are much higher than health care costs for the general population. For example, overall health care costs are approximately 3x higher among patients receiving Medication Assisted Treatment for

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[452] Howard Weiss-Tisman, *Opioid Abuse Continues to Strain Vermont's Child Welfare System*, Vermont Public Radio (December 5, 2017), http://digital.vpr.net/post/opioid-abuse-continues-strain-vermonts-child-welfare-system#stream/0; Vermont Dept. for Children and Families Family Services Div., *2016 Report on Child Protection in Vermont*, http://legislature.vermont.gov/assets/Legislative-Reports/Child-Protection-Report-2016.pdf.

[453] Matrix Global Advisors, *Health Care Costs from Opioid Abuse: A State-by-State Analysis* (April 2015), https://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf, at 5.

[454] Chen (Vermont Department of Health), *Status of Opioid Treatment Efforts*, *supra* n.10, at 22.

opioid addiction than is true for the general Medicaid population.[455] The average national private payer cost per person with opioid use disorder was $63,356 (in 2015).[456]

510. The prevalence of opioids in Vermont also places a greater burden on law enforcement—increased costs associated with investigating and prosecuting crimes related to opioid use and abuse, as well as increased costs for treating incarcerated residents for opioid use disorder.

511. The costs of incarceration—which include Medication Assisted Treatment for addiction and other related costs—are largely paid by the State. Crimes associated with prescription drugs—chiefly robbery and burglary—have risen.[457] Data collected by the Vermont Intelligence Center show that law enforcement consistently averages between one and two seizures of illicit opioids per day.[458] In a small state like Vermont, this steady drumbeat of opioid seizures has become a focal point of police time and attention.

512. Purdue's prescription opioids continue to be a central cause of the opioid crisis in Vermont, and Purdue also has retained a significant market share of the dollars spent by the State on opioid prescriptions. Using the Vermont State Employees' health plan data as just one example, Purdue's opioids alone account for more than 55% of the State of Vermont's total opioid prescription spending, from April 2010 to June 2018.

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[455] Vermont Department of Health, *The Opioid Addiction Treatment System* (January 13, 2013), http://www.leg.state.vt.us/reports/2013externalreports/285154.pdf, at 9.

[456] Chen (Vermont Department of Health), *Status of Opioid Treatment Efforts*, *supra* n.10.

[457] Vermont Department of Health, *Issue Brief: Prescription Drug Misuse in Vermont,* at 12 (Feb. 12, 2013), http://thehungryheartmovie.org/wp-content/uploads/2013/09/SEOW_Rx_Issue_Brief_Final_02_12_13.pdf.

[458] *Opioid Seizures: Number of Opioid Seizures as Reported by Vermont Law Enforcement,* Vermont Intelligence Center (January 2017), last updated June 2015, last on website May 18, 2018 (available at https://webcache.googleusercontent.com/search?q=cache:u92N642SthsJ:https://app.resultsscorecard.com/perfmeasure/embed/101519+&cd=2&hl=en&ct=clnk&gl=us).

F. The Sacklers, Who Knew that Purdue's Marketing of Opioids Was False and Misleading, Instructed the Company to Fraudulently Conceal Its Misconduct and Hide their Own Involvement.

513. Purdue made, promoted, and profited from its misrepresentations about the risks and benefits of opioids for chronic pain, even though it knew that its marketing was false and misleading. Purdue also actively concealed its unfair and deceptive conduct from regulators and others who were working to curb the growing opioid epidemic.

514. The medical profession's historic understanding of the risks that opioids pose, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of serious adverse outcomes. FDA and other regulators warned Purdue of this, and Purdue entered into settlements in the hundreds of millions of dollars with the United States and numerous states (including Vermont) in 2007 to address similar misconduct. Purdue had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers.

515. The Sacklers knew all of this, too. They were not merely passive overseers who met yearly, approved budgets, and took distributions. The Sacklers were deeply involved in the running of Purdue, were highly knowledgeable about Purdue products and sales tactics, and were knowledgeable about what types of statements and practices were lawful. In addition, as discussed in Section B, the Corporate Integrity Agreement they approved in 2007 required them to be trained on marketing rules and report violations.

516. Notwithstanding this knowledge, at all times relevant to this Complaint, the Sacklers either directed Purdue to engage in the deceptive and unconscionable practices described herein or were aware of the conduct and responsible for it. They then took the additional step of

directing or sanctioning the steps taken by Purdue to avoid detection of and to conceal Purdue's wrongful conduct.

517. In the 2007 settlement with Vermont, Purdue committed that it would not make written or oral claims about OxyContin that were deceptive, and that it would not market OxyContin in a way that was inconsistent with the "Indication and Usage" section of the Package Insert. Purdue also promised to provide "fair balance" statements in its marketing of OxyContin, including statements regarding OxyContin's potential for abuse, addiction, or physical dependence, and that it would not make misrepresentations about OxyContin's potential for abuse, addiction, or physical dependence.

518. However, unbeknownst to the State, Purdue continued its deceptive and misleading marketing. As alleged in greater detail above, Purdue sales representatives rarely discussed the risks of addiction during sales calls, and instead were trained to distinguish it from physical dependence (while omitting key information about the risks of physical dependence) and "appropriate patient selection" (implying that the risks of dependence and addiction can be avoided through prescriber vigilance). These deflections misleadingly reassured doctors that they could safely prescribe Purdue's opioids long-term for chronic pain without fear of addiction.

519. In fact, only when Purdue was being investigated a second time by the State, did it make an attempt to educate prescribers about the risk of addiction posed by its drugs. There are zero references in the call note records to any addiction materials or handouts provided by Purdue sales representatives to Vermont prescribers prior to October 26, 2016. Yet, suddenly, in the fourteen-month period between October 26, 2016 and December 6, 2017 (the last date for which the State received call note records from Purdue), there are 62 references to a "Risk of Addiction"

handout provided to prescribers (the handout was provided in approximately 47% of the 131 Vermont detailer visits that occurred between October 26, 2016 and December 6, 2017).

520. Purdue also disguised its own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third-party advocates, and professional associations. Purdue purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Purdue's false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue masked or never disclosed its role in shaping, editing, and approving the content of this information. Purdue also distorted the meaning or import of studies it cited and offered them as evidence for propositions the studies did not support.

521. Purdue failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse" and "strong record of coordination with law enforcement."[459] The Sacklers received regular updates on just how many "Reports of Concern" had been submitted to the company and how few of those were even investigated, much less reported to law enforcement.

