IN THE SUPREME COURT OF THE STATE OF NEVADA

CITY OF RENO,

Appellant,

vs.

TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ENDO HEALTH SOLUTIONS, INC.; ENDO PHARMACEUTICALS INC.; ALLERGAN USA, INC.; ALLERGAN FINANCE, LLC F/K/A ACTAVIS, INC. F/K/A WATSON PHARMACEUTICALS, INC.; ACTAVIS PHARMACY, INC. F/K/A WATSON PHARMA, INC.; AND ACTAVIS LLC,

Respondents.

Supreme Court No. 85412

District Court Case No.: CV18-01895

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APPELLANT'S APPENDIX VOLUME 9

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CHRONOLOGICAL INDEX TO APPELLANT'S APPENDIX

ALPHABETICAL INDEX TO APPELLANT'S APPENDIX

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 15th day of April 2023, I served a true and correct copy of the foregoing **APPELLANT'S APPENDIX VOLUME 9** upon each of the parties by electronic service through the E-Flex rules of service.

By: /s/ *Jennifer Lopez*
An Employee of EGLET ADAMS

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DISTRICT COURT

CLARK COUNTY, NEVADA

STATE OF NEVADA,

Plaintiff,

vs.

MCKESSON CORPORATION; CARDINAL HEALTH INC.; CARDINAL HEALTH 105, INC.; CARDINAL HEALTH 108, LLC; CARDINAL HEALTH 110, LLC; CARDINAL HEALTH 200, LLC; CARDINAL HEALTH 414, LLC; CARDINAL HEALTH PHARMACY SERVICES, LLC; AMERISOURCEBERGEN DRUG CORPORATION; WALGREENS BOOTS ALLIANCE, INC.; WALGREEN CO.; WALGREEN EASTERN CO., INC.; WALMART INC.; CVS PHARMACY, INC.; TEVA PHARMACEUTICALS USA.;TEVA PHARMACEUTICAL INDUSTRIES, LTD.; CEPHALON, INC.; ACTAVIS PHARMA, INC.; ALLERGAN FINANCE, LLC (fka ACTAVIS, INC. fka WATSON PHARMACEUTICALS, INC.); WATSON LABORATORIES, INC.;

Case No.: A-19-796755-B
Dept. No.: XI

SECOND AMENDED COMPLAINT

REQUEST FOR BUSINESS COURT

EXEMPT FROM ARBITRATION

ACTAVIS, LLC; PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; PURDUE HOLDINGS, L.P.; THE PURDUE FREDERICK COMPANY, INC.; P.F. LABORATORIES, INC.; RICHARD S. SACKLER; JONATHAN D. SACKLER, MORTIMER D.A. SACKLER; KATHE A. SACKLER; ILENE SACKLER LEFCOURT; DAVID A. SACKLER; BEVERLY SACKLER; THERESA SACKLER; PLP ASSOCIATES HOLDINGS L.P.; ROSEBAY MEDICAL COMPANY L.P.; BEACON COMPANY;; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; PAR PHARMACEUTICAL, INC.; MALLINCKRODT PLC; MALLINCKRODT LLC; SPECGX LLC; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; CVS TN DISTRIBUTION LLC; LONGS DRUG STORE CALIFORNIA LLC; AMERICAN DRUG STORES; STEVEN A. HOLPER; STEVEN A HOLPER MD PROFESSIONAL CORPORATION; HOLPER OUT-PATIENTS MEDICAL CENTER, LTD.; ROBERT GENE RAND; RAND FAMILY CARE LLC; DEVENDRA I. PATEL; PATEL NORTH EASTERN NEVADA CARDIOLOGY PC; HORACE PAUL GUERRA IV; ALEJANDRO JIMINEZ INCERA; ROBERT D. HARVEY; INCERA-IUVENTUS MEDICAL GROUP PC; INCERA LLC; DOE ENTITIES 1-10.

Defendants.

Plaintiff, the State of Nevada, by and through Aaron D. Ford, Attorney General, and the undersigned attorneys (the "State") brings this Complaint against Defendants McKesson Corporation; Cardinal Health, Inc.; Cardinal Health 105, Inc.; Cardinal Health 108, LLC; Cardinal Health 110, LLC; Cardinal Health 200, LLC; Cardinal Health 414, LLC; Cardinal Health Pharmacy Services, LLC; AmerisourceBergen Drug Corporation; Walgreens Boots Alliance, Inc.; Walgreen Co.; Walgreen Eastern Co., Inc.; Walmart Inc.; CVS Pharmacy, Inc.; Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries, Ltd.; Cephalon, Inc.; Actavis Pharma, Inc.; Allergan Finance, LLC (fka Actavis, Inc. fka Watson Pharmaceuticals, Inc.); Watson Laboratories, Inc.; Actavis, LLC; Purdue Pharma L.P.; Purdue Pharma Inc.; Purdue Holdings L.P.; The Purdue Frederick Company, Inc.; P.F. Laboratories, Inc.; Richard S. Sackler; Jonathan D. Sackler; Mortimer D.A. Sackler; Kathe A. Sackler; Ilene Sackler Lefcourt; David A. Sackler; Beverly Sackler; Theresa Sackler; PLP Associates Holdings L.P.; Rosebay Medical Company L.P.; Beacon Company; Doe Entities 1-10; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Mallinckrodt plc; Mallinckrodt LLC; SpecGx LLC; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Noramco, Inc.; CVS TN Distribution LLC; Longs Drug Store California LLC; American Drug Stores; Steven A. Holper; Steven A. Holper MD Professional Corporation; Holper Out-Patients Medical Center, Ltd.; Robert Gene Rand; Rand Family Care LLC; Devendra I. Patel; Patel North Eastern Nevada Cardiology PC; Horace Paul Guerra IV; Alejandro Jiminez Incera; Robert D. Harvey; Incera-Iuventus Medical Group PC; Incera LLC (collectively "Defendants") and alleges, upon information and belief, as follows:

I. INTRODUCTION

1. The State of Nevada, by and through Aaron Ford, Attorney General for the State of Nevada, and Ernest Figueroa, Consumer Advocate, files this Complaint on behalf of the State to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance in this State, and to recover civil fines arising out of Defendants' false, deceptive

and unfair marketing and/or unlawful diversion of prescription opioids (hereinafter "opioids").[1] Such economic damages were foreseeable to Defendants and were sustained because of Defendants' negligent intentional and/or unlawful actions and omissions.

2. The State asserts two categories of claims: (1) claims against the pharmaceutical manufacturers of prescription opioid drugs and their consultants that engaged in a massive false marketing campaign to drastically expand the market for such drugs and their own market share and (2) claims against entities in the supply chain that reaped enormous financial rewards by refusing to monitor and restrict the improper distribution of those drugs.

3. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[2]

4. The Centers for Disease Control ("CDC") recently estimated that prescription opioid misuse costs the United States $78.5 billion per year, taking into account healthcare expenses, lost productivity, addiction treatment, and criminal justice involvement.[3] In 2015, over 33,000 Americans died as a result of opioid overdose, while an estimated 2 million people in the United States suffered from substance abuse disorders relating to prescription opioids.[4]

5. This case arises from the worst man-made epidemic in modern medical history— the misuse, abuse, diversion, and over-prescription of opioids. Nevada has been greatly impacted by this opioid crisis. By 2016, Defendants had flooded the State with enough opioid prescriptions for 87 out of every 100 Nevadans and Nevadan overdoses well exceeded the national average for opioid deaths.[5] The impact of Defendants' scheme to misinform and deceptively promote the use of opioids is evident in the numerous instances of overprescribing

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[1] As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

[2] *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

[3] *See* Curtis S. Florence, et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States*, 2013, 54 Medical Care 901 (2016).

[4] *See* Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 Morbidity & Mortality Wkly. Rep. 1445 (2016); Substance Abuse and Mental Health Servs. Admin., U.S. Dep't of Health and Human Servs., *National Survey on Drug Use and Health, 2015 Detailed Tables* (2016).

[5] Nev. Div. of Pub. and Behavioral Health, *The Scope of Opioid Use in Nevada*, 2016, NEV. DIV. OF PUB. AND BEHAVIORAL HEALTH (DPBH), 1 (Oct. 18, 2017), http://dpbh.nv.gov/uploadedFiles/dpbhnvgov/content/Resources/opioids/Opioid%20Infographic.pdf.

in Nevada communities; for example, Dr. Robert Rand, Reno's notorious "Pill Mill" case, Dr. Steven Holper in Clark County who has been indicted for prescribing excess quantities of opioids to his patients, and Lam's Pharmacy, the Las Vegas top five seller of OxyContin in the nation.

6. The opioid crisis is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[6]

7. Opioids are regulated as Schedule II controlled substances under both Nevada and federal law. *See* NAC § 435.520(a).[7] Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. *See* NAC, §§ 435.510 to 435.550. The Nevada Controlled Substances Act imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally are categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

8. Opioids, as discussed in this Complaint, include prescription opioids in all forms, including in cocktail drugs wherein an opioid formulation is blended with another medication if such cocktail drugs are considered as part of the Defendants' suspicious order monitoring evaluations.

9. ***Hydrocodone*** is the most frequently prescribed opioid in the United States and is associated with more drug abuse and diversion than any other licit or illicit opioid. Its street

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[6] *See* Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

[7] The Nevada Controlled Substances Act and Administrative Code incorporate by reference relevant federal laws and regulations. NAC 435.100, 435.140, 435.150, 639.426, 639.266, 639.295. References made to the federal Controlled Substances Act, 21 USC § 801 et seq. ("CSA") are for reference only and to state the duty owed under Nevada tort law, *not* to allege an independent federal cause of action and *not* to allege any substantial federal question. *See* Section III, *infra*.

names include Hydro, Norco, and Vikes. It is an orally active agent most frequently prescribed for the treatment of moderate to moderately severe pain. There are numerous brand and generic hydrocodone products marketed in the United States. The most frequently prescribed combination is hydrocodone and acetaminophen (for example, Vicodin®, Lorcet®, and Lortab®). Other examples of combination products include those containing aspirin (Lortab ASA®), ibuprofen (Vicoprofen®) and antihistamines (Hycomine®). Most often these drugs are abused by oral rather than intravenous administration.[8]

10. ***Oxycodone*** is a semi-synthetic narcotic analgesic and historically has been a popular drug of abuse among the narcotic abusing population. Its street names include Hillbilly Heroin, Kicker, OC, Ox, Oxy, Perc, and Roxy. Oxycodone is marketed alone as OxyContin® in 10, 20, 40 and 80 mg controlled-release tablets and other immediate-release capsules like 5 mg OxyIR®. It is also marketed in combination products with aspirin such as Percodan® or acetaminophen such as Roxicet®. Oxycodone is abused orally or intravenously. The tablets are crushed and sniffed or dissolved in water and injected. Some abusers place a tablet on foil, heat it and then inhale the vapors.[9]

11. By now, most Americans have been affected, either directly or indirectly, by the opioid disaster. But few realize that this crisis arose from the opioid manufacturers' deliberately deceptive marketing strategy to expand opioid use, together with the distributors' equally deliberate efforts to evade restrictions on opioid distribution. Manufacturers and distributors alike acted without regard for the lives that would be trammeled in pursuit of profit.

12. From 1999 through 2016, overdoses killed more than 350,000 Americans.[10] Over 200,000 of them, more than were killed in the Vietnam War, died from opioids prescribed by doctors to treat pain.[11] These opioids include brand-name prescription medications such as

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[8] *See* Drug Enf't Admin., *Drug Fact Sheet: Hydrocodone* (n.d.), https://www.dea.gov/druginfo/drug_data_sheets/Hydrocodone.pdf.
[9] *See* Drug Enf't Admin., *Drug Fact Sheet: Oxycodone* (n.d.), https://www.dea.gov/druginfo/drug_data_sheets/Oxycodone.pdf.
[10] *Understanding the Epidemic*, Ctrs. for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Aug. 30, 2017).
[11] *Prescription Opioid Overdose Data*, Ctrs. for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/data/overdose.html (last updated Aug. 1, 2017).

OxyContin, Opana ER, Vicodin, Subsys, and Duragesic, as well as generics like oxycodone, hydrocodone, and fentanyl.

13. Most of the overdoses from non-prescription opioids are also directly related to prescription pills. Many opioid users, having become addicted to but no longer able to obtain prescription opioids, have turned to heroin. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade started with prescription opioids—which, at the molecular level and in their effect, closely resemble heroin. In fact, people who are addicted to prescription opioids are 40 times more likely than people not addicted to prescription opioids to become addicted to heroin, and the Centers for Disease Control and Prevention ("CDC") identified addiction to prescription opioids as the strongest risk factor for heroin addiction.[12]

14. As a result, in part, of the proliferation of opioid pharmaceuticals between the late 1990s and 2015, the life expectancy for Americans decreased for the first time in recorded history. Drug overdoses are now the leading cause of death for Americans under 50.

15. Meanwhile, the Defendants made blockbuster profits. In 2012 alone, opioids generated $8 billion in revenue for drug companies. By 2015, sales of opioids grew to approximately $9.6 billion.

16. The State brings this suit against the manufacturers of these highly addictive drugs. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids, turning patients into drug addicts for their own corporate profit. Such actions were intentional and/or unlawful.

17. The State also brings this suit against the wholesale distributors of these highly addictive drugs, who breached their legal duties under *inter alia* the Nevada Controlled

[12] *Today's Heroin Epidemic*, "Overdose Prevention" tab, Ctrs. for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/opioids/heroin.html (last updated Aug. 29, 2017); *see also Today's Heroin Epidemic*, Ctrs. for Disease Control and Prevention https://www.cdc.gov/vitalsigns/heroin/index.html (last updated July 7, 2015).