522. Purdue's public stance long has been that opioid abuse and diversion to illicit secondary channels are to blame for widespread addiction and deaths. But Purdue has consistently failed to address the problems caused by over-prescribing opioids. Instead, Purdue funded various drug abuse prevention programs nationwide and introduced abuse-deterrent opioids reformulated to make non-oral ingestion more difficult. Purdue also generated papers for presentation at

[459] Purdue Pharma L.P., "Setting The Record Straight On OxyContin's FDA-Approved Label" (May 5, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Purdue Pharma L.P., "Setting The Record Straight On Our Anti-Diversion Programs" (July 11, 2016), http://www.purduepharma.com/ news-media/ get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

conferences of addiction prevention professionals that stressed the importance of patient selection and touted the efficacy of its "abuse deterrent" opioids. Depicting the opioid crisis as a problem of misuse and diversion, and promoting its pills as solutions, allowed Purdue to present itself as a responsible corporate citizen while continuing to profit from the commonplace prescribing of its drugs, even at high doses for long-term use. Richard Sackler devised this narrative and memorialized it in a marketing memo in 2001, and it has been the foundation for Purdue's approach to the opioid crisis ever since, as directed and sanctioned by the Sacklers.

523. At the heart of Purdue's public outreach has been its claim that the Company works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation features in virtually all of Purdue's recent pronouncements in response to public scrutiny of opioid abuse: "[W]e are acutely aware of the public health risks these powerful medications create .... That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse ...."[460]

524. Purdue's statement on "Opioids Corporate Responsibility" likewise stated, until recently, that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with ... communities, law enforcement, and government." But Purdue has failed to accurately and diligently report to authorities illicit or suspicious prescribing of its opioids, even as it publicly and repeatedly touted its "constructive role in the fight against opioid abuse" and "strong record of coordination with law enforcement." In responding to criticism of its failure to report suspicious prescribing to government regulatory and enforcement authorities,

[460] Purdue Pharma L.P., *Opioids With Abuse-Deterrent Properties*, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/ (last visited Aug. 6, 2018).

Purdue's website similarly proclaimed that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."

525. These public pronouncements created the misimpression that Purdue is proactively working with law enforcement and government authorities, nationwide and in Vermont, to root out drug diversion, including the illicit prescribing that can lead to diversion. They aimed to distance Purdue from its past, publicly-admonished conduct in deceptively marketing opioids, which gave rise to 2007 criminal pleas, and to make its current marketing seem more trustworthy and truthful. In fact, Purdue has consistently failed to report suspicious prescribing to authorities, despite having all the necessary tools—detailed prescribing data and the eyes and ears of its sales force—to observe such practices.

526. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. According to Purdue, physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing volume. Purdue has said publicly that "[o]ur procedures help ensure that whenever we observe potential abuse or diversion activity, we discontinue our company's interaction with the prescriber or pharmacist and initiate an investigation." According to Purdue, it prohibits the detailing of health care providers added to the database, and sales representatives receive no compensation tied to these providers' prescriptions.

527. Yet, according to a 2016 investigation by the *Los Angeles Times*, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. In an interview with the *Los Angeles Times*, Purdue's former

senior compliance officer acknowledged that, in five years of investigating suspicious pharmacies, Purdue consistently failed to report suspicious dispensing or to stop supplies to the pharmacy, even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers. Despite its knowledge of illicit prescribing, Purdue did not report its suspicions, for example, until years after law enforcement shut down a Los Angeles clinic that Purdue's district manager described internally as "an organized drug ring" and that had prescribed more than 1.1 million OxyContin tablets.[461] The New York Attorney General's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. As described in Section C, the Sacklers were briefed in detail on Purdue's efforts to blunt the impact of the *Times'* story, including by collaborating on more favorable reporting by a *Times* competitor. After receiving that briefing, Richard Sackler went so far as to demand from the *Times* that it send him all the paper's correspondence with Purdue.

528. Purdue thus successfully concealed from the medical community, patients, and the State facts sufficient to arouse suspicion of the claims that the State now asserts. The State was unaware of the existence or scope of Purdue's unlawful conduct and reasonable diligence would not have revealed this information at the time it was occurring. Only by conducting a second investigation of Purdue's marketing conduct, beginning in 2016, was the State able to gain access to information about Purdue's continued deceptive and misleading marketing conduct.

529. The Sacklers sought to hide their role as well. After vacating executive positions within the company before 2007, they continued to serve on the Board of Directors. On information and belief, they did so recognizing that it was crucial to install a CEO who would be

[461] Harriet Ryan *et al.*, *More than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/

loyal to the family. The Sacklers also hid behind the façade that they operated as a normal board, approving high-level strategy and budgets but no more, as discussed in Section C above. When Dr. Richard Sackler announced his plan to accompany sales representatives on their prescriber visits in 2011, staff agreed that he needed to be "mum and anonymous." Contemporaneous correspondence indicates that he was warned on this point and further advised that his participation in sales visits constituted a compliance risk under the terms of the federal Corporate Integrity Agreement. Most shocking of the Sacklers' efforts to erase their comprehensive direction of Purdue was the 2017 statement—which disclaimed any leadership of a company that was characterized as "owned by the family trust."

CAUSES OF ACTION

COUNT ONE
DECEPTIVE ACTS AND PRACTICES
VIOLATIONS OF THE VERMONT CONSUMER PROTECTION ACT

The State realleges and incorporates by reference each of the allegations contained in all paragraphs of this Complaint as though fully set forth herein.

530. Each Defendant engaged in deceptive practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), by causing material misrepresentations and omissions regarding the risks and benefits of their opioid products to be made to Vermont prescribers and consumers. Through this deception, Defendants succeeded in getting many Vermont doctors to prescribe and Vermont patients to take and remain on Purdue's opioids.

531. Defendants are personally liable for the conduct described herein because each of Purdue's misrepresentations and omissions was either undertaken at Defendants' explicit direction, undertaken to fulfill Defendants' explicit directions, or was conduct that Defendants were personally aware of and responsible for. Defendants approved the hiring of sales representatives, targets for volume of sales representative activity, and sales objectives with the

knowledge that Purdue would engage in the misrepresentations and omissions described in this Complaint.

532. The material misrepresentations and omissions about the use of opioids to treat chronic pain that are the subject of this Complaint were not supported by or were contrary to scientific evidence, as confirmed by recent pronouncements of the CDC and FDA based on that evidence, and the material omissions (which were false and misleading in their own right) which rendered even seemingly truthful statements about opioids false and misleading because they were materially incomplete.

533. These misrepresentations and omissions were likely to mislead prescribers and consumers, affecting their decisions regarding the prescribing and use of opioids. The meaning Plaintiff ascribes to these misrepresentations and omissions herein is reasonable, given the nature thereof.