Substances Act, Nev. Rev. Stat., §§ 453.005 to 453.730 and the Nev. Admin. Code, §§ 639.010 to 639.978, to monitor, detect, investigate, refuse, and report suspicious orders of prescription opiates. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers, distributors, and pharmacies who failed to maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls. Defendants have contributed substantially to the opioid crisis by knowingly selling and distributing far greater quantities of prescription opioids than could be necessary for legitimate medical uses, while failing to report or to take steps to halt suspicious orders when they were identified or should have been identified, thereby contributing to the oversupply of such drugs and fueling an illegal secondary market.

18. Defendants' conduct has exacted, and foreseeably so, a financial burden on the State of Nevada. Categories of damages sustained by the State include, but are not limited to, Medicaid funds paid out as a result of Defendants' wrongful conduct within the State of Nevada and the prospective damages associated with abating the nuisance created by the Defendants, as well as fines attributable to Defendants' violations of Nevada laws.

19. The State brings this action exclusively under the law of the State of Nevada. No federal claims are being asserted, and to the extent that any claim or factual assertion set forth herein may be construed to have stated any claim for relief arising under federal law, such claim is expressly and undeniably disavowed and disclaimed by the State.

20. In addition, notwithstanding anything to the contrary, under no circumstance is the State bringing this action against, or bringing an action or claim of any kind directed to, any federal officer or person acting under any office of the United States for or relating to any act under color of such office; nothing in this Complaint raises such an action, and to the extent that anything in the Complaint could be interpreted as potentially bringing an action against or directed to any federal officer or person acting under any office of the United States for or relating to any act under color of such office, then all such claims, actions, or liability, in law or in equity, are denied and disavowed in their entirety. Specifically, and without limitation, nothing in the State's Complaint seeks to bind the McKesson Corporation, or any other

Defendant, in law or in equity, or to otherwise impose any liability or injunction, related to any United States government contract, including without limitation any Pharmaceutical Prime Vendor (PPV) contract that the McKesson Corporation (or any affiliated entity) or any other Defendant has or had with the United States Veterans Administration. Specifically, and without limitation, nothing in this Complaint challenges in any way, in law or in equity or otherwise, actions of McKesson pursuant to a contract it has or ever had with the United States Veterans Administration.

21. Nor does the State bring this action on behalf of a class or any group of persons that can be construed as a class. The claims asserted herein are brought solely by the State and are wholly independent of any claims that individual users of opioids may have against Defendants.

II. PARTIES

A. Plaintiff

22. The State of Nevada is a body politic created by the Constitution and laws of the State; as such, it is not a citizen of any state. This action is brought by the State in its sovereign capacity in order to protect the interests of the State of Nevada and its residents as *parens patriae*, by and through Aaron D. Ford, the Attorney General of the State of Nevada. Attorney General Ford is acting pursuant to his authority under, *inter alia*, NRS 228.310, 338.380, 228.390, and 598.0963(3).

B. Defendants

23. Plaintiff is informed and believes, and based thereupon alleges, that at all relevant times, each Defendant has occupied agency, employment, joint venture, or other relationships with each of the other named Defendants; that at all times herein mentioned each Defendant has acted within the course and scope of said agency, employment, joint venture, and/or other relationship; that each other Defendant has ratified, consented to, and approved the

acts of its agents, employees, joint venturers, and representatives; and that each has actively participated in, aided and abetted, or assisted one another in the commission of the wrongdoing alleged in this Complaint.

24. At all relevant times Defendants, together and independently, have engaged in the business of, or were successors in interest to, entities engaged in the business of researching, licensing, designing, formulating, developing, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, distributing, and/or selling the prescription opioid drugs to individuals and entities in the State of Nevada.

25. At all relevant times, Defendants have sold and supplied opioid prescription drugs to individuals and entities located within every county of the State of Nevada.

1. Manufacturer Defendants

26. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs.

a. Teva/Allegan Entities

27. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009. Teva USA is a wholly-owned subsidiary of Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation regularly engaged in business in the United States of America and the state of Nevada.

28. Defendant Cephalon, Inc., is a Delaware corporation with its principal place of business located in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

29. Defendant Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) is registered to do business with the Nevada Secretary of State as a Delaware corporation with its principal place of business in Parsippany-Troy Hills, New Jersey. Actavis Pharma, Inc. was previously responsible for sales of Kadian and Norco. Actavis Pharma, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

30. Defendant Allergan Finance, LLC (fka Actavis, Inc., fka Watson Pharmaceuticals, Inc.) is a limited liability company incorporated in Nevada and headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly-owned subsidiary of Allergan plc. In 2008, Actavis, Inc. (nka Allergan Finance, LLC), acquired the opioid Kadian through its subsidiary, Actavis Elizabeth LLC, which had been the contract manufacturer of Kadian since 2005. Since 2008, Kadian's label has identified the following entities as the manufacturer or distributor of Kadian: Actavis Elizabeth LLC, Actavis Kadian LLC, Actavis Pharma, Inc., and Allergan USA, Inc. Currently, Allergan USA, Inc. is contracted with UPS SCS, Inc. to distribute Kadian on its behalf.

31. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California. Watson Laboratories, Inc. was sold to Teva Pharmaceutical Industries Ltd. As part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Watson Laboratories, Inc. was a direct subsidiary of Actavis, Inc. (nka Allergan Finance, LLC). Between 2000 and 2015, Watson Laboratories, Inc. held the ANDAs for Norco and was the manufacturer of the drug. Watson Laboratories, Inc. was also the ANDA holder of various generic opioids.

32. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

33. Teva USA, Teva Ltd. and Actavis Pharma, Inc., together with their DEA and Nevada registrant and licensee subsidiaries and affiliates (collectively, "Teva"), work together to manufacture, promote, distribute and sell brand name and generic versions (including Kadian, Duragesic, and Opana) of opioids nationally, and in Nevada, including the following:

Product Name	Chemical Name
Actiq	Fentanyl citrate
Fentora	Fentanyl buccal
Kadian	Morphine sulfate, extended release
Norco	Hydrocodone bitartrate and acetaminophen

34. From 2000 forward, Teva, directly and through its named and unnamed subsidiaries and/or agents, has made thousands of payments to physicians nationwide, many of whom were not oncologists and did not treat cancer pain, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services. In fact, these payments were made to deceptively promote and maximize the use of opioids.

b. Purdue Entities and the Sackler Defendants

35. Defendant Purdue Pharma L.P. ("PPL") is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut and is registered with the Nevada Secretary of State to do business in Nevada.

36. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business in Stamford, Connecticut.

37. Defendant Purdue Holdings L.P. ("PHL") is a Delaware limited partnership and wholly owns the limited partnership interest in Purdue Pharma L.P.

38. Defendant The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business in Stamford, Connecticut.

39. Defendant P.F. Laboratories, Inc. ("PF Labs") is a New Jersey corporation with its principal place of business in Totowa, New Jersey.

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40. PPL, PPI, PHL, PFC, and PF Labs, together with their Drug Enforcement Administration ("DEA") and Nevada registrant and licensee subsidiaries and affiliates (collectively, "Purdue"), are engaged in the manufacture, promotion, distribution, and sale of opioids nationally, and in Nevada, including the following:

Product Name	**Chemical Name**
OxyContin	Oxycodone hydrochloride, extended release
MS Contin	Morphine sulfate, extended release
Dilaudid	Hydromorphone hydrochloride
Dilaudid-HP	Hydromorphone hydrochloride
Butrans	Buprenorphine
Hysingla ER	Hydrocodone bitrate
Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride

41. Purdue made thousands of payments to physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services. In fact, these payments were made to deceptively promote and maximize the use of opioids.

42. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $3.1 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers). Sales of OxyContin (launched in 1996) went from a mere $49 million in its first full year on the market to $1.6 billion in 2002.

43. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay a $635 million fine – at the time, one of the largest settlements with a drug company for marketing misconduct. None of this stopped Purdue. In fact, even after getting caught, Purdue continued to create the false perception that opioids were safe and

effective for long-term use by using unbranded marketing methods to circumvent the system. On May 8, 2007, as part of these settlements, Purdue entered into a consent judgment with the State of Nevada, in which it agreed to a number of terms intended to prevent any further misleading marketing in the State of Nevada. In short, Purdue paid the fine when caught and then continued business as usual, deceptively marketing and selling billions of dollars of opioids each year.

44. At all relevant times, Purdue, which is a collection of private companies, has been controlled by members of the extended Sackler family, who are the ultimate intended beneficiaries of virtually all of Purdue's profit distributions. The individual Defendants named in this action are the remaining living Sackler family members who served on the board of Purdue Pharma, Inc. (the "Purdue board"), which functioned as the nexus of decision-making for all of Purdue.

45. Defendant 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. He resides in New York, Florida, and Texas. He currently holds an active license to practice medicine issued by the New York State Education Department. He is a trustee of the Sackler School of Medicine, a director and the vice president of the Raymond and Beverly Sackler Foundation, and a director and the president and treasurer of the Richard and Beth Sackler Foundation, Inc., all three of which are New York Not-for-Profit Corporations.

46. Defendant Jonathan D. Sackler was a member of Purdue's board from 1990 through 2018. He resides in Connecticut. He is a trustee of the Sackler School of Medicine, the president and CEO of the Raymond and Beverly Sackler Foundation, and the vice president of the Richard and Beth Sackler Foundation Inc., all three of which are New York Not-for-Profit Corporations.

47. Defendant Mortimer D.A. Sackler has been a member of Purdue's Board since 1993. He resides in New York. Mortimer is a director and the president of the Mortimer and Jacqueline Sackler Foundation, and a director and the vice president and treasurer of the Mortimer D. Sackler Foundation, Inc., both of which are New York Not-for-Profit Corporations.

48. Defendant Kathe A. Sackler was a member of Purdue's board from 1990 through 2018. She resides in New York and Connecticut. Kathe is a director and president of the Shack Sackler Foundation, a director and vice president and secretary of the Mortimer D. Sackler Foundation Inc. and is a governor of the New York Academy of Sciences, all three of which are New York Not-for-Profit Corporations.

49. Defendant Ilene Sackler Lefcourt was a member of Purdue's board between 1990 and 2018. She resides in New York. She is a director of Columbia University and is the president of the Sackler Lefcourt Center for Child Development Inc., both of which are New York Not-for-Profit Corporations.

50. Defendant David A. Sackler was a member of Purdue's board from 2012 through 2018. He resides in New York.

51. Defendant Beverly Sackler was a member of Purdue's board from 1993 through 2017. She resides in Connecticut. Beverly Sackler serves as a Director and the Secretary and Treasurer of the Raymond and Beverly Sackler Foundation, a New York Not-for-Profit Corporation.

52. Defendant Theresa Sackler was a member of Purdue's board from 1993 through 2018. She resides in New York and the United Kingdom.

53. These individual Defendants used a number of known and unknown entities named as Defendants herein as vehicles to transfer funds from Purdue directly or indirectly to themselves. These include the following:

54. Defendant PLP Associates Holdings L.P., is a Delaware limited partnership and a limited partner of Purdue Holdings L.P. Its partners are PLP Associates Holdings Inc. and BR Holdings Associates L.P.

55. Defendant Rosebay Medical Company L.P., is a Delaware limited partnership ultimately owned by trusts for the benefit of one or more of the individual Defendants. Its general partner is Rosebay Medical Company, Inc., a citizen of Delaware and Connecticut. The Board of Directors of Rosebay Medical Company, Inc. includes board members Richard S. Sackler and Jonathan D. Sackler.

56. Defendant Beacon Company, is a Delaware general partnership ultimately owned by trusts for the benefit of members of one or more of the individual Defendants.

57. Defendant Doe Entities 1-10, are unknown trusts, partnerships, companies, and/or other legal entities, which are ultimately owned and/or controlled by, and the identities of which are particularly within the knowledge of, one or more of the individual Defendants.

58. The foregoing individual Defendants are referred to collectively as "the Sacklers." The foregoing entities used the Sacklers as vehicles to transfer funds from Purdue directly or indirectly to themselves are referred to as "the Sackler Entities." Together, the Sacklers and the Sackler Entities are referred to collectively as "the Sackler Defendants."

c. Endo Entities

59. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

60. Defendant Endo Pharmaceuticals, Inc. ("EPI") is a wholly-owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

61. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical Companies, Inc. (and by extension its subsidiary, Par Pharmaceutical, Inc.,) (collectively, "Par Pharmaceutical") was acquired by Endo International plc in September 2015 and is currently an operating company of Endo International plc.

62. EHS, EPI, and Par Pharmaceutical, and their DEA registrant subsidiaries and affiliates, (collectively, "Endo"), manufacture opioids sold nationally, and in Nevada. Among the drugs Endo manufactures or manufactured are the following:

Product Name	**Chemical Name**
Opana ER	Oxymorphone hydrochloride, extended release
Opana	Oxymorphone hydrochloride
Percodan	Oxymorphone hydrochloride and aspirin
Percocet	Oxymorphone hydrochloride and acetaminophen
Generic	Oxycodone
Generic	Oxymorphone
Generic	Hydromorphone
Generic	Hydrocodone

63. Endo made thousands of payments to physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services. In fact, these payments were made to deceptively promote and maximize the use of opioids.

64. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012, accounting for over 10% of Endo's total revenue; Opana ER yielded revenue of $1.15 billion from 2010 to 2013. Endo also manufactures and sells generic opioids, in the United States and Nevada, both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

65. The Food and Drug Administration requested that Endo remove Opana ER from the market in June 2017. The FDA relied on post-marketing data on the risk of abuse in concluding Opana ER should be pulled from the market.

d. SpecGX and Mallinckrodt Entities

66. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 with the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri.

67. Defendant Mallinckrodt LLC is a limited liability company organized and existing under the laws of the State of Delaware.

68. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri, and is registered with the Nevada Secretary of State to do business in Nevada.

69. Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC, together with their DEA and Nevada registrant and licensee subsidiaries and affiliates (collectively, "Mallinckrodt"), manufacture, market, sell, and distribute pharmaceutical drugs throughout the United States, and in Nevada. Based on prescriptions, Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States.

70. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. Exalgo was approved for the treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

71. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers with mail-order pharmacies, and hospital buying groups.

72. Among the drugs Mallinckrodt manufactures or has manufactured are the following:

Product Name	**Chemical Name**
Exalgo	Hydromorphone hydrochloride, extended release
Roxicodone	Oxycodone hydrochloride
Xartemis XR	Oxycodone hydrochloride and acetaminophen
Methadose	Methadone hydrochloride

Product Name	Chemical Name
Generic	Morphine sulfate, extended release
Generic	Morphine sulfate oral solution
Generic	Fentanyl transdermal system
Generic	Oral transmucosal fentanyl citrate
Generic	Oxycodone and acetaminophen
Generic	Hydrocodone bitartrate and acetaminophen
Generic	Hydromorphone hydrochloride
Generic	Hydromorphone hydrochloride, extended release
Generic	Naltrexone hydrochloride
Generic	Oxymorphone hydrochloride
Generic	Methadone hydrochloride
Generic	Oxycodone hydrochloride
Generic	Buprenorphine and naloxone

73. Mallinckrodt made thousands of payments to physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services. In fact, these payments were made to deceptively promote and maximize the use of opioids.

e. Johnson & Johnson Entities

74. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

75. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly-owned subsidiary of Johnson & Johnson. Johnson & Johnson corresponds with the Food and Drug Administration ("FDA") regarding Janssen Pharmaceuticals, Inc.'s products. Janssen Pharmaceuticals, Inc.

was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutical, Inc.

76. Defendant Noramco, Inc. is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of Johnson & Johnson and its manufacturer of active pharmaceutical ingredients until July 2016 when Johnson & Johnson sold its interests to SK Capital.

77. Johnson & Johnson, Janssen Pharmaceuticals, Inc., and Noramco, Inc., together with their DEA and Nevada registrant and licensee subsidiaries and affiliates (collectively, "J&J"), are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally, and in the State of Nevada. Among the drugs Johnson & Johnson manufactures or manufactured are the following:

Product Name	**Chemical Name**
Duragesic	Fentanyl
Nucynta[13]	Tapentadol hydrochloride, immediate release
Nucynta ER	Tapentadol hydrochloride, extended release

78. Janssen, like many other companies, has a corporate code of conduct, which clarifies the organization's mission, values, and principles. Janssen's employees are required to read, understand, and follow its Code of Conduct for Health Care Compliance. Johnson & Johnson imposes this code of conduct on Janssen as a pharmaceutical subsidiary of Johnson & Johnson. Documents posted on Johnson & Johnson's and Janssen's websites confirm Johnson & Johnson's control of the development and marketing of opioids by Janssen. The "Ethical Code for the Conduct of Research and Development" posted on the Janssen website is Johnson

[13] Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

& Johnson's company-wide Ethical Code, which it requires all of its subsidiaries, including Janssen, to follow.

79. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a Johnson & Johnson company-wide code that describes Janssen as one of the "Pharmaceutical Companies of Johnson & Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees and sales associates must certify that they have "read, understood and will abide by" the Code of Conduct. Johnson & Johnson's Code of Conduct governs all of the forms of marketing at issue in this case.

80. Johnson & Johnson made thousands of payments to physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services. In fact, these payments were made to deceptively promote and maximize the use of opioids. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014 alone. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

81. Johnson & Johnson made payments to prescribing physicians. At least one prescriber who previously served on Janssen's speaker's bureau received payment, ostensibly for speaking fees, meals, and travel from Johnson & Johnson. Upon information and belief, Johnson & Johnson would have similarly made payments to other prescribers in Janssen's speaker's bureau. Information from the U.S. Department of Justice's Office of the Inspector General shows that Johnson & Johnson made payments to prescribers, but does not indicate which drug was being promoted.

2. Distributor Defendants

82. The Distributor Defendants are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription drug opioids, without fulfilling their fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The State alleges that the unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing the State and that the negligence of those Distributor Defendants caused catastrophic harm to the state of Nevada and its residents.[14]

a. McKesson Corporation

83. Defendant McKesson Corporation is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson Corporation, together with and through its DEA and Nevada registrant and licensee subsidiaries and affiliates (collectively, "McKesson"), is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Nevada. McKesson operated as a licensed pharmacy wholesaler in the State of Nevada and is and was at all relevant times registered with the Nevada Secretary of State as a Delaware corporation with its principal office located in San Francisco, California.

84. In January 2017, McKesson paid a record $150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan and Colorado. The DOJ described these "staged suspensions" as "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."

[14] Although addressed in Section 1(e), Defendant Mallinckrodt LLC and related entities are direct distributors of drugs relevant to this action in the state of Nevada and should be considered both a manufacturer defendant as well as distributor defendant.

b. Cardinal Health Entities

85. Defendant Cardinal Health, Inc. and its subsidiaries Cardinal Health 105, Inc., Cardinal Health 108, LLC, Cardinal Health 110, LLC, Cardinal Health 200, LLC, Cardinal Health 414, LLC, and Cardinal Health Pharmacy Services, LLC operated as licensed pharmacy wholesalers in the State of Nevada and will be referred to collectively herein as "Cardinal Health."

86. Defendant Cardinal Health, Inc. is an Ohio corporation with its principal place of business in Dublin, Ohio. Cardinal Health, Inc. describes itself as a "global, integrated health care services and products company," and is the fifteenth largest company by revenue in the U.S., with annual revenue of $121 billion in 2016. Based on Defendant Cardinal Health's own estimates, one out of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

87. Defendant Cardinal Health 105, Inc. d/b/a Xiromed, LLC is an Ohio corporation with its principal place of business in Dublin, Ohio.

88. Defendant Cardinal Health 108, LLC f/k/a Cardinal Health 108, Inc. is and was at all relevant times registered to do business with the Nevada Secretary of State as a Delaware limited liability company with its principal place of business in Tennessee.

89. Defendant Cardinal Health 110, LLC d/b/a ParMed Pharmaceuticals is and was at all relevant times registered to do business with the Nevada Secretary of State as a Delaware limited liability company with its principal place of business in Dublin, Ohio.

90. Defendant Cardinal Health 200, LLC is and was at all relevant times registered to do business with the Nevada Secretary of State as a Delaware limited liability company with its principal place of business in Waukegan, Illinois.

91. Defendant Cardinal Health 414, LLC is and was at all relevant times registered to do business with the Nevada Secretary of State as a Delaware limited liability company with its principal place of business in Dublin, Ohio.

92. Defendant Cardinal Health Pharmacy Services, LLC is and was at all relevant times registered to do business with the Nevada Secretary of State as a Delaware limited liability company with its principal place of business in Houston, Texas.

c. AmerisourceBergen Drug Corporation

93. Defendant AmerisourceBergen Drug Corporation, together with and through its DEA and Nevada registrant and licensee subsidiaries and affiliates (collectively, "AmerisourceBergen"), is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Nevada. AmerisourceBergen, at all relevant times, operated as a licensed pharmacy wholesaler in the State of Nevada and is and was registered to do business with the Nevada Secretary of State as a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of $147 billion in 2016.

3. Distributor and National Retail Pharmacy Defendants

a. Walgreens Entities

94. Defendant Walgreens Boots Alliance, Inc. is a Delaware corporation with its principal place of business in Illinois.

95. Defendant Walgreen Co. is and was registered to do business with the Nevada Secretary of State as an Illinois company with its principal place of business in Deerfield, Illinois. Walgreen Co. is a subsidiary of Walgreens Boots Alliance, Inc. and does business under the trade name Walgreens.

96. Defendant Walgreen Eastern Co., Inc. is a New York corporation with its principal place of business in Deerfield, Illinois.

97. Defendants Walgreens Boots Alliance, Inc., Walgreen Eastern Co., and Walgreen Co. are collectively referred to as "Walgreens." Walgreens, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Walgreens distributed prescription opioids

throughout the United States, including in Nevada. At all relevant times, this Defendant operated as a licensed pharmacy wholesaler in the State of Nevada.

b. Walmart Entities

98. Defendant Walmart Inc., ("Walmart") formerly known as Wal-Mart Stores, Inc., is and was registered to do business with the Nevada Secretary of State as a Delaware corporation with its principal place of business in Arkansas. Walmart, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor under named business entities including Wal-Mart Warehouse #6045 a/k/a Wal-Mart Warehouse #45. At all times relevant to this Complaint, Walmart distributed prescription opioids throughout the United States, including in Nevada. At all relevant times, this Defendant operated as a licensed pharmacy wholesaler in the State of Nevada.

c. CVS Entities

99. Defendant CVS Pharmacy, Inc. ("CVS Pharmacy") is a Rhode Island corporation with its principal place of business in Woonsocket, Rhode Island. CVS Pharmacy is the primary wholly owned subsidiary of the parent corporation, CVS Health Corporation. CVS Pharmacy is both a registered "distributor" and a registered "dispenser" of prescription opioids and cocktail drugs and is registered to do business in Nevada. CVS Pharmacy is a national retail chain pharmacy and controlled substance distributor to its own CVS pharmacies nationwide. It owns, designs, operates, and implements most aspects of marketing, sales, decision making, policies, procedures, directives, contracting, receipt, distribution, dispensing, legal compliance and monitoring of controlled substances delivered to, sold, and consumed in the state of Nevada, including but not limited to opioids and cocktail drugs, deriving revenue from controlled substances delivered to, sold, and consumed within the State of Nevada and nationwide. CVS Pharmacy owns, operates, and pays for licensure of all the CVS pharmacies nationwide including those located in Nevada and directly employs most of the personnel involved with all of the above referenced endeavors and activities.

100. CVS Pharmacy's La Habra, CA and Ennis, TX distribution centers both participated directly and indirectly in supplying and monitoring controlled substances, including opioids and cocktail drugs into the state of Nevada for dispensing at CVS pharmacies located in Nevada to derive revenue within and from the State of Nevada for CVS Pharmacy and ultimately the parent company, CVS Health Corporation.

101. CVS TN Distribution, LLC is a Tennessee corporation with its principal place of business in Knoxville, TN, and DEA registrant and licensee of CVS's controlled substance distribution center located in Knoxville, TN. The CVS distribution center in Knoxville, TN has participated directly and indirectly in supplying and monitoring controlled substances, including opioids and cocktail drugs into the state of Nevada for dispensing at CVS pharmacies located in Nevada to derive revenue within and from the State of Nevada for CVS Pharmacy and ultimately the parent company, CVS Health Corporation.

102. Longs Drug Store California LLC aka Longs Drug Stores is a California LLC headquartered in Rhode Island. Longs Drug Stores were acquired, in their entirety, by CVS Health Corporation in 2008, and remains an active Nevada LLC. Additionally, Longs Drug Stores is a licensed drug wholesaler in Nevada. Longs Drug Stores is a CVS controlled distribution center that has participated directly and indirectly in supplying and monitoring controlled substances, including opioid and cocktail drugs delivered into the State of Nevada for dispensing at CVS pharmacies located in Nevada to derive revenue within and from the State of Nevada for CVS Pharmacy and ultimately the parent company, CVS Health Corporation.

103. American Drug Stores LLC is a Delaware LLC headquartered in Boise, ID. American Drug Stores were purchased by CVS in 2006 and rebranded to CVS in 2007. American Drug Stores are believed to have been a DEA registered distributor of controlled substances, including opioids and cocktail drugs, that distributed into the State of Nevada for dispensing at CVS pharmacies within the State of Nevada to derive revenue within and from the State for CVS Pharmacy and ultimately the parent company, CVS Health Corporation.

104. CVS Pharmacy, Inc., CVS TN Distribution, LLC, Longs Drug Store LLC aka Longs Drug Stores, and American Drug Stores are referred to collectively herein as "CVS." CVS conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, CVS distributed prescription opioids throughout the United States, including in Nevada.

4. Health Care Provider Defendants

105. The Health Care Provider Defendants are defined below. At all relevant times, the Health Care Provider Defendants played an integral role in the chain of opioids being sold and distributed throughout the State of Nevada. The State alleges that the unlawful conduct by the Health Care Provider Defendants is a substantial cause for the volume of prescription opioids plaguing the State and that the actions of those Health Care Provider Defendants caused catastrophic harm to the state of Nevada and its residents.

a. Holper Defendants

106. Defendant Steven A. Holper is, and was at all times relevant herein, a resident of Clark County, Nevada, and was a licensed medical doctor in the State of Nevada. Upon information and belief, and at all times relevant hereto, Defendant Steven A. Holper conducted business and provided medical services as Defendant Steven A. Holper MD Professional Corporation, a Nevada Domestic Professional Corporation in Clark County, Nevada. Defendant Holper Out-Patients Medical Center, Ltd. (collectively, with Steven A. Holper and Steven A. Holper M.D., PC, "Holper Defendants"), is, and was at all times relevant herein, a Nevada Domestic Corporation with its principal place of business in Clark County, Nevada, and served as the location from which Defendant Steven A. Holper provided his medical services.

107. The Holper Defendants habitually prescribed and delivered highly addictive and potentially lethal opioid medications to patients in the State of Nevada who did not meet the qualifications for such medication.

108. The Holper Defendants participated in a deceptive scheme to obtain authorization for such prescriptions from health insurance providers.

109. On or about December 10, 2018, Defendant Steven A. Holper pleaded guilty to one count of distribution of a controlled substance.

b. Rand Defendants

110. Defendant Robert Gene Rand is, and was at all times relevant herein, a resident of Washoe County, Nevada and was a licensed medical doctor in the State of Nevada. Defendant Rand Family Care LLC (collectively, with Robert G. Rand, "Rand Defendants"), is, and was at all times relevant herein, a limited liability company organized and existing under the laws of the State of Nevada and served as the location from which Defendant Robert G. Rand provided his medical services.