534. Defendants also engaged in deceptive practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), because the representations caused by them were not substantiated by competent and reliable scientific evidence.

COUNT TWO
UNFAIR ACTS AND PRACTICES
VIOLATIONS OF THE VERMONT CONSUMER PROTECTION ACT

The State realleges and incorporates by reference each of the allegations contained in all paragraphs of this Complaint as though fully alleged herein.

535. Each Defendant engaged in unfair practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), by: causing material misrepresentations and omissions regarding the risks and benefits of their opioid products to be made to Vermont prescribers and consumers; causing Purdue to target a vulnerable population—the elderly—for

promotion of opioids to treat chronic pain in the face of the known, heightened risks of opioid use to that population, including risks of addiction, adverse effects, hospitalization, and death; causing Purdue to target opioid-naïve patients and patients using IR or weaker (Schedule III) opioids for conversion to Purdue's ER/LA opioid products; authorizing and approving unbranded marketing, front groups, and key opinion leaders to evade FDA oversight and rules prohibiting deceptive marketing and to deceive prescribers and consumers regarding the impartiality of the information conveyed; and directing Purdue to offer Savings Cards as an incentive to use Purdue's prescription opioids. Through this conduct, Defendants succeeded in getting many Vermont doctors to prescribe and Vermont patients to take and remain on their opioids.

536. Defendants are personally liable for the unfair acts and practices described herein because the conduct was either undertaken at Defendants' explicit direction, was undertaken to fulfill Defendants' explicit directions, or was conduct that Defendants were personally aware of, condoned, and were responsible for. Defendants approved the hiring of sales representatives, targets for volume of sales representative activity, and sales objectives with the knowledge that Purdue would engage in the unfair acts and practices described in this Complaint.

537. These acts or practices may be deemed unfair in that they offend public policy reflected in (a) the CPA, which protects consumers and competitors from deceptive marketing and to ensure an honest marketplace, and (b) federal law, which requires the truthful and balanced marketing of prescription drugs, 21 C.F.R. § 202.1(e).

538. These acts or practices were unfair because they unethically deprived prescribers of the information they needed to appropriately prescribe-or not prescribe-these dangerous drugs. Patients who use opioids can quickly become dependent and addicted, such

that neither the patient nor the prescriber can avoid injury by simply stopping or choosing an alternate treatment.

539. Because of Defendants' conduct, Vermont consumers have suffered substantial injury by reason of the health risks associated with opioid use, including the pain, and suffering associated with opioid addiction, injury, disability, overdose, and death, as well as the associated financial costs.

COUNT THREE
PUBLIC NUISANCE

540. The Defendants, through the actions described in the Complaint, have created—or were a substantial factor in creating— a public nuisance by causing an unreasonable interference with a right that is common to the general public and that harms the health, safety, peace, comfort, or convenience of the general community.

541. The State and its citizens have a public right to be free from the substantial injury to public health, safety, peace, comfort, and convenience that has resulted from the Defendants' conduct in causing the illegal and deceptive marketing of opioids for the treatment of chronic pain.

542. This injury to the public includes, but is not limited to (a) widespread dissemination of false and misleading information regarding the risks and benefits of opioids to treat chronic pain; (b) a distortion of the medical standard of care for treating chronic pain, resulting in pervasive overprescribing of opioids and the failure to provide more appropriate pain treatment; (c) high rates of opioid abuse, injury, overdose, and death, and their impact on Vermont families and communities; (d) increased health care costs for individuals, families, employers, and the State; (e) lost employee productivity resulting from the cumulative effects of long-term opioid use, addiction, and death; (f) the creation and maintenance of a secondary, criminal market for opioids;

and (g) greater demand for emergency services and law enforcement paid for by the State at the ultimate cost of taxpayers.

543. At all times relevant to the Complaint, the Defendants' conduct substantially and unreasonably interfered in the enjoyment of this public right by the State and its citizens. Purdue engaged in a pattern of conduct that (a) overstated the benefits of chronic opioid therapy, including by misrepresenting OxyContin's duration of efficacy and by failing to disclose the lack of evidence supporting long-term use of opioids; and (b) obscured or omitted the serious risk of addiction arising from such use. This conduct was either undertaken at Defendants' explicit direction, was undertaken to fulfill Defendants' explicit directions, or was conduct that Defendants were personally aware of and responsible for. This conduct effected and maintained a shift in health care providers' willingness to prescribe opioids for chronic pain, resulting in a dramatic increase in opioid prescribing and the injuries described above.

544. At all times relevant to the Complaint, Defendants exercised control over the instrumentalities constituting the nuisance—i.e., Purdue's marketing as conveyed through sales representatives, other speakers, and publications, and its program to identify suspicious prescribing. As alleged herein, Defendants created, or were a substantial factor in creating, the nuisance through multiple vehicles, including (a) Purdue's in-person sales calls that contained false or misleading statements or material omissions; (b) Purdue's dissemination of deceptive advertisements and publications; (c) Purdue's sponsorship and creation of flawed and biased scientific research and prescribing guidelines; and (d) Purdue's sponsorship of and collaboration with third parties to disseminate false and misleading messages about opioids.

545. Defendants' actions were a substantial factor in creating the public nuisance because it caused prescribers and patients to be deceived about the risks and benefits of opioids

and distorted the medical standard of care for treating chronic pain. Without Defendants' actions, opioid use would not have become so widespread, and the opioid epidemic that now exists in Vermont would have been averted or would be much less severe.

546. The public nuisance was foreseeable to Defendants. As alleged herein, Purdue engaged in widespread promotion of opioids in which it misrepresented the risks and benefits of opioids to treat chronic pain. Defendants knew that there was no evidence showing a long-term benefit of opioids on pain and function, and that opioids carried serious risks of addiction, injury overdose, and death. Defendants were positioned to foresee not only a vastly expanded market for chronic opioid therapy as the likely result of Purdue's conduct, but also the widespread problems of opioid addiction and abuse that have, in fact, materialized. Defendants were on notice and aware of signs that the broader use of opioids was causing just the kinds of injuries described in this Complaint.

547. This public nuisance can be abated—in part—through health care provider and consumer education on appropriate prescribing, honest marketing of the risks and benefits of long-term opioid use, addiction treatment, disposal of unused opioids, and other means.

COUNT FOUR
UNJUST ENRICHMENT

548. The State realleges and incorporates by reference each of the allegations contained in all paragraphs of this Complaint as if set forth fully herein.

549. As an expected and intended result of their wrongdoing as set forth in this Complaint, each Defendant has profited and benefited from the sale of their opioids within the State.

550. Each Defendant has accepted the profits and benefits conferred on them through the sale of their opioids within the State, including by accepting disbursements from Purdue which included funds that came from Vermont.

551. Each Defendant's retention of the profits and benefits conferred on them through the increased sales of their opioids within the State is inequitable. Each Defendant has unjustly enriched themselves at the State's expense, while the State has borne the cost of remedying and mitigating the harms caused by Defendants' conduct.

PRAYER FOR RELIEF

WHEREFORE, the State respectfully requests that this Court grant the following relief after a trial on the merits:

A. Determine that all Defendants engaged in unfair and deceptive acts and practices in violation of 9 V.S.A. § 2453, and the regulations promulgated thereunder;

B. Permanently enjoin all Defendants from engaging in unfair and deceptive acts and practices;

C. Order all Defendants to disgorge all payments received as a result of their unlawful conduct;

D. Order all Defendants to pay civil penalties of up to $10,000 for each and every violation of the Vermont Consumer Protection Act;

E. Award the State of Vermont all investigative and litigation costs and fees;

F. Determine that all Defendants created a public nuisance;

G. Order all Defendants to abate the nuisance, to reimburse the cost of the State's abatement efforts, and to pay compensatory damages for harms caused by the nuisance; and

H. Grant all other relief as the Court may deem just and proper.

JURY DEMAND

The State demands a trial by jury on all issues properly so tried.

Dated: May 21, 2019

Respectfully submitted,

THOMAS J. DONOVAN JR.
ATTORNEY GENERAL

By: _____

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FILED

2007 JUN 25 A 8:54

SUPERIOR COURT
WASHINGTON UNIT

STATE OF VERMONT

WASHINGTON COUNTY SUPERIOR COURT

STATE OF VERMONT	)	
	)	
v.	)	**DOCKET NO.** 349-5-07 Wncv
	)	
PURDUE PHARMA L.P., et al.	)	

CONSENT JUDGMENT

This Consent Judgment (hereinafter referred to as "Judgment") is entered into between the Attorneys General or other entities[1] of the States and Commonwealths of Arizona, Arkansas, California, Connecticut, District of Columbia, Idaho, Illinois, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Montana, Nebraska, Nevada, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, and Wisconsin (hereinafter referred to as "Signatory Attorneys General"), acting on behalf of their respective states, and pursuant to their respective consumer protection statutes; and Purdue Pharma L.P., et al (hereinafter referred to as "Purdue").

[1] For the purposes of this agreement, when the entire group is referred to as "Signatory Attorneys General," such designation, as it pertains to CONNECTICUT, shall refer to the Commissioner of the Department of Consumer Protection, who enters this Consent pursuant to the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. Sec. 42-110j, acting by and through his counsel, Richard Blumenthal, Attorney General for the State of Connecticut. For MONTANA, such designation shall refer to the Consumer Protection Office of the Department of Justice who enters into this settlement pursuant to the Montana Unfair Trade and Consumer Protection Act of 1973 MCA 30-14-101 *et al.*, acting by and through his counsel, Mike McGrath, Attorney General for the State of Montana.

I. DEFINITIONS

1. The following definitions shall be used in construing this Consent Judgment (hereinafter "Judgment"):

A. "Covered Persons" shall mean all officers, employees and all contract or third-party sales representatives, including Medical Liaisons, of Purdue or retained by Purdue having direct responsibility for marketing and promoting OxyContin to Health Care Professionals.

B. "Effective Date" shall mean the date on which Purdue receives a copy of this Judgment, duly executed by Purdue and by the Signatory Attorney General and filed with the Court.

C. "FDA Guidances for Industry" shall mean documents published by the United States Department of Health and Human Services, Food and Drug Administration ("FDA") that represent the FDA's current recommendations on a topic.

D. "Health Care Professional" or "Health Care Professionals" shall mean any person or persons duly licensed by relevant federal and/or state law to prescribe Schedule II pharmaceutical products, as well as duly licensed pharmacists, nurses and other licensed health professionals.

E. "Off-Label Promotion" shall mean the marketing and promotion of an Off-Label Use. Off-Label Promotion shall not mean discussion of the abuse and diversion of OxyContin that is not inconsistent with the Package Insert.

F. "Off-Label Use" shall mean any use inconsistent with the "Indications and Usage" section of the Package Insert.

G. "OxyContin" shall mean any controlled-release drug distributed by Purdue which contains oxycodone as an active pharmaceutical ingredient.

H. "Package Insert" shall mean the FDA approved label (as described in 21 C.F.R. §§ 201.56 and 57) for OxyContin, including all modifications to the label theretofore approved by the FDA.

I. "Parties" shall mean Purdue and the Signatory Attorneys General.

J. "Purdue" shall mean Purdue Pharma Inc., Purdue Pharma L.P., The Purdue Frederick Company, Inc (d/b/a The Purdue Frederick Company), and all of their United States affiliates, subsidiaries, predecessors, successors, parents and assigns, who manufacture, sell, distribute and/or promote OxyContin.

K. "Remuneration" shall mean any gift, fee, or payment, exceeding twenty-five dollars ($25.00) in value, provided by Purdue directly or indirectly in connection with marketing or promotion of OxyContin.

L. "Signatory Attorney General" shall mean the Attorney General, or his or her designee, who has agreed to this Judgment.

M. "Subject Matter of this Judgment" shall mean the investigation under the State Consumer Protection Laws[2] of Purdue's promotional and marketing practices regarding OxyContin.

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[2] ARIZONA Consumer Fraud Act, Ariz. Rev. Stat. §44-1521, *et. seq.*; ARKANSAS - Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101 *et seq.*; CALIFORNIA Business and Professions Code § 17200 *et seq* 17500 *et seq* ; CONNECTICUT – Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. §42-110 *et seq.*; DISTRICT OF COLUMBIA – District of Columbia Consumer Protection Procedures Act, D.C. Code § 28-3901 *et seq.*; IDAHO - Consumer Protection Act, Idaho Code § 48-601 *et seq.*; ILLINOIS - Consumer Fraud and Deceptive Business Practices Act, 815 ILCS § 505/1 *et seq.* (2002); KENTUCKY - Consumer Protection Statute, KRS 367.170; LOUISIANA – Unfair Trade Practices and Consumer Protection Law, LSA-R.S. 51:1401 *et seq.*; MAINE – Unfair Trade Practices Act, 5 M.R.S.A. section 205-A *et.* seq; MARYLAND - Consumer Protection Act, Maryland Commercial Law Code Annotated § 13-101 *et seq.*; MASSACHUSETTS - Consumer Protection Act, M.G.L. c. 93A *et seq.*; MONTANA - Mont. Code Ann. § 30-14-101 *et seq.*; NEBRASKA – Consumer Protection Act:

II. COMPLIANCE PROVISIONS

2. In the promotion and marketing of OxyContin, Purdue shall not make any written or oral claim that is false, misleading or deceptive.