111. The Rand Defendants habitually prescribed and delivered highly addictive and potentially lethal opioid medications to patients in the State of Nevada who did not meet the qualifications for such medication.

112. The Rand Defendants participated in a deceptive scheme to obtain authorization for such prescriptions from health insurance providers.

113. Defendant Robert G. Rand pleaded guilty to involuntary manslaughter and distribution of a controlled substance.

c. Patel Defendants

114. Defendant Devendra I. Patel, a/k/a Devendrakumar I. Patel, is, and was at all times relevant herein, a resident of Elko County, Nevada and was a licensed medical doctor in the State of Nevada. Defendant Patel North Eastern Nevada Cardiology PC (collectively, with Devendra I. Patel, "Patel Defendants"), is, and was at all times relevant herein, a Nevada

Domestic Professional Corporation in Elko County, Nevada, and served as the location from which Defendant Devendra I. Patel provided his medical services.

115. The Patel Defendants habitually prescribed and delivered highly addictive and potentially lethal opioid medications to patients in the State of Nevada who did not meet the qualifications for such medication.

116. The Patel Defendants participated in a deceptive scheme to obtain authorization for such prescriptions from health insurance providers.

117. On or about November 26, 2018, Defendant Devendra I. Patel pleaded guilty to distribution of a controlled substance.

d. Incera Defendants

118. Defendant Horace Paul Guerra IV is, and was at all times relevant herein, a resident of Clark County, Nevada and was a licensed medical doctor in the State of Nevada. Defendant Alejandro Jiminez Incera is, and was at all times relevant herein, a resident of Clark County, Nevada and was a licensed nurse practitioner in the State of Nevada. Defendant Robert D. Harvey is, and was at all times relevant herein, a resident of Clark County, Nevada, and was a surgical technician in the State of Nevada. Upon information and belief, and at all times relevant hereto, Defendant Horace Paul Guerra IV and Defendant Alejandro J. Incera conducted business and provided medical services as Defendant Incera-Iuventus Medical Group PC, a Nevada Domestic Professional Corporation in Clark County, Nevada. Defendant Incera LLC. (collectively, with Horace P. Guerra IV, Alejandro J. Incera, Robert D. Harvey, and Incera-Iuventus Medical Group PC, "Incera Defendants"), is, and was at all times relevant herein, a limited liability company organized and existing under the laws of the State of Nevada and served as the location from which Defendants Horace P. Guerra IV, Alejandro J. Incera, and Robert D. Harvey provided their medical services.

119. The Incera Defendants habitually prescribed and delivered highly addictive and potentially lethal opioid medications to patients in the State of Nevada who did not meet the qualifications for such medication.

120. The Incera Defendants participated in a deceptive scheme to obtain authorization for such prescriptions from health insurance providers.

121. On or about July 25, 2018, Defendant Horace P. Guerra IV pleaded guilty to one count of conspiracy to distribute a controlled substance. On or about October 2, 2018, Defendant Alejandro J. Incera pleaded guilty to eight counts of distribution of a controlled substance and eight counts of health care fraud, while Defendant Robert D. Harvey pleaded guilty to one count of conspiracy to distribute a controlled substance and three counts of distribution of a controlled substance.

C. Agency and Authority

122. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

III. JURISDICTION & VENUE

123. Subject matter jurisdiction for this case is conferred upon this Court pursuant to, inter alia, Article 6, Section 6 of the Nevada Constitution.

124. This Court has personal jurisdiction over Defendants because Defendants do business in Nevada and/or have the requisite minimum contacts with Nevada necessary to constitutionally permit the Court to exercise jurisdiction with such jurisdiction also within the contemplation of the Nevada "long arm" statute, NRS § 14.065.

125. The instant Complaint does not confer diversity jurisdiction upon the federal courts pursuant to 28 USC § 1332, as the State is not a citizen of any state and this action is not subject to the jurisdiction of the Class Action Fairness Act of 2005. Likewise, federal question subject matter jurisdiction pursuant to 28 USC § 1331 is not invoked by the Complaint, as it sets forth herein exclusively viable state law claims against Defendants. Nowhere herein does

Plaintiff plead, expressly or implicitly, any cause of action or request any remedy that arises under federal law. The issues presented in the allegations of this Complaint do not implicate any substantial federal issues and do not turn on the necessary interpretation of federal law. No federal issue is important to the federal system as a whole under the criteria set by the Supreme Court in *Gunn v. Minton*, 568 U.S. 251 (2013) (*e.g.*, federal tax collection seizures, federal government bonds). Specifically, the causes of action asserted, and the remedies sought herein, are founded upon the positive statutory, common, and decisional laws of Nevada. Further, the assertion of federal jurisdiction over the claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities. Accordingly, any exercise of federal jurisdiction is without basis in law or fact.

126. In this Complaint, Plaintiff cites federal statutes and regulations. Plaintiff does so to state the duty owed under Nevada tort law, *not* to allege an independent federal cause of action and *not* to allege any substantial federal question under *Gunn v. Minton.* "A claim for negligence in Nevada requires that the plaintiff satisfy four elements: (1) an existing duty of care, (2) breach, (3) legal causation, and (4) damages." *Turner v. Mandalay Sports Entertainment, LLC*, 124 Nev. 213, 180 P.3d 1172 (Nev. 2008). The element of duty is to be determined as a matter of law based on foreseeability of the injury. *Estate of Smith ex rel. Smith v. Mahoney's Silver Nugget, Inc*., 127 Nev. 855, 265 P.3d 688, 689 (Nev. 2011). To be clear, Plaintiff cites federal statutes and federal regulations for the sole purpose of stating the duty owed under Nevada law to the residents of Nevada. Thus, any attempted removal of this complaint based on a federal cause of action or substantial federal question is without merit.

127. Venue is proper in this Court pursuant to NRS § 598.0989(3) because Defendants' conduct alleged herein took place in Clark County, Nevada.

IV. FACTUAL ALLEGATIONS COMMON TO ALL CLAIMS[15]

A. Opioids and Their Effects

128. Opioids are a class of drugs that bind with opioid receptors in the brain and includes natural, synthetic, and semi-synthetic opioids. Natural opioids are derived from the opium poppy. Generally used to temporarily relieve pain, opioids block pain signals but do not treat the source of the pain. Opioids produce multiple effects on the human body, the most significant of which are analgesia, euphoria, and respiratory depression.

129. The medicinal properties of opioids have been recognized for millennia—as has their potential for abuse and addiction. The opium poppy contains various opium alkaloids, three of which are used in the pharmaceutical industry today: morphine, codeine, and thebaine. Early use of opium in Western medicine was with a tincture of opium and alcohol called laudanum, which contains all of the opium alkaloids and is still available by prescription today. Chemists first isolated the morphine and codeine alkaloids in the early 1800s.

130. In 1827, the pharmaceutical company Merck began large-scale production and commercial marketing of morphine. During the American Civil War, field medics commonly used morphine, laudanum, and opium pills to temporarily relieve the pain of the wounded, and many veterans were left with morphine addictions. By 1900, an estimated 300,000 people were addicted to opioids in the United States, and many doctors prescribed opioids solely to prevent their patients from suffering withdrawal symptoms. The nation's first Opium Commissioner, Hamilton Wright, remarked in 1911, "The habit has this nation in its grip to an astonishing extent. Our prisons and our hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and made them beasts who prey upon their fellows . . . it has become one of the most fertile causes of unhappiness and sin in the United States."[16]

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[15] The allegations in this Complaint are made upon facts, as well as upon information and belief. The State reserves the right to seek leave to amend or correct this Complaint based upon analysis of DEA data or other discovery, including, upon analysis of the ARCOS, IMS Health, and other date and upon further investigation and discovery.

[16] Nick Miroff, *From Teddy Roosevelt to Trump: How Drug Companies Triggered an Opioid Crisis a Century Ago*, The Wash. Post (Oct. 17, 2017),

131. Pharmaceutical companies tried to develop substitutes for opium and morphine that would provide the same analgesic effects without the addictive properties. In 1898, Bayer Pharmaceutical Company began marketing diacetylmorphine (obtained from acetylation of morphine) under the trade name "Heroin." Bayer advertised heroin as a non-addictive cough and cold remedy suitable for children, but as its addictive nature became clear, heroin distribution in the U.S. was limited to prescription only in 1914 and then banned altogether a decade later.

132. Although heroin and opium became classified as illicit drugs, there is little difference between them and prescription opioids. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.

133. Due to concerns about their addictive properties, prescription opioids have usually been regulated at the federal level as Schedule II controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970.

134. Throughout the twentieth century, pharmaceutical companies continued to develop prescription opioids like Percodan, Percocet, and Vicodin, but these opioids were generally produced in combination with other drugs, with relatively low opioid content.

135. In contrast, OxyContin, the product whose launch in 1996 ushered in the modern opioid epidemic, is pure oxycodone. Purdue initially made it available in the following strengths: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. The weakest OxyContin delivers as much narcotic as the strongest Percocet, and some OxyContin tablets delivered sixteen times that.

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https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-drug-fiends-in- the-world-an-american-opioid-crisis-in-1908/?utm_term=.7832633fd7ca.

136. Medical professionals describe the strength of various opioids in terms of morphine milligram equivalents ("MME"). According to the CDC, doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and one study found that patients who died of opioid overdose were prescribed an average of 98 MME/day.

137. Different opioids provide varying levels of MMEs. For example, just 33 mg of oxycodone provides 50 MME. Thus, at OxyContin's twice-daily dosing, the 50 MME/day threshold is nearly reached by a prescription of 15 mg twice daily. One 160 mg tablet of OxyContin, which Purdue took off the market in 2001, delivered 240 MME.

138. The wide variation in the MME strength of prescription opioids renders misleading any effort to capture "market share" by the number of pills or prescriptions attributed to Purdue or other manufacturers. Purdue, in particular, focuses its business on branded, highly potent pills, causing it to be responsible for a significant percent of the total amount of MME in circulation, even though it currently claims to have a small percentage of the market share in terms of pills or prescriptions.

139. Fentanyl is a synthetic opioid that is 100 times stronger than morphine and 50 times stronger than heroin. First developed in 1959, fentanyl is showing up more and more often in the market for opioids created by Manufacturer Defendants' promotion, with particularly lethal consequences.

140. The effects of opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" (also referred to as "breakthrough pain") and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours. Still other short-term opioids are designed to be taken in addition to long-acting opioids to specifically address breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer. The Manufacturer Defendants promoted the idea that pain should be treated

by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic or "breakthrough" pain.

141. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the "high." However, opioids depress respiration, and at very high doses can and often do arrest respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

142. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

143. As a leading pain specialist doctor put it, the widespread, long-term use of opioids "was a *de facto* experiment on the population of the United States. It wasn't randomized, it wasn't controlled, and no data was collected until they started gathering death statistics."

B. <u>J&J's Creation of Raw Materials for Use in Prescription Opioids</u>

144. From the 1990s through at least 2016, Defendant J&J wholly owned two subsidiaries that, together, supplied other opioid manufacturers with active pharmaceutical ingredients (APIs) to be used in opioid drugs. First, J&J owned a subsidiary based in Tasmania, Tasmanian Alkaloids Pty Limited ("Tasmanian Alkaloids"), which cultivated and processed opium poppy plants to manufacture narcotic raw materials that were imported into the U.S. to be processed and made into APIs necessary to manufacture opioid drugs. Second, J&J owned a subsidiary based in the U.S., Noramco, Inc. ("Noramco"), which imported the narcotic raw materials produced by Tasmanian Alkaloids, processed these materials into APIs then sold these APIs to other opioid manufacturers in the U.S

145. In approximately 2015, J&J elected to drop pain as a therapeutic area of focus for their business. Upon doing so, in 2016, J&J sold Nucynta and sold the Noramco/Tasmanian Alkaloids business and recorded the earnings for these transactions to have totaled approximately $1.65 billion to the company in its Form 10-Q filed with the U.S. Securities and Exchange Commission and signed by J&J's CEO, Alex Gorsky.

146. Up until 2016, Tasmanian Alkaloids and Noramco were sister companies, as both of them were members of J&J's family of companies. Upon information and belief, Tasmanian Alkaloids and Noramco shared employees and a central treasury with J&J. Both Tasmanian Alkaloids and Noramco were part of J&J's pain management franchise, which included all of J&J's pain products.

147. J&J, through its subsidiaries, supplied at least the following opioid APIs to other drug manufacturers in the U.S.: oxycodone, hydrocodone, morphine, codeine, fentanyl, sufentanil, buprenorphine, hydromorphone, and naloxone. J&J's "Noramco World Wide Narcotics Franchise," comprised of Noramco and Tasmanian Alkaloids, had become the top supplier of Narcotic APIs in the U.S., the world's largest market.

148. That is, through various subsidiaries and sister companies that comprised the pain management franchise, J&J was in the business of producing and selling all three (3) types of opioids: (i) natural opium (*e.g.*, codeine, morphine, thebaine); (ii) semisynthetics (*e.g.*, oxycodone and hydrocodone); and (iii) J&J's own branded synthetics (*e.g.* fentanyl, tramadol, and tapentadol).

149. J&J was aware that: (1) all Schedule II opioids have high abuse potential; (2) one Schedule II opioid pill can potentially lead to death; and (3) one Schedule II opioid patch can potentially lead to death. Despite this awareness, J&J, continued to manufacture its own opioid medications and supply the materials to other Defendant Manufacturers for their prescription opioids.

150. Under longstanding U.S. law, narcotic raw materials may only be imported into the U.S. from certain authorized countries, which include Australia. *See* 21 CFR § 1312.13(f)-

(g). Specifically, a DEA regulation, often called the "80/20 Rule," provides that narcotic raw materials may only be imported into the U.S. by: (i) two historically "traditional suppliers" of narcotic raw materials, India and Turkey, must be the source of at least 80 percent of the narcotic raw materials imported by the U.S.; while (ii) five "non-traditional supplier" countries-Australia, France, Hungary, Poland and Yugoslavia-may be the source of not more than 20 percent of the narcotic raw materials imported by the U.S. *See* 21 C.F.R. §1312.13(f)-(g).

151. DEA and other regulatory quotas on the amount of drugs that manufacturers may produce represent the "ceiling" or the maximum amount of a drug the manufacturer may produce. Drug manufacturers do not have to make all of the drugs in the quota to fulfill the maximum ceiling level. The supply of opioid drugs in the U.S. has been regulated since before 1922. Despite this regulation of supply of opioid drugs, the U.S. did not experience a medical opioid addiction epidemic until the end of the 20th Century.

152. In the 1980s, J&J acquired and formed two companies, Tasmanian Alkaloids and Noramco, in order to ensure a reliable source of narcotic raw materials and security of supply for its Tylenol with Codeine range of pain medications.

153. Tasmanian Alkaloids, located off the coast of Australia, cultivates and processes opium poppy plants, grown in Tasmania, to produce the narcotic raw materials necessary to manufacture APIs used in opioid drugs. Specifically, Tasmanian Alkaloids separates poppy seed from poppy straw, then extracts alkaloids from the poppy straw to produce concentrate of poppy straw ("CPS"). Once produced, CPS is then sold as the narcotic raw material necessary to manufacture the APIs in opioids. The principal alkaloids extracted from CPS include morphine, thebaine, and oripavine.

154. Noramco, located in the U.S., imports the narcotic raw materials produced by Tasmanian Alkaloids, like morphine or thebaine, into the U.S., processes them into API, then sells them to drug manufacturers in the U.S. Noramco was a key part of J&J's "pain franchise" from the mid-1990s until at least after 2010. J&J 's ownership of these subsidiaries uniquely positioned its "pain management franchise" to provide U.S. drug manufacturers,

including J&J itself, with "Security of Supply" and "Direct Access to Narcotic Raw Material—From Our Fields to Your Formulations." Through Noramco, J&J supplied oxycodone API to other drug manufacturers.

155. The scope of operations at J&J's subsidiaries, Tasmanian Alkaloids and Noramco, changed dramatically in the 1990s due to a "transformational technology" developed by J&J's scientists at Tasmanian Alkaloids.

156. Because the U.S. 80/20 Rule is calculated based solely on the amount of morphine alkaloid contained in the narcotic raw material, but not the thebaine alkaloid content of these materials, the importation of thebaine is not restricted by the 80/20 Rule.

157. Thebaine is not itself used in therapy, but it is an important raw material in the manufacture of several opioids, including oxycodone.

158. Until 1996, Tasmania was a small producer of thebaine.

159. In 1994, however, J&J, in concert with its subsidiary, Tasmanian Alkaloids, anticipated the demand for oxycodone.

160. Specifically, J&J's scientists at Tasmanian Alkaloids began a project in 1994 in order to develop a high thebaine poppy variety to meet the anticipated demand. The result of Defendants' research project was the creation of a mutant "high thebaine" poppy, called the "Norman Poppy," which J&J internally described as a transformational technology that enabled the growth of oxycodone. In 1994, Purdue filed the first drug application for OxyContin.

161. J&J honored its scientist, Dr. A.J. Fist, who developed this "transformational" Norman Poppy by awarding the "Johnson Medal."

162. Through Noramco, J&J met the anticipated opioid demand by selling API, including oxycodone, to drug manufacturers.

163. In 1998, Noramco began pursuing long-term supply agreements with drug manufacturers in order to supply opioid API.

164. J&J's "Franchise Strategy" for their Noramco Worldwide Narcotics Franchise included partnering with the best-cost technology focused manufacturers of narcotics and participating in growth through partnerships.

165. J&J's corporate structure was organized in such a way that J&J is the parent company, followed by Janssen Pharmaceutical, under which there is Noramco, Inc. and Tasmanian Alkaloids. J&J's "pain management franchise" or "pain franchise" included all of J&J's pain products.

166. Upon information and belief, Noramco played a significant role influencing International Narcotics Control Board ("INCB") and DEA policies.

167. Noramco sold the majority of its controlled substance via long-term agreements, which included all seven (7) of the top U.S. generic drug companies. Through Noramco, J&J supplied other U.S. opioid manufacturers with opioid APIs, including: oxycodone, hydrocodone, morphine, codeine, buprenorphine, hydromorphone, and naloxone.

168. As the demand for opioids continued to climb, J&J's subsidiary, Tasmanian Alkaloids, had to increase its poppy acreage in Tasmania. Between 1996 and 2001, Tasmanian Alkaloids increased its crop area sown to the thebaine-focused, mutant Norman Poppy at a rate of 50-100% per year.

169. Following the development and commercial production of the Norman Poppy, Tasmanian Alkaloids managed to increase the alkaloid content in its poppies by at least 300% from 1999 through 2015 – an unparalleled increase in the drug industry.

170. By 2015, J&J's subsidiary, Tasmanian Alkaloids, produced 300 tons of narcotic raw materials annually, which represented over 40% of the world's supply of narcotic raw materials including 77% of the world's thebaine.

171. Between 2006 and 2011, the volume of APIs that J&J produced through Noramco doubled. Demand for Noramco's APIs increased at such a rate during this time period that Noramco had reached production capacity by 2014, necessitating the investment of millions of dollars into new facilities to expand its production capacity.

172. Noramco grew to become the top narcotic API supplier of oxycodone, hydrocodone, codeine, and morphine in the United States. Noramco maintained this top position for several years.

173. During the relevant time period, Noramco, owned a large percentage of the market for both oxycodone and hydrocodone.

174. J&J implemented a Code of Business Conduct, which includes the company's "Credo."

175. J&J requires its subsidiaries, its family of companies to follow the Code of Conduct and adhere to the company's Credo while conducting business, including conducting business in the State of Nevada.

176. J&J's Credo provides that the company and family of companies are responsible to the communities in which they perform work, which includes the State of Nevada.

177. J&J's Code of Conduct purportedly sets a foundation for company policies, procedures, and guidelines. Any time anyone in the family of J&J companies becomes aware of a violation of the Code, company policy, or the law, the companies must address the problem. Additionally, J&J required that applicable portions of the Code of Conduct be included in the contracts of third-party suppliers, manufacturers, contractors, vendors, and distributors doing business on behalf of the J&J family of companies.

178. Upon information and belief, J&J's Code of Conduct requires all employees within its family of companies to follow all laws and regulations regarding the promotion, marketing, and sales of their products, including the requirement that all marketing and promotion be truthful and consistent with regulatory approvals for the products.

C. <u>The Resurgence of Opioid Use in the United States</u>

1. The Sackler Family Integrated Advertising and Medicine.

179. Given the history of opioid abuse in the U.S. and the medical profession's resulting wariness, the commercial success of the Manufacturer Defendants' prescription

opioids would not have been possible without a fundamental shift in prescribers' perception of the risks and benefits of long-term opioid use.

180. As it turned out, Purdue Pharma was uniquely positioned to execute just such a maneuver, thanks to the legacy of a man named Arthur Sackler. The Sackler family is the sole owner of Purdue and one of the wealthiest families in America, with a net worth of $13 billion as of 2016. All of the company's profits go to Sackler family trusts and entities.[17] Yet the Sacklers have avoided publicly associating themselves with Purdue, letting others serve as the spokespeople for the company.

181. The Sackler brothers—Arthur, Mortimer, and Raymond—purchased a small patent-medicine company called the Purdue Frederick Company in 1952. It was Arthur Sackler who created the pharmaceutical advertising industry as we know it, laying the groundwork for the OxyContin promotion that would make the Sacklers billionaires.

182. Arthur Sackler was both a psychiatrist and a marketing executive. He pioneered both print advertising in medical journals and promotion through physician "education" in the form of seminars and continuing medical education courses. He also understood the persuasive power of recommendations from fellow physicians and did not hesitate to manipulate information when necessary. For example, one promotional brochure produced by his firm for Pfizer showed business cards of physicians from various cities as if they were testimonials for the drug, but when a journalist tried to contact these doctors, he discovered that they did not exist.[18]

183. It was Arthur Sackler who, in the 1960s, made Valium into the first $100-million drug, so popular it became known as "Mother's Little Helper." When Arthur's client, Roche, developed Valium, it already had a similar drug, Librium, another benzodiazepine, on the market for treatment of anxiety. So, Arthur invented a condition he called "psychic

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[17] David Armstrong, *The Man at the Center of the Secret OxyContin Files*, STAT News (May 12, 2016), https://www.statnews.com/2016/05/12/man-center-secret-oxycontin-files/.

[18] Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death,* 204 (Rodale 2003) (hereinafter "Meier").

tension"—essentially stress—and pitched Valium as the solution.[19] The campaign, for which Arthur was compensated based on volume of pills sold,[20] was a remarkable success.

184. Arthur Sackler created not only the advertising for his clients but also the vehicle to bring their advertisements to doctors—a biweekly newspaper called the *Medical Tribune*, which was distributed for free to doctors nationwide. Arthur also conceived a company called IMS Health Holdings Inc. (now called IQVIA), which monitors prescribing practices of every doctor in the U.S and sells this valuable data to pharmaceutical companies like Manufacturer Defendants, who utilize it to target and tailor their sales pitches to individual physicians.

2. Purdue Developed and Aggressively Promoted OxyContin.

185. After the Sackler brothers acquired the Purdue Frederick Company in 1952, Purdue sold products ranging from earwax remover to antiseptic, and it became a profitable business. As an advertising executive, Arthur Sackler was not involved, on paper at least, in running Purdue, which would have been a conflict of interest. Raymond Sackler became Purdue's head executive, while Mortimer Sackler ran Purdue's UK affiliate.

186. In the 1980s, Purdue, through its UK affiliate, acquired a Scottish drug producer that had developed a sustained-release technology suitable for morphine. Purdue marketed this extended-release morphine as MS Contin, and it quickly became Purdue's bestseller. As the patent expiration for MS Contin loomed, Purdue searched for a drug to replace it. Around that time, Raymond's oldest son, Richard Sackler, who was also a trained physician, became more involved in the management of the company. Richard had grand ambitions for the company; according to a long-time Purdue sales representative, "Richard really wanted Purdue to be big—I mean *really* big."[21] Richard believed Purdue should develop another use for its "Contin" timed-release system.

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[19] *Id.* at 202; see also, One Family Reaped Billions From Opioids, *WBUR On Point (Oct. 23, 2017), http://www.wbur.org/onpoint/2017/10/23/one-family-reaped-billions-from-opioids.*
[20] Meier, *supra*, at 201-203.
[21] Christopher Glazek, *The Secretive Family Making Billions from the Opioid Crisis*, Esquire (Oct. 16, 2017), http://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/.

187. In 1990, Purdue's vice president of clinical research, Robert Kaiko, sent a memo to Richard and other executives recommending that the company work on a pill containing oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely because it was most commonly prescribed as Percocet, a relatively weak oxycodone-acetaminophen combination pill. MS Contin was not only approaching patent expiration but had always been limited by the stigma associated with morphine. Oxycodone did not have that problem, and what's more, it was sometimes mistakenly called "oxycodeine," which also contributed to the perception of relatively lower potency, because codeine is weaker than morphine. Purdue acknowledged using this to its advantage when it later pled guilty to criminal charges of "misbranding" in 2007, admitting that it was "well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine" and "did not want to do anything 'to make physicians think that oxycodone was stronger or equal to morphine' or to 'take any steps . . . that would affect the unique position that OxyContin'" held among physicians.[22]

188. For Purdue and OxyContin to be "I mean *really* big,"[23] Purdue needed to both distance its new product from the traditional view of narcotic addiction risk and broaden the drug's uses beyond cancer pain and hospice care. A marketing memo sent to Purdue's top sales executives in March 1995 recommended that if Purdue could show that the risk of abuse was lower with OxyContin than with traditional immediate-release narcotics, sales would increase. As discussed below, Purdue did not find or generate any such evidence, but that did not stop Purdue from making the claim.

189. To achieve its marketing goals and avoid the "stigma" attached to less potent opioids, Purdue persuaded the FDA examiner, over internal objections within the FDA, to approve a label stating: "Delayed absorption as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug."

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[22] *Id.*
[23] *Id.*

190. The basis for this reduced abuse liability claim was entirely theoretical and not based on any actual research, data, or empirical scientific support, and the FDA ultimately pulled this language from OxyContin's label in 2001.

191. Nonetheless, as set forth in detail below, Purdue made reduced risk of addiction and abuse the cornerstone of its marketing efforts.