3. In the promotion and marketing of OxyContin, Purdue shall not market or promote OxyContin in a manner that is, directly or indirectly, inconsistent with the "Indication and Usage" section of the Package Insert for OxyContin. Further, Purdue shall, consistent with the Package Insert, or as otherwise permitted by the FDA, not promote or market OxyContin in a manner that: (a) avoids or minimizes the fact that OxyContin is indicated for moderate to severe pain when a continuous around-the-clock analgesic is needed for an extended period of time; or (b) avoids, minimizes, or is inconsistent with individualizing treatment using a plan of pain management, such as outlined by the World Health Organization, the Agency for Healthcare Research and Quality (formerly known as the Agency for HealthCare Policy and Research), the Federation of State Medical Boards Model Guidelines or the American Pain Society , as referenced in the Package Insert.

Neb.Rev.Stat. 59-1601, *et seq.* (Reissue 2004 & RS Supp. 2006), Uniform Deceptive Trade Practices Act: Neb.Rev.Stat. 87-301 *et seq.* (Reissue 1999 & RS Supp. 2006); NEVADA - Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 *et seq.*; NEW MEXICO – Unfair Practices Act" NMSA 1978, S 57-12-1 *et seq.* (1967); NORTH CAROLINA - Unfair and Deceptive Trade Practices Act, N.C.G.S. § 75-1.1 *et seq.*; OHIO - Consumer Sales Practices Act, R.C. § 1345.01 *et seq.*; OREGON - Unlawful Trade Practices Act, ORS 646.605 to 646.656; PENNSYLVANIA - Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 *et seq.*; SOUTH CAROLINA - Unfair Trade Practices Act, Sections 39-5-10 *et seq.*; TENNESSEE - Consumer Protection Act, Tenn. Code Ann. § 47-18-101 *et seq.*, (1977); TEXAS - Deceptive Trade Practices and Consumer Protection Act, Tex. Bus. And Com. Code § 17.41 *et seq.*, (Vernon 2002); VERMONT - Consumer Fraud Act, 9 V.S.A. § 2451 *et seq.*; VIRGINIA - Virginia Consumer Protection Act, Va. Code Ann. § 59.1 -196 *et seq.*; WASHINGTON - Washington Consumer Protection Act – R.C.W. 1986 *et seq*; WISCONSIN - Wis. Stat. § 100.18 (Fraudulent Representations).

4. In the promotion and marketing of OxyContin, Purdue shall provide "fair balance" statements, as defined in 21 C.F.R. §202.1 as may be amended or supplemented, or as appearing in FDA Guidances for Industry from time to time, regarding contraindications and adverse events, including but not limited to statements regarding OxyContin's potential for abuse, addiction, or physical dependence as set forth in the Package Insert.

5. In the promotion and marketing of OxyContin, Purdue shall not make misrepresentations with respect to OxyContin's potential for abuse, addiction, or physical dependence as set forth in the Package Insert. Further to this general prohibition on misrepresentations, Purdue, in the promotion and marketing of OxyContin, shall not represent, except as may be set forth in the Package Insert, that: a) OxyContin is "nonaddictive" or "virtually nonaddictive"; b) addiction to OxyContin occurs in "less than 1%" of patients being treated with OxyContin; or c) OxyContin's potential for abuse, addiction or physical dependence differs from any other Schedule II opioid analgesic.

6. In the promotion and marketing of OxyContin, Purdue shall not make any written or oral promotional claim of safety or effectiveness for Off-Label Uses of OxyContin in a manner that violates the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), and accompanying regulations as may be amended or supplemented, or as appearing in FDA Guidances for Industry from time to time.

7. Except upon a request for such information without solicitation by Purdue to make the request, Purdue shall not provide to Health Care Professionals written materials describing the Off-Label Use of OxyContin that have not appeared in a

scientific or medical journal or reference publication or any portion thereof. Purdue shall maintain records for three (3) years of the identity of all Health Care Professionals to whom such materials relating to the Off-Label Use of OxyContin have been provided. "Scientific or medical journal" is a publication whose articles are published in accordance with regular peer-reviewed procedures; that uses experts to review or provide comment on proposed articles; and that is not in the form of a special supplement that has been funded in whole or in part by one or more manufacturers. "Reference publication" is a publication that has no common ownership or other corporate affiliation with a pharmaceutical or medical device manufacturer; that has not been written, edited, excerpted, or published specifically for, or at the request of, such a manufacturer; and that has not been edited or significantly influenced by such a manufacturer.

8. A. When Purdue provides an individual or entity with any educational grant, research grant, or other similar Remuneration relating to OxyContin, Purdue shall obtain the recipient's agreement: (i) to clearly and conspicuously disclose the existence of said funding or Remuneration to the readers of any resulting letter, study, research or other materials which was supported by said funding or Remuneration, and (ii) to refund said funding or Remuneration if such disclosure is not made.

B. Purdue shall require that a recipient of any Remuneration from Purdue for the promotion of OxyContin agree: (i) to clearly and conspicuously disclose the existence, nature and purpose of the Remuneration to the participants in any educational event at which the recipient discusses an Off-Label Use of OxyContin, and (ii) to refund said Remuneration if such disclosure is not made.

C. Purdue shall itself clearly and conspicuously disclose the existence of any grant or other form of Remuneration that it has provided for the publication of a letter, study, research or other material relating to OxyContin when Purdue disseminates or refers to said letter, study, research or other material in communications with Health Care Professionals.

9. Purdue shall comply with all applicable Accreditation Council for Continuing Medical Education ("ACCME") Guidelines.

10. Purdue shall comply with paragraphs 2, 3, 4, 5, 7 and 8 of the Pharmaceutical Research and Manufacturers of America Code (effective on July 1, 2002) with respect to payments, gifts and other compensation to Health Care Professionals regarding OxyContin.

11. In the promotion and marketing of OxyContin, Purdue shall not misrepresent the existence, non-existence, or findings of any medical or scientific evidence, including anecdotal evidence, relating to Off-Label Uses of OxyContin. Purdue shall not provide any information that is misleading or lacking in fair balance, as defined in 21.C.F.R. 202.1, as may be amended or supplemented, or as appearing in FDA Guidances for Industry from time to time, in any discussion of the Off-Label Uses of OxyContin.