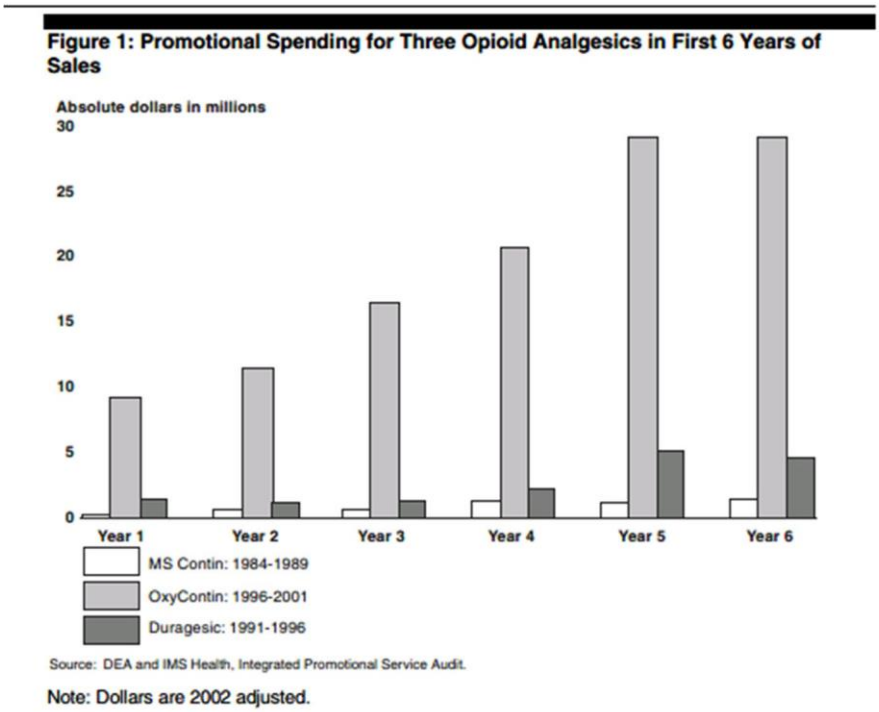
192. At the OxyContin launch party, Richard Sackler asked the audience to imagine a series of natural disasters: an earthquake, a volcanic eruption, a hurricane, and a blizzard. He said, "the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white…."

193. Armed with this and other misrepresentations about the risks and benefits of its new drug, Purdue was able to open an enormous untapped market: patients with non-end-of-life, non- acute, everyday aches and pains. As Dr. David Haddox, a Senior Medical Director at Purdue, declared on the Early Show, a CBS morning talk program, "There are 50 million patients in this country who have chronic pain that's not being managed appropriately every single day. OxyContin is one of the choices that doctors have available to them to treat that."[24]

194. In pursuit of these 50 million potential customers, Purdue poured resources into OxyContin's sales force and advertising, particularly to a far broader audience of primary care physicians who treated patients with chronic pain complaints. The graph below shows how promotional spending in the first six years following OxyContin's launch dwarfed Purdue's spending on MS Contin:[25]

[24] Meier, *supra*, at 269.

[25] U.S. General Accounting, *OxyContin Abuse and Diversion and Efforts to Address the Problem*, Office Report to Congressional Requesters at 22 (Dec. 2003), http://www.gao.gov/new.items/d04110.pdf.



195. Prior to Purdue's launch of OxyContin, no drug company had ever promoted such a pure, high-strength Schedule II narcotic to so wide an audience of general practitioners.

196. In the two decades following OxyContin's launch, Purdue continued to devote substantial resources to its promotional efforts.

197. Purdue has generated estimated sales of more than $35 billion from opioids since 1996, raking in more than $3 billion in 2015 alone. Remarkably, its opioid sales continued to climb even after a period of media attention and government inquiries regarding OxyContin abuse in the early 2000s and a criminal investigation culminating in guilty pleas in 2007. Purdue proved itself skilled at evading full responsibility and continuing to sell through the controversy. The company's annual opioid sales of $3 billion in 2015 represent a four-fold increase from its 2006 sales of $800 million.

198. Facing increasing domestic scrutiny from the public and increasing awareness of the harm their drugs cause, Purdue and Richard Sackler now have their eyes on even greater profits. Under the name of Mundipharma International, the Sacklers are looking to new markets for their opioids—employing the exact same playbook in South America, China, and India as they did in the United States.

199. In May 2017, a dozen members of Congress sent a letter to the World Health Organization, warning it of the deceptive practices Purdue is unleashing on the rest of the world through Mundipharma:

> We write to warn the international community of the deceptive and dangerous practices of Mundipharma International—an arm of Purdue Pharmaceuticals. The greed and recklessness of one company and its partners helped spark a public health crisis in the United States that will take generations to fully repair. We urge the World Health Organization (WHO) to do everything in its power to avoid allowing the same people to begin a worldwide opioid epidemic. Please learn from our experience and do not allow Mundipharma to carry on Purdue's deadly legacy on a global stage. . . .
>
> Internal documents revealed in court proceedings now tell us that since the early development of OxyContin, Purdue was aware of the high risk of addiction it carried. Combined with the misleading and aggressive marketing of the drug by its partner, Abbott Laboratories, Purdue began the opioid crisis that has devastated American communities since the end of the 1990s. Today, Mundipharma is using many of the same deceptive and reckless practices to sell OxyContin abroad. . . .
>
> In response to the growing scrutiny and diminished U.S. sales, the Sacklers have simply moved on. On December 18, the Los Angeles Times published an extremely troubling report detailing how in spite of the scores of lawsuits against Purdue for its role in the U.S. opioid crisis, and tens of thousands of overdose deaths, Mundipharma now aggressively markets OxyContin internationally. In fact, Mundipharma uses many of the same tactics that caused the opioid epidemic to flourish in the U.S., though now in countries with far fewer resources to devote to the fallout.[26]

[26] Letter from Members of Congress to Dr. Margaret Chan, Director-General, World Health Organization (May 3, 2017), http://katherineclark.house.gov/_cache/files/a577bd3c-29ec-4bb9- bdba-1ca71c784113/mundipharma-letter-signatures.pdf.

200. With the opioid epidemic in the United States now a national public health emergency, Purdue announced on February 9, 2018, that it had reduced its sales force and would no longer promote opioids directly to prescribers. Under this new policy, sales representatives will no longer visit doctors' offices to discuss opioid products. Despite its new policy, however, Purdue continues to use the same aggressive sales tactics to push opioids in other countries. Purdue's recent pivot to untapped markets—after extracting substantial profits from American communities and leaving local governments to address the devastating and still growing damage the company caused—only serves to underscore that Purdue's actions have been knowing, intentional, and motivated by profits throughout this entire story.

3. Other Manufacturer Defendants Leapt at the Opioid Opportunity.

201. Purdue created a market for the use of opioids for a range of common aches and pains by misrepresenting the risks and benefits of its opioids, but it was not alone. The other Manufacturer Defendants—already manufacturers of prescription opioids—positioned themselves to take advantage of the opportunity Purdue created, developing both branded and generic opioids to compete with OxyContin, while, together with Purdue and each other, misrepresenting the safety and efficacy of their products. These misrepresentations are described in greater detail below.

202. Endo, which already sold Percocet and Percodan, was the first to submit an application for a generic extended-release oxycodone to compete with OxyContin. At the same time, Endo sought FDA approval for another potent opioid, immediate-release and extended-release oxymorphone, branded as Opana and Opana ER. Oxymorphone, like OxyContin's active ingredient oxycodone, is not a new drug; it was first synthesized in Germany in 1914 and sold in the U.S. by Endo beginning in 1959 under the trade name Numorphan. However, Numorphan tablets proved highly susceptible to abuse. Called "blues" after the light blue color of the 10 mg pills, Numorphan provoked, according to some users, a more euphoric high than heroin. As the National Institute on Drug Abuse observed in its 1974 report, "Drugs and Addict

Lifestyle," Numorphan was extremely popular among addicts for its quick and sustained effect. Endo withdrew oral Numorphan from the market in 1979.[27]

203. Two decades later, however, as communities around the U.S. were first sounding the alarm about prescription opioids and Purdue executives were being called to testify before Congress about the risks of OxyContin, Endo essentially reached back into its inventory, dusted off a product it had previously shelved after widespread abuse, and pushed it into the marketplace with a new trade name, Opana.

204. The clinical trials submitted with Endo's first application for approval of Opana were insufficient to demonstrate efficacy, and some subjects in the trials overdosed and had to be revived with naloxone. Endo then submitted new "enriched enrollment" clinical trials, in which trial subjects who do not respond to the drug are excluded from the trial, and obtained FDA approval. Endo began marketing Opana and Opana ER in 2006.

205. Like Numorphan, Opana ER was highly susceptible to abuse. On June 8, 2017, the FDA sought removal of Opana ER. In its press release, the FDA indicated that "[t]his is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse."[28] On July 6, 2017, Endo agreed to withdraw Opana ER from the market due to the public health consequences of abuse.[29]

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[27] John Fauber & Kristina Fiore, *Abandoned Painkiller Makes a Comeback*, MedPage Today (May 10, 2015), https://www.medpagetoday.com/psychiatry/addictions/51448.

[28] Press Release, U.S. Food & Drug Admin., *FDA Requests Removal of Opana ER for Risks Related to Abuse* (June 8, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.

[29] *Endo Pulls Opioid as U.S. Seeks to Tackle Abuse Epidemic*, Reuters (July 6, 2017, 9:59am), https://www.reuters.com/article/us-endo-intl-opana-idUSKBN19R2II.

206. By adding additional opioids or expanding the use of their existing opioid products, the other Marketing Defendants took advantage of the market created by Purdue's aggressive promotion of OxyContin and reaped enormous profits. For example, Opana ER alone generated more than $1 billion in revenue for Endo in 2010 and again in 2013. J&J also passed the $1 billion mark in sales of Duragesic in 2009.

207. Actavis also pursued a broader chronic pain market. Its predecessor, Watson Pharmaceuticals, Inc., obtained approval for Norco (hydrocodone and acetaminophen) and launched the product in 1997. Actavis also developed Kadian (morphine sulfate) and was the contract manufacturer for Kadian starting in 2005. Actavis then acquired Kadian in December 2008.[30] Kadian sales grew 50 percent from 2007 to 2011 to approximately $275 million for the year ending September 30, 2011 and Actavis then introduced a generic version of the drug.[31] As described with more particularity below, Actavis deceptively promoted Kadian to its highest-volume prescribers to increase sales and stated that Kadian was less likely to be abused when it had no evidence of this.

208. Mallinckrodt also pursued a broader chronic pain market - marketing its branded and generic drugs by misrepresenting their addictive nature and falsely claiming that the drugs could be taken in higher doses but without disclosing the greater risks of addiction. From 2009 to 2014, Mallinckrodt expanded its branded opioid portfolio while also maintaining its role as leading manufacturer of generic opioids. As described with more particularity below, Mallinckrodt, through its website, sales force, and unbranded communications, promoted its opioids by consistently mischaracterizing the risk of addiction. Specifically, Mallinckrodt promoted both Exalgo (hydromorphone hydrochloride) and Xartemis XR (oxycodone hydrochloride and acetaminophen) as formulated to reduce abuse when it had no evidence of

[30] *Actavis Acquires Kadian; Extends Specialty Drug Portfolio in U.S.*, Business Wire (December 30, 2008) https://www.businesswire.com/news/home/20081230005227/en/Actavis-Acquires- Kadian-Extends-Specialty-Drug-Portfolio.

[31] *Actavis Launches Generic KADIAN® Capsules in the U.S.*, PR Newswire, (Nov. 11, 2011), https://www.prnewswire.com/news-releases/actavis-launches-generic-kadian-capsules-in-the-us- 133689873.html.

this. In anticipation of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it.

209. By adding opioid products or expanding the use of their existing opioid products, the other Manufacturer Defendants took advantage of the market created by Purdue's aggressive promotion of OxyContin and reaped enormous profits. For example, Opana ER alone generated more than $1 billion in revenue for Endo in 2010 and again in 2013.

D. <u>Defendants' Conduct Created an Abatable Public Nuisance.</u>

210. As alleged throughout this Complaint, Defendants' conduct created a public health crisis and a public nuisance.

211. The public nuisance—*i.e.*, the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated by, *inter alia*, (a) educating prescribers (especially primary care physicians and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing effective, long-term addiction treatment to patients who are already addicted to opioids; (c) making naloxone and other overdose reversal drugs widely available so that overdoses are less frequently fatal; and (d) ensuring that state regulators have the information they need to investigate compliance.

212. Defendants have the ability to act to abate the public nuisance, and the law recognizes that they are uniquely well-positioned to do so. It is the manufacturer of a drug that has primary responsibility to assure the safety, efficacy, and appropriateness of a drug's marketing and promotion. All companies in the supply chain of a controlled substance are primarily responsible for ensuring that such drugs are only distributed and dispensed to appropriate patients and not diverted. These responsibilities exist, independent of any FDA or DEA regulation, to ensure that their products and practices meet state consumer protection laws and regulations, as well as the obligations under the Nevada Controlled Substances Act and the Nevada Administrative Code. As registered manufacturers and distributors of controlled

substances, Defendants are placed in a position of special trust and responsibility and are uniquely positioned, based on their knowledge of prescribers and orders, to act as a first line of defense.

E. The Manufacturer Defendants' Multi-Pronged Scheme to Change Prescriber Habits and Public Perception to Increase Demand for Opioids

213. In order to accomplish the fundamental shift in perception that was key to successfully marketing their opioids, the Manufacturer Defendants designed and implemented a sophisticated and deceptive marketing strategy. Lacking legitimate scientific research to support their claims, the Manufacturer Defendants turned to the marketing techniques first pioneered by Arthur Sackler to create a series of misperceptions in the medical community and ultimately reverse the long-settled understanding of the relative risks and benefits of opioids.

214. The Manufacturer Defendants promoted, and profited from, their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, 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 very serious adverse outcomes. The FDA and other regulators warned Manufacturer Defendants of these risks. The Manufacturer Defendants 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 and are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC issued pronouncements based on existing medical evidence that conclusively expose the known falsity of these Defendants' misrepresentations.

215. The deceptive marketing scheme to increase opioid prescriptions centered around nine categories of misrepresentations, which are discussed in detail below. The Manufacturer Defendants disseminated these misrepresentations through various channels,

including through advertising, sales representatives, purportedly independent organizations these defendants funded and controlled, "Front Groups," so-called industry "Key Opinion Leaders," and Continuing Medical Education ("CME") programs discussed below.

1. The Manufacturer Defendants Promoted Multiple Falsehoods About Opioids.

216. The Manufacturer Defendants' misrepresentations fall into the following nine categories:

a. False or misleading claims that the risk of addiction from chronic opioid therapy is low.

b. False or misleading claims that to the extent there is a risk of addiction, it can be easily identified and managed.

c. False or misleading claims that signs of addictive behavior are actually signs of "pseudoaddiction," requiring more opioids.

d. False or misleading claims that opioid withdrawal can be avoided by tapering.

e. False or misleading claims that there are no risks associated with taking increased doses of opioids.

f. False or misleading claims that long-term opioid use improves functioning.

g. False or misleading claims that alternative forms of pain relief pose greater risks than opioids.

h. False or misleading claims that certain opioids, including, but not limited to OxyContin, provide twelve hours of pain relief.

i. False or misleading claims that new formulations of certain opioids successfully deter abuse.

217. Each of these propositions was false. The Manufacturer Defendants knew this, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.

218. The categories of misrepresentations are offered to organize the numerous statements the Manufacturer Defendants made and to explain their role in the overall marketing

effort, not as a checklist for assessing each Manufacturer Defendant's liability. While each Manufacturer Defendant deceptively promoted its opioids specifically, and, together with other Manufacturer Defendants, opioids generally, not every Manufacturer Defendant propagated (or needed to propagate) each misrepresentation. Each Manufacturer Defendant's conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risk and benefits of opioids. While this Complaint endeavors to document examples of each Manufacturer Defendant's misrepresentations and the manner in which they were disseminated, they are just that—examples. The Complaint is not, especially prior to discovery, an exhaustive catalog of the nature and manner of each deceptive statement by each Manufacturer Defendant.

a. Falsehood #1: The risk of addiction from chronic opioid therapy is low.

219. Central to the Manufacturer Defendants' promotional scheme was the misrepresentation that opioids are rarely addictive when taken for chronic pain. Through their marketing efforts, the Manufacturer Defendants advanced the idea that the risk of addiction is low when opioids are taken as prescribed by "legitimate" pain patients. That, in turn, directly led to the expected and intended result that doctors prescribed more opioids to more patients—thereby enriching the Manufacturer Defendants and substantially contributing to the opioid epidemic.

220. Each of the Manufacturer Defendants claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support those claims. None of them has acknowledged, retracted, or corrected its false statements.

221. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, "even at recommended dose,"[32] and the risk substantially increases with more than three months of

[32] *FDA Announces Safety Labeling Changes and Postmarket Study Requirements For Extended- Release and Long-Acting Opioid Analgesics*, MagMutual (Aug. 18, 2016), https://www.magmutual.com/learning/article/fda-

use.[33] As the CDC Guideline states, "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[34]

i. Purdue's misrepresentations regarding addiction risk

222. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this "research" in the form of a one-paragraph letter to the editor published in the *New England Journal of Medicine* (NEJM) in 1980.

223. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction "rare" for patients treated with opioids.[35] They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients' records.

224. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.[36]

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announces-safety-labeling-changes-and- postmarket-study-requirements-opioids; *see also* Press Release, U.S. Food & Drug Admin., *Announces Enhanced Warnings For Immediate-Release Opioid Pain Medications Related to Risks of Misuse, Abuse, Addiction, Overdose and Death*, FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[33] Deborah Dowell, M.D. et al., *CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016*, 65(1) Morbidity & Mortality Wkly. Rep. 1, 21 (Mar. 18, 2016) (hereinafter "CDC Guideline").

[34] *Id.* at 2.

[35] Jane Porter & Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) New Eng. J. Med. 123 (Jan. 10, 1980), http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

[36] Meier, *supra*, at 174.

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.

225. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper.[37] Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. Purdue was the first Manufacturer to rely upon this letter to assert that its opioids were not addictive, but the other Manufacturer Defendants eventually followed suit, citing to the letter as a basis for their misrepresentations regarding the addictive nature of their products. Dr. Jick, author of the letter, later stated "that's not in any shape or form what we suggested in our letter."

226. Purdue specifically used the Porter and Jick letter in its 1998 promotional video "I got my life back," in which Dr. Alan Spanos says "In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%*."[38] Purdue trained its sales

[37] J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, *supra*.
[38] Our Amazing World, *Purdue Pharma OxyContin Commercial*, YouTube (Sept. 22, 2016), https://www.youtube.com/watch?v=Er78Dj5hyeI.

representatives to tell prescribers that fewer than 1% of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)"[39]

227. Other Manufacturer Defendants relied on and disseminated the same distorted messaging. The enormous impact of Manufacturer Defendants' misleading amplification of this letter was well-documented in another letter published in the NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and, in some cases, "grossly misrepresented." In particular, the authors of this letter explained:

> [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy . . .[40]

228. "It's difficult to overstate the role of this letter," said Dr. David Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern."[41]

229. Alongside its use of the Porter and Jick letter, Purdue also crafted its own materials and spread its deceptive message through numerous additional channels. In its 1996 press release announcing the release of OxyContin, for example, Purdue declared, "The fear of addiction is exaggerated."[42]

230. At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue

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[39] Patrick R. Keefe, *The Family That Built an Empire of Pain,* New Yorker (Oct. 30, 2017) (hereinafter, "Keefe, *Empire of Pain*").

[40] Pamela T.M. Leung, B.Sc. Pharm., *et al., A 1980 Letter on the Risk of Opioid Addiction*, 376 New Engl. J. Med. 2194, 2194-95 (June 1, 2017), http://www.nejm.org/doi/full/10.1056/NEJMc1700150.

[41] Marilynn Marchione, Assoc. Press, *Painful Words: How a 1980 Letter Fueled the Opioid Epidemic*, STAT News (May 31, 2017), https://www.statnews.com/2017/05/31/opioid-epidemicnejm-letter/.

[42] Press Release, Purdue Pharma L.P., *New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996, 3:47pm), http://documents.latimes.com/oxycontin-press-release-1996/.

emphasized "legitimate" treatment, dismissing cases of overdose and death as something that would not befall "legitimate" patients: "Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional."[43]

231. Purdue spun this baseless "legitimate use" distinction out even further in a patient brochure about OxyContin, called "A Guide to Your New Pain Medicine and How to Become a Partner Against Pain." In response to the question "Aren't opioid pain medications like OxyContin Tablets 'addicting'?," Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, "medical" purposes:

> Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.[44]

232. Sales representatives marketed OxyContin as a product "'to start with and to stay with.'"[45] Sales representatives also received training in overcoming doctors' concerns about addiction with talking points they knew to be untrue about the drug's abuse potential. One of Purdue's early training memos compared doctor visits to "firing at a target," declaring that "[a]s you prepare to fire your 'message,' you need to know where to aim and what you want to hit!"[46] According to the memo, the target is physician resistance based on concern about addiction: "The physician wants pain relief for these patients without addicting them to an opioid."[47]

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[43] *Oxycontin: Its Use and Abuse: Hearing Before the House Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (Statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG- 107hhrg75754.htm.

[44] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and a set of medical education resources distributed to prescribers by sales representatives. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

[45] Keefe, *Empire of Pain, supra*.

[46] Meier, *supra*, at 102.

[47] *Id.*

233. Purdue, through its unbranded website *Partners Against Pain*, stated the following: "Current Myth: Opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids." "Addiction risk also appears to be low when opioids are dosed properly for chronic, noncancer pain."

234. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors' objections to prescribing opioids. The most common objection he heard about prescribing OxyContin was that "it's just too addictive."[48] May and his coworkers were trained to "refocus" doctors on "legitimate" pain patients, and to represent that "legitimate" patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less "habit-forming" than painkillers that need to be taken every four hours.

235. According to interviews with prescribers and former Purdue sales representatives, Purdue has continued to distort or omit the risk of addiction while failing to correct its earlier misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

236. With regard to addiction, Purdue's label for OxyContin has not sufficiently disclosed the true risks to, and experiences of, its patients. Until 2014, the OxyContin label stated in a black-box warning that opioids have "abuse potential" and that the "risk of abuse is increased in patients with a personal or family history of substance abuse."

[48] David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), The New Yorker (Oct. 27, 2017), https://www.newyorker.com/podcast/the-new- yorker-radio-hour/how-oxycontin-was-sold-to-the-masses.

ii. As the Owners of Purdue, members of Purdue's Board and Former Officers of the Company, the Sacklers had actual knowledge of, sanctioned, and participated in Purdue's deceptive, misleading, and otherwise illegal practices

237. Purdue's deliberate actions to mislead prescribers and the public about the risks and benefits of long-term opioid treatment were orchestrated by the Sacklers from the launch of OxyContin through the present. Purdue is not a publicly traded company, but rather a family business: it is completely Sackler-owned and Sackler-led. The Sacklers were directly involved in development and sanctioning Purdue's deceptive and illegal activities, and they each participated in its decisions to mislead Nevada providers, patients, government authorities, and insurers to normalize opioid prescribing and generate a financial windfall for themselves.

238. The Sacklers control Purdue. Each of them took seats on the board of PPI and many served as officers of Purdue entities. Together, they always controlled the directorate that gave them total power over Purdue and its officers and other employees, and they frequently exercised that power in person at Purdue headquarters, some working there on a daily basis. From 1990 to 2018, the Sacklers made up a majority of the Purdue Board of Directors and, in some years, the Board consisted only of members of the Sackler family.

239. Each of the Sacklers knew and intended that the sales representatives and Purdue's other marketing employees would not disclose to Nevada providers and patients the truth about Purdue's opioids. They each intended and directed Purdue staff to reinforce these misleading messages throughout Nevada, including by sending deceptive publications to Nevada doctors and deceptively promoting Purdue opioids at CME events in the State of Nevada. And they each knew and intended that patients, prescribers, pharmacists, and insurers in Nevada would rely on Purdue's deceptive sales campaign to request, prescribe, dispense, and reimburse claims for Purdue's opioids.

240. The Sacklers—Defendants Richard, Ilene, Jonathan, Kathe, Theresa, Beverly, and Mortimer Sackler—took seats on the Board from PPI's inception in 1990. David Sackler joined the Board in July 2012.

241. Richard Sackler played an active and central role in the management of Purdue. He is named as inventor on dozens of patents relating to oxycodone and other pain medications, including patents issued as late as 2016. Most of these patents were assigned to Purdue. He began working for Purdue as assistant to the president in the 1970s. He later served as vice president of marketing and sales. In the early 1990's he became senior vice president, which was the position he held at the time OxyContin was launched in 1996. In 1999, he became president/CEO, and he served in that position until 2003.

242. Richard Sackler resigned as President in 2003 but he continued to serve as co-chair of the Purdue board. He was actively involved in the invention, development, marketing, promotion, and sale of Purdue's opioids, including OxyContin. And he saw to it that Purdue launched OxyContin with an unprecedented marketing campaign causing OxyContin to generate a billion dollars in sales within five year of its introduction in the pain management market. For example, in 1998, Richard Sackler instructed Purdue's executives that OxyContin tablets provide more than merely "therapeutic" value and instead "enhance personal performance."

243. Defendant Jonathan Sackler served as a vice president of Purdue during the period of development, launch, promotion, and marketing of OxyContin. He resigned that officer position in or after 2003, but he continued to serve on the board of Purdue

244. Defendant Mortimer D. A. Sackler also served as a vice president of Purdue during the period of development, launch, promotion, and marketing of OxyContin. He resigned that position in or after 2003, but he continued to serve on the board of Purdue.

245. Defendant Kathe Sackler also served as a vice president of Purdue during the period of development, launch, promotion, and marketing of OxyContin. She resigned that position in or after 2003, but continued to serve on the board of Purdue.

246. Defendant Ilene Sackler served as a vice president of Purdue during the period of development, launch, promotion, and marketing of OxyContin. Like Richard, Jonathan, Mortimer, and Kathe, Ilene resigned that position in or after 2003, but continued to serve on the board of Purdue.

247. Defendant David A. Sackler served as a member of Purdue's board between 2012 and 2018.

248. Defendant Beverly Sackler served on Purdue's board between 1993 and 2017. During the relevant time period, she also served as a trustee of one or more trusts that beneficially own and control Purdue.

249. Defendant Theresa Sackler served as a member of Purdue's board between 1993 and 2017.

250. Through their positions as the owners, directors, and officers of Purdue, the Sacklers had oversight and control over the unlawful sales and marketing described in this complaint.

251. From the beginning, the Sacklers were behind Purdue's decision to deceive doctors and patients about opioids' risk of abuse and addiction. In 1997, Richard Sackler, Kathe 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, even as a substitute for Tylenol.

252. The Sacklers who were involved in running the family business knew since at least the summer of 1999 that prescription opioids lead to addiction, and specifically that OxyContin could be, and was, abused. In summer 1999, a Purdue sales representative wrote to the president of Purdue reporting widespread abuse of OxyContin. "We have in fact picked up references to abuse of our opioid products on the internet," Purdue Pharma's general counsel, Howard R. Udell, wrote in early 1999 to another company official.

253. In January 2001, Richard Sackler received an email from a Purdue sales representative describing a community meeting at a local high school that organized by mothers whose children overdosed on OxyContin and died. The sales representative wrote: "Statements were 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."

254. In February 2001, a federal prosecutor reported 59 deaths from OxyContin in a single state. Defendant Richard Sackler wrote to Purdue executives: "This is not too bad. It could have been far worse."

255. In 2007, Richard Sackler applied for a patent to treat opioid addiction. He finally received it in January 2018 and assigned it to Rhodes, 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.

256. At no point during the relevant time period did the Sacklers receive information showing that prescription opioid abuse had abated.

257. Instead, in 2010, staff gave the Sacklers a map, which showed a correlation between the location of dangerous prescribers with reports of oxycodone poisonings, burglaries and robberies.