12. Purdue shall not sponsor or fund any educational events where Purdue has knowledge at the time the decision for sponsorship or funding is made that a speaker will recommend the Off-Label Use of OxyContin. Further, Purdue shall not promote or fund Health Care Professionals' attendance at educational events where Purdue has

knowledge, at the time of said promotion, that Off-Label Use of OxyContin will be recommended or encouraged.

13. Purdue shall, no later than thirty (30) business days after the Effective Date of this Judgment, establish, implement and follow an OxyContin abuse and diversion detection program consisting of internal procedures designed to identify potential abuse or diversion of OxyContin in certain settings (the "OxyContin Abuse and Diversion Detection Program"). The OxyContin Abuse and Diversion Detection Program will apply to Purdue employees and contract or third-party sales representatives, including Medical Liaisons, who contact practicing Health Care Professionals in person or by telephone for the purpose of promoting OxyContin. That Program directs those persons to report to the Office of the General Counsel situations, including, but not limited to the following examples, to the extent that such information or activities are observed or learned of by them: a) an apparent pattern of an excessive number of patients for the practice type, such as long lines of patients waiting to be seen, waiting rooms filled to standing-room-only capacity, or patient-prescriber interactions that are exceedingly brief or non-existent; b) an atypical pattern of prescribing techniques or locations, such as repeated prescribing from an automobile, or repeated prescribing at atypical times, such as after usual office hours when the Health Care Professional is not on call; c) information from a highly credible source or several sources (e.g., pharmacists, law enforcement, other health care workers) that a Health Care Professional or their patients are abusing or diverting medications; d) sudden, unexplained changes in prescribing or dispensing patterns that are not accounted for by changes in patient numbers or practice type; e) a Health Care Professional who has a disproportionate

number of patients who pay for office visits and dispensed medications with cash; f) multiple allegations that individuals from a particular practice have overdosed; or g) unauthorized individuals signing prescriptions or dispensing controlled substances. Upon identification of potential abuse or diversion involving a Health Care Professional with whom Purdue employees or its contract or third-party sales representatives, including Medical Liaisons, interact, Purdue will conduct an internal inquiry which will include but not be limited to a review of the Health Care Professional's prescribing history, to the extent such history is available and relevant, and shall take such further steps as may be appropriate based on the facts and circumstances, which may include ceasing to promote Purdue products to the particular Health Care Professional, providing further education to the Health Care Professional about appropriate use of opioids, or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities. Purdue's obligations under this Section shall expire ten (10) years following the Effective Date of this Judgment or three months from the date on which the last of Purdue's patents covering OxyContin expires, whichever is earlier, but in no event shall be earlier than seven (7) years following the Effective Date of this Judgment.

14. Purdue shall implement and maintain a training and education program with respect to the OxyContin Abuse and Diversion Detection Program, and shall require all Purdue employees and contract or third-party sales representatives, including Medical Liaisons, who contact practicing Health Care Professionals in person or by telephone for the purpose of promoting OxyContin to complete the training and education program no later than thirty (30) business days after the Effective Date of this Judgment. Further, Purdue shall require those Purdue employees and contract or third-party sales

representatives, including Medical Liaisons, who contact practicing Health Care Professionals in person or by telephone for the purpose of promoting OxyContin to complete the training and education program before being allowed to market or promote OxyContin. Purdue's obligations under this Section shall expire ten (10) years following the Effective Date of this Judgment or three months from the date on which the last of Purdue's patents covering OxyContin expires, whichever is earlier, but in no event shall be earlier than seven (7) years following the Effective Date of this Judgment.

15. Within 90 days of the Effective Date of this Judgment, Purdue shall provide to each Health Care Professional whom Covered Persons contact, written, non-branded educational information related to detecting and preventing abuse and diversion of opioid analgesics. To the extent that Purdue concludes that a specific Health Care Professional needs repeated exposure to such non-branded educational materials, Purdue will provide those materials. Purdue's obligations under this Section will remain in effect for ten (10) years following the Effective Date of this Judgment.

16. Purdue shall continue to review news media stories addressing the abuse or diversion of OxyContin and undertake appropriate measures as reasonable under the circumstances to address abuse and diversion so identified, including but not limited to, (i) correcting misinformation, (ii) offering non-branded educational materials to local substance abuse prevention and treatment initiatives, or (iii) directing Health Care Professionals to Purdue's Medical Services group for fair and balanced information on appropriate use of opioid analgesics, prevention and detection of abuse and diversion. Purdue's obligations under this Section shall expire ten (10) years following the Effective Date of this Judgment or three months from the date on which the last of Purdue's patents

covering OxyContin expires, whichever is earlier, but in no event shall be earlier than seven (7) years following the Effective Date of this Judgment.

17. No sales incentive (bonus) program for sales of OxyContin shall allow incentive credit to be earned for a Health Care Professional who has been identified through the OxyContin Abuse and Diversion Detection Program as one upon whom sales representatives shall not call. In addition, Purdue shall not employ a compensation structure for persons involved in marketing or promoting OxyContin that is based exclusively on the volume of OxyContin sales.

18. For a period of ten (10) years following the Effective Date of this Judgment, Purdue's performance evaluation of persons involved in marketing or promoting OxyContin shall meaningfully take into account that sales persons inform Health Care Professionals to whom the sales persons promote OxyContin about its potential for abuse and diversion, and how to minimize those risks; failure to do so shall be considered as a basis for disciplinary action, including, but not limited to censure, probation and termination.

19. In its promotion and marketing of OxyContin, Purdue shall not misrepresent, in any written or oral claim relating to OxyContin, that its sales, medical or research personnel have experience or credentials or are engaging in research activities if they do not in fact possess such credentials or experience, or are not engaging in such activities.

20. All material used in promoting OxyContin, regardless of format (audio, internet, video, print) and whether directed primarily to patients or to Health Care Professionals, shall, not inconsistent with the Package Insert, contain only information

that is truthful, balanced, accurately communicated, and not minimize the risk of abuse, addiction or physical dependence associated with the use of OxyContin.

21. Purdue shall not provide samples of OxyContin to Health Care Professionals.

22. The obligations of Purdue under this Judgment shall be prospective only. No Signatory Attorney General shall institute any proceeding or take any action against Purdue under its State Consumer Protection Laws or any similar state authority, or under this Judgment, based on Purdue's prior promotional or marketing practices for OxyContin.

23. Nothing in this Judgment shall require Purdue to:

(a) take an action that is prohibited by the FDCA, the Controlled Substances Act or any regulation promulgated thereunder, or by FDA or the Drug Enforcement Administration;

(b) fail to take an action that is required by the FDCA, the Controlled Substances Act or any regulation promulgated thereunder, or by FDA or the Drug Enforcement Administration;

(c) refrain from dissemination of safety information concerning OxyContin; or

(d) refrain from making any written or oral promotional claim which is the same or substantially the same as the language permitted by FDA under the OxyContin Package Insert and which accurately portrays the data or other information referenced in the OxyContin Package Insert.

24. Purdue shall:

(a) to the extent necessary for compliance with this Judgment, no later than ninety (90) days after the Effective Date of this Judgment, institute compliance procedures which are designed to begin training currently employed Covered Persons on the contents of this Judgment, and about how to comply with this Judgment;

(b) submit to the Attorney General (per the Notice below), no later than one hundred and twenty (120) days after the Effective Date of this Judgment, a written description of such training;

(c) submit to the Attorney General (per the Notice below), one (1) year after the Effective Date of this Judgment, a written affirmation setting forth Purdue's compliance with this paragraph;

(d) for a period of three (3) years from the Effective Date of this Judgment, Purdue shall advise in writing all Covered Persons of the requirements of Paragraphs 2 through 23 of this Judgment;

(e) beginning one (1) year after the Effective Date of this Judgment, for a period of three (3) years, produce and provide on an annual basis to the Attorney General on the anniversary of the Effective Date of this Consent Judgment a report containing basic statistics on Purdue's Abuse and Diversion Detection Program including, but not limited to, statistics on the number of reports , the number of investigations, and a summary of the results, including the number of "Do Not Call" determinations, but shall not include the names of any specific Health Care Professionals; and

(f) upon written request, the Attorney General may obtain state-specific information as described in subsection (e). In addition, Purdue agrees to accept service

of a civil investigative demand or similar process by the Attorney General requesting the names of any specific Health Care Professionals described in subsection (e). The Attorney General in receipt of such information shall not disclose it except as provided by law.

III. PAYMENT TO THE STATES

25. No later than thirty (30) days after the Effective Date of this Judgment, Purdue shall pay nineteen million and five hundred thousand U.S. dollars ($19,500,000.00), to be paid by Purdue to the States by electronic fund transfer made payable to the Oregon Department of Justice (as instructed by that Office) which shall divide and distribute these funds as designated by and in the sole discretion of the Signatory Attorneys General as part of the consideration for the termination of their respective investigations under the State Consumer Protection Laws regarding the Subject Matter of this Judgment. Said payment shall be used by the States as and for attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to, the consumer protection enforcement fund, including future consumer protection enforcement, consumer education, litigation or local consumer aid fund or revolving fund, used to defray the costs of the inquiry leading hereto, and may be used to fund or assist in funding programs directed at combating prescription drug abuse, addiction and/or diversion, including, but not limited to, education, outreach, prevention or monitoring programs, or for other uses permitted by state law, at the sole discretion of each Signatory Attorney General.

IV. GENERAL PROVISIONS

26. This Judgment shall be governed by the laws of the state of Vermont.

27. This Judgment is entered into by the Parties as their own free and voluntary act and with full knowledge and understanding of the nature of the proceedings and the obligations and duties imposed by this Judgment.

28. Nothing in this Judgment constitutes any agreement by the Parties concerning the characterization of the amounts paid pursuant to this Judgment for purposes of the Internal Revenue Code or any state tax laws, or the resolution of any other matters.

29. This Judgment does not constitute an approval by the Attorney General of any of Purdue's business practices, including its promotional or marketing practices, and Purdue shall make no representation or claim to the contrary.

V. REPRESENTATIONS AND WARRANTIES

30. Purdue warrants and represents that it and its predecessors, successors and assigns manufactured, sold and promoted OxyContin. Purdue further acknowledges that it is a proper party to this Judgment. Purdue further warrants and represents that the individual(s) signing this Judgment on behalf of Purdue is doing so in his (or her) official capacity and is fully authorized by Purdue to enter into this Judgment and to legally bind Purdue to all of the terms and conditions of the Judgment.

31. Each of the Parties represents and warrants that it negotiated the terms of this Judgment in good faith.

32. Each of the Signatory Attorneys General warrants and represents that he or she is signing this Judgment in his or her official capacity, and that he or she is fully authorized by his or her state to enter into this Judgment, including but not limited to the authority to grant the release contained in Paragraphs 34 and 35 of this Judgment, and to legally bind the state to all of the terms and conditions of this Judgment.

33. Purdue acknowledges and agrees that the Attorney General has relied on all of the representations and warranties set forth in this Judgment and that, if any representation is proved false, unfair, deceptive, misleading, or inaccurate in any material respect, the Attorney General has the right to seek any relief or remedy afforded by law or equity in the state.

VI. RELEASE

34. Based on his or her inquiry into Purdue's promotion of OxyContin, the Attorney General has concluded that this Judgment is the appropriate resolution of any alleged violations of the State Consumer Protection Laws. The Attorney General acknowledges by his or her execution hereof that this Judgment terminates their inquiry under the State Consumer Protection Laws into Purdue's promotion of OxyContin prior to the Effective Date of this Judgment.

35. In consideration of the Compliance Provisions, payments, undertakings, and acknowledgments provided for in this Judgment, and conditioned on Purdue's making full payment of the amount specified in Paragraph 25, and subject to the limitations and exceptions set forth in Paragraph 36, the State releases and forever discharges, to the fullest extent permitted by law, Purdue and its past and present officers, directors, shareholders, employees, co-promoters, affiliates, parents, subsidiaries, predecessors, assigns, and successors (collectively, the "Releasees"), of and from any and all civil causes of action, claims, damages, costs, attorney's fees, or penalties that the Attorney General could have asserted against the Releasees under the State Consumer Protection Law by reason of any conduct that has occurred at any time up to and including the Effective Date of this Judgment relating to or based upon the Subject Matter of this Judgment ("Released Claims").

36. The Released Claims set forth in Paragraph 35 specifically do not include the following claims:

(a) private rights of action by consumers, provided, however, that this Judgment does not create or give rise to any such private right of action of any kind;

(b) claims relating to Best Price, Average Wholesale Price or Wholesale Acquisition Cost reporting practices or Medicaid fraud or Abuse;

(c) claims of antitrust, environmental or tax liability;

(d) claims for property damage;

(e) claims to enforce the terms and conditions of this Judgment; and

(f) any state or federal criminal liability that any person or entity, including Releasees, has or may have to the State.

VII. NO ADMISSION OF LIABILITY

37. This Judgment does not constitute an admission by Purdue for any purpose, of any fact or of a violation of any state law, rule, or regulation, nor does this Judgment constitute evidence of any liability, fault, or wrongdoing, by Purdue nor does Purdue's agreement in this Judgment not to engage in certain conduct constitute an admission that Purdue has ever engaged in such conduct. Purdue enters into this Judgment for the purpose of resolving the concerns of the Attorney General regarding Purdue's promotional and marketing practices regarding OxyContin. Purdue does not admit any violation of the State Consumer Protection Laws, and does not admit any wrongdoing that could have been alleged by the Attorney General.

38. This Judgment shall not be construed or used as a waiver or any limitation of any defense otherwise available to Purdue. This Judgment is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. Nothing in this

Judgment, including this paragraph, shall be construed to limit or to restrict Purdue's right to use this Judgment to assert and maintain the defenses of res judicata, collateral estoppel, payment, compromise and settlement, accord and satisfaction, or any other legal or equitable defenses in any pending or future legal or administrative action or proceeding.

VIII. DISPUTES REGARDING COMPLIANCE

39. For the purposes of resolving disputes with respect to compliance with this Judgment, should the Attorney General have legally sufficient cause (which shall include, at a minimum, a reasonable basis to believe that Purdue has violated a provision of this Judgment) to object to any promotional or marketing practices relating to OxyContin subsequent to the Effective Date of this Judgment, then the Attorney General shall notify Purdue in writing of the specific objection, identify with particularity the provisions of this Judgment and/or the State Consumer Protection Laws that the practice appears to violate, and give Purdue thirty (30) business days to respond to the notification; provided, however, that the Attorney General may take any action upon notice to Purdue where the Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

40. Upon receipt of written notice and within the thirty (30) business-day period, Purdue shall provide a good faith written response to the Attorney General's objection. The response shall include an affidavit containing either:

(a) A statement explaining why Purdue believes it is in compliance with the Judgment; or

(b) A detailed explanation of how the alleged violation[s] occurred; and

i. A statement that the alleged breach has been cured and how it has been cured; or

ii. A statement that the alleged breach cannot be reasonably cured within thirty (30) business days from receipt of the notice, but (1) Purdue has begun to take corrective action to cure the alleged breach; (2) Purdue is pursuing such corrective action with reasonable and due diligence; and (3) Purdue has provided the Attorney General with a detailed and reasonable time table for curing the alleged breach.

41. Nothing herein shall prevent the Attorney General from agreeing in writing to provide Purdue with additional time beyond the thirty (30) business-day period to respond to the notice.

42. Nothing herein shall be construed to exonerate any failure to comply with any provision of this Judgment after the date of entry or to compromise the authority of the Signatory Attorney General to initiate a proceeding for failure to comply. Further, nothing in this subsection shall be construed to limit the authority of the Signatory Attorney General to protect the interests of the State.

43. The Signatory Attorney General represents that he or she will seek enforcement of the provisions of this Judgment with due regard for fairness and, in so doing, shall take into account efforts that Purdue has taken to cure any claimed violation of this Judgment.

44. Upon giving Purdue thirty (30) business days to respond to the notification described in Paragraph 39 above, the Attorney General shall be permitted to request and Purdue shall produce relevant, non-privileged, non-work-product records and documents

in the possession, custody or control of Purdue that relate to Purdue's compliance with each provision of this Judgment as to which legally sufficient cause has been shown.

IX. MODIFICATION OF CERTAIN OPERATIONAL PROVISIONS

45. Any party to this Judgment may petition the Court for modification on thirty (30) days' notice to all other parties to this Judgment. Purdue may petition for modification if it believes that the facts and circumstances that led to the Attorney General's action against Purdue have changed in any material respect. The parties by stipulation may agree to a modification of this Judgment, which agreement shall be presented to this Court for consideration; provided that the parties may jointly agree to a modification only by a written instrument signed by or on behalf of both Purdue and the Attorney General. If Purdue wishes to seek a stipulation for a modification from the State, it shall send a written request for agreement to such modification to the Attorney General at least 30 days prior to filing a motion with the Court for such modification. Within 30 days of receipt from Purdue of a written request for agreement to modify, the Attorney General shall notify Purdue in writing if the Attorney General agrees to the requested modification. The Attorney General shall not unreasonably withhold his/her consent to the modification.

X. PENALTIES FOR FAILURE TO COMPLY

46. The State may assert any claim that Purdue has violated this Judgment in a separate civil action to enforce this Judgment, or to seek any other relief afforded by law. In any such action or proceeding, relevant evidence of conduct that occurred before the Effective Date shall be admissible on any material issue, including alleged willfulness, intent, knowledge, or breach, to the extent permitted by law. By this Paragraph, Purdue

does not waive any evidentiary objection or any other objection it may have as permitted by law to the admissibility of any such evidence.

XI. COMPLIANCE WITH ALL LAWS

47. Except as expressly provided in this Judgment, nothing in this Judgment shall be construed as:

(a) relieving Purdue of its obligation to comply with all state laws, regulations or rules, or granting permission to engage in any acts or practices prohibited by such law, regulation or rule; or

(b) limiting or expanding in any way any right the State may otherwise have to obtain information, documents or testimony from Purdue pursuant to any state law, regulation or rule, or any right Purdue may otherwise have to oppose any subpoena, civil investigative demand, motion, or other procedure issued, served, filed, or otherwise employed by the State pursuant to any such state law, regulation, or rule.

XII. NOTICES

48. Any notices required to be sent to the State or to Purdue by this Judgment shall be sent by overnight United States mail. The documents shall be sent to the following addresses:

For the State:

Julie Brill, Assistant Attorney General
Office of the Vermont Attorney General
109 State Street
Montpelier, VT 05601-1009
802-828-3658 – phone
802-828-2154 – fax

For Purdue:

Vice President, Associate General Counsel
Purdue Pharma L.P.
One Stamford Forum
Stamford, CT 06901-3431

APPROVED:

Mary Miles Teachout
Washington County Superior Court Judge, Presiding

June 21, 2007
Date

FOR PURDUE

Robin E Abrams

Robin E. Abrams
Vice President, Associate General Counsel
Purdue Pharma L.P.
The Purdue Frederick Company
Purdue Pharma Inc.
Tel: 203-588-8477
Fax: 203-588-6204

Date: May 1, 2007

Ritchie Berger
Dinse, Knapp and McAndrew, P.C.
P.O. Box 988
209 Battery Street
Burlington, VT 05402-0988
Tel: 802-864-5751
Fax: 802-862-6409
VT Bar No. 187

Date: May 4, 2007

FOR THE STATE OF VERMONT

WILLIAM H. SORRELL
ATTORNEY GENERAL OF VERMONT

By: Julie Brill Date: May 8, 2007

Julie Brill
Assistant Attorney General
Vermont Attorney General's Office
109 State Street
Montpelier, VT 05609-1001
802-828-3658 – phone
802-828-2154 - fax