258. In March 2013, staff reported to the Sacklers on the devastation caused by prescription opioids. 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. They told the Sacklers that tens of thousands of deaths were only the "tip of the iceberg," and that, for every death, there were more than a hundred people suffering from prescription opioid dependence or abuse.

259. Just two months later, at a May 2013 board meeting, staff reported to the Sacklers that they were successfully pushing opioid savings cards through direct mail and email to get patients to "remain on therapy longer."

260. In February 2001, Richard Sackler dictated Purdue's strategy for responding to the increasing evidence of abuse of prescription opioids and addiction to Purdue's opioids: blame and stigmatize their own victims. Richard Sackler wrote in an email: "we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals."

261. When *Time* magazine published an article about OxyContin deaths in New England, Purdue employees told Richard Sackler they were concerned. Richard responded with a message to his staff. He wrote that *Time's* coverage of people who lost their lives to OxyContin was not "balanced," and the deaths were the fault of "the drug addicts," instead of Purdue.

262. The Sacklers' full understanding of opioids' abuse and addiction risk is underscored by their willingness to research, quantify and ultimately monetize opioid abuse and addiction by pursuing the development of medications to treat the addiction their own opioids caused.

263. Defendants Kathe Sackler, Richard Sackler, and Purdue's staff determined that millions of people who became addicted to opioids were the Sackler Families' next business opportunity. A PowerPoint stated: "It is an attractive market. Large unmet need for vulnerable, underserved and stigmatized patient population suffering from substance abuse, dependence and addiction."

264. In September 2014, Kathe Sackler participated in a call about *Project Tango*—a plan for Purdue to expand into the business of selling drugs to treat opioid addiction. In their internal documents, defendant Kathe Sackler and staff memorialized what Purdue publicly denied for decades: "Pain treatment and addiction are naturally linked." They illustrated this point, and the business opportunity it presented, with a funnel beginning with pain treatment and leading to opioid addiction treatment:

265. The same presentation also provided: "[Opioid addiction] can happen to anyone 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."

266. Defendant Kathe Sackler and Purdue's *Project Tango* team reviewed findings that the "market" of people addicted to opioids had doubled from 2009 to 2014. Kathe and the staff found that the national catastrophe they caused provided an excellent compound annual growth rate ("CAGR"): "Opioid addiction (other than heroin) has grown by ~20% CAGR from 2000 to 2010."

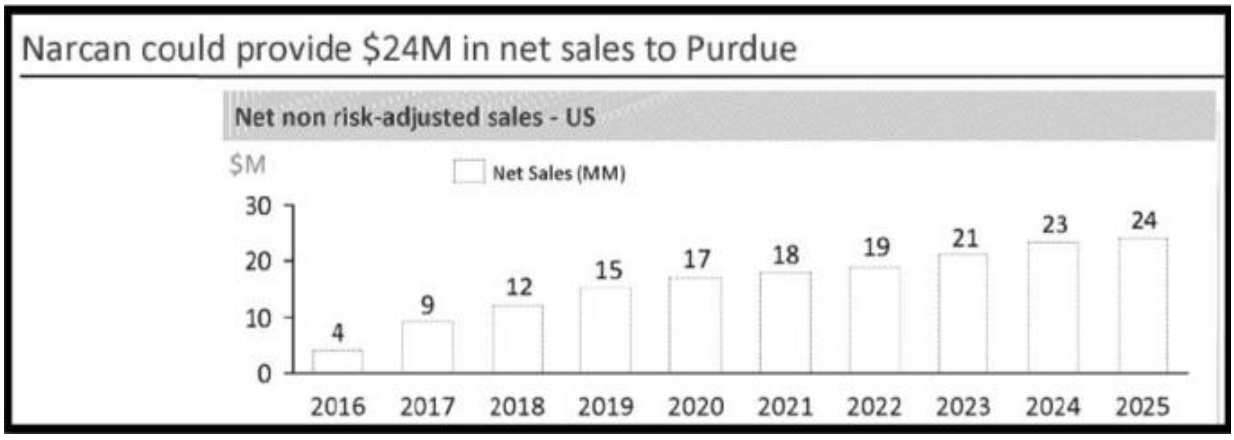
267. Defendant Kathe Sackler ordered staffs "immediate attention, verification, and assessment" of reports of children requiring hospitalization after swallowing buprenorphine as

a film that melts in your mouth, and staff assured Kathe that children were *overdosing on pills like OxyContin,* not films, "which is a positive for *Tango*."

268. In February 2015, staff presented Kathe Sackler's work on *Project Tango* to Purdue's board. The plan was for a joint venture controlled by the Sacklers to sell the addiction medication suboxone and would result in the Sacklers' acquisition of the "market lead[] in the addiction medicine space."

269. During the presentation, 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 customers: even after patients were done buying suboxone the first time, 40-60% would relapse and need it again.

270. In June 2016, the Sacklers met to discuss a revised version of *Project Tango* and considered a scheme to sell the overdose antidote NARCAN. At this meeting, the Sacklers and the Purdue board calculated that the need for NARCAN to reverse overdoses could provide a growing source of revenue, tripling from 2016 to 2018.



271. The Sacklers 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. The Sacklers planned to "leverage the current Purdue sales force" to "drive direct promotion to targeted opioid prescribers" and determined that Purdue could profit from government efforts to use NARCAN to save lives.

272. In December 2016, Richard, Jonathan and Mortimer Sackler had a call with staff regarding yet another version of *Project Tango* to discuss acquiring 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."

273. Despite having full knowledge of opioids' risk of addiction, abuse, and diversion, the Sacklers, as the owners of Purdue involved with each and every material decision relating to the development and sale of Purdue's opioids, were actively involved in marketing Purdue's opioids in a way that deceptively minimized those risks and overstated the benefits."

274. For example, the Sacklers oversaw:

- Purdue's research, including research that contradicted its marketing. Purdue's board received reports about studies of Purdue opioids in "opioid-naïve" patients and patients with osteoarthritis, down to the details of the strategy behind the studies and the enrollment of the first patients.

- Purdue's improper response to signs of abuse and diversion by high-prescribing doctors.

- Purdue's strategy to pay high prescribers to promote Purdue's opioids. A report for the Purdue board listed the exact number of conferences and dinner meetings, with attendance figures and the board was told the amounts paid to certain doctors, and they received detailed reports on the Return on Investment that Purdue gained from paying doctors to promote its drugs.

- Purdue's strategy to push patients to higher doses of opioids which are more dangerous, more addictive, and more profitable. The Board routinely received reports on Purdue's efforts to push patients to higher doses and to use higher doses of opioids to keep patients on drugs for longer periods of time. These internal communications only increased as Purdue's market share for its opioids declined.

- Purdue's push to steer patients away from safer alternatives. They tracked the company's effort to emphasize "the true risk and cost consequence of acetaminophen-related liver toxicity."

275. The Sacklers focused their attention on the sales force, directing both the messaging and their tactics and closely monitoring compliance with their directives and the results. The Sacklers tracked the exact number of sales representatives and the exact number of visits they made to urge doctors to prescribe Purdue opioids. They knew which drugs were promoted; how many visits sales representatives averaged per workday; how much each visit cost Purdue. They knew the company's plan for sales visits in each upcoming quarter and approved specific plans to hire new sales representatives, hire and promote new District and Regional managers, and create sales "territories" in which representatives would target doctors. The Sacklers knew how many visits sales representatives averaged per workday and required their sales representatives to average 7.5 prescribers per day. As with the daily visits per representative, the Sacklers tracked the total number of sales visits per quarter until at least 2014.

276. The Sacklers made key decisions relating to Purdue's sales representatives. For example, they considered and approved hiring more sales representatives. They decided to approve sales representatives' compensation, and they even voted to gift sales representatives with laptops.

277. The Sacklers oversaw the tactics that sales representatives used to push their opioids. For example, a Purdue board report analyzed a Purdue initiative to use iPads during sales visits, which increased the average length of the sales meeting with the doctor.

278. The Sacklers even monitored sales representatives' emails. Purdue held thousands of face-to-face sales meetings with doctors, but the company prohibited its sales representatives from writing emails to doctors, which could create evidence of Purdue's misconduct. When Purdue found that some sales representatives had emailed doctors, the company conducted an "investigation" and reported to the board that sales representatives had been disciplined and that their emails would be discussed at the board meeting.

279. Even after Purdue's 2007 guilty plea and the Corporate Integrity Agreement binding Purdue's directors, the Sacklers maintained their control over Purdue's deceptive sales campaign. Richard Sackler even went into the field to supervise representatives face to face.

280. The Sacklers directed Purdue to hire hundreds of sales representatives to carry out their deceptive sales campaign subsequent to the 2007 guilty plea. Complying with those orders, Purdue staff reported to the Sacklers in January 2011 that a key initiative in Q4 2010 had been the expansion of the sales force.

281. In November 2012, the Sacklers voted to set Purdue's budget for Sales and Promotion for 2013 at $312,563,000.

282. Further demonstrating how intimately involved the Sackler Defendants were in decisions concerning the sales force: in February 2012, during a lengthy exchange between some Sackler individual Defendants and Purdue's officers, Defendant Mortimer Sackler suggested that Purdue reschedule its January annual sales meeting to February so that sales representatives "get back to work for January and back in front of doctors who enter the new year refreshed...". Mortimer also suggested that representatives take " three full weeks" to " visit all their doctors while they are still fresh from the winter break." Mortimer posed these questions *despite* Purdue's robust sales during that time period. In response to this exchange defendant Richard Sackler suggested the annual meeting be canceled altogether.

283. In October 2013, Mortimer Sackler pressed for more information on dosing and "the breakdown of OxyContin market share by strength." 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." 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. Staff promised to increase the budget for 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.

284. In 2013, staff reported to the Sacklers that net sales for 2013 had been $377 million 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." The Sacklers agreed.

285. 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 "[c]ontinued pressure against long term use of opioids." Staff told the Sacklers that Purdue's best 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.

286. The Sacklers knew that Purdue's marketing had an immense effect in driving opioid prescriptions. According to Purdue's analysis in February 2014, its sales and marketing tactics generated an additional 560,036 prescriptions of OxyContin in 2012 and 2013.

287. Purdue and the Sacklers disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through patient advocacy and professional Front Groups and KOLs. They purposefully hid behind these individuals and organizations to avoid regulatory scrutiny and to prevent doctors and the public from discounting their messages.

288. Purdue and the Sacklers generated and approved the deceptive content used by the KOLs and professional Front Groups.

289. In 2013, Purdue abolished the detailed Quarterly Reports that had created a paper trail of targets for sales visits and been emailed among the Board and staff. For 2014, Purdue decided to limit many of its official board reports to numbers and graphs, and relay other information orally. The Sacklers continued to demand information about sales tactics, and their control of Purdue's deceptive marketing did not change.

290. While Purdue was under investigation by the U.S. Attorney's Office for its opioid marketing practices, the Sacklers formed a new company to enter the generic opioid business: Rhodes. According to a former senior manager at Purdue, "Rhodes was set up as a 'landing pad' for the Sackler family in 2007, to prepare for the possibility that they would need to start afresh following the crisis then engulfing OxyContin."

291. Rhodes Pharmaceuticals L.P. is a Delaware limited partnership, and Rhodes Technologies is a Delaware general partnership, and each are 100% owned by Coventry Technologies L.P., a Delaware limited partnership, which is ultimately owned by the same various trusts for the benefit of members of the Sacklers. The general partner of Rhodes Pharma is Rhodes Pharmaceuticals Inc., and the managing general partner of Rhodes Tech is Rhodes Technologies Inc. Together, these entities are referred to as "Rhodes." In 2009, Rhodes began selling generic opioids and further enriched the Sacklers.

292. Purdue and the Sacklers oversaw and approved all Rhodes-related activity. The Sacklers received the agendas for Rhodes Pharma and Rhodes Tech board of directors' meetings in addition to Rhodes' financial statements and financial results. Some of the individual Sackler Defendants served on Rhodes' committees. For example, in 2015, Theresa Sackler (Chairperson), Kathe Sackler, and Jonathan Sackler served on Rhodes' Governance committee. And in 2017, Rhodes' Business Development Committee included individual Sackler Defendants Kathe Sackler, Jonathan Sackler, Mortimer Sackler, and David Sackler. In 2018, defendant Richard Sackler was listed on Rhodes' patent for a drug to treat opioid addiction and further profit from the opioid crisis the Sackler Families created. Rhodes relied on Purdue for compliance; for example, in 2018, Rhodes' Compliance Committee discussed the suspicious ordering system and statistics for 2018 as provided by Purdue. Rhodes also made distributions to defendants Rosebay Medical L.P. and the Beacon Company in the millions, for the benefit of the Sackler Families.

293. According to the *Financial Times*, in 2016, Rhodes had a substantially larger share of prescriptions in the U.S. prescription opioid market than Purdue.[49] Purdue has often argued that it is a relatively small producer of opioids in the United States, but those claims regarding market share completely omit Rhodes, which when combined with Purdue, the

[49] David Crow, *How Purdue's 'One-Two' Punch Fueled the Market for Opioids*, Financial Times, Sept. 9, 2018, *available at* https://www.ft.com/content/8e64ec9c-bl33-l Ie8-8dl4-6f049d06439c.

Sacklers control up to six percent of the United States opioid market. By 2018, the two companies owned by the Sacklers, Rhodes and Purdue, ranked seventh in terms of market share for opioids when combined.[50]

294. Whereas the Sacklers have reduced Purdue's operations and size, Rhodes continues to grow and sell opioids for the benefit of the Sackler families.

295. The Sacklers caused Purdue and other associated companies that they beneficially owned and controlled to distribute to the Sackler Families billions of dollars in connection with the sale of Purdue's opioids.

296. From the 2007 convictions to 2018, the Sacklers voted to pay their families hundreds of millions of dollars each year, reflecting both the Sacklers' personal incentives to sell as many opioids as possible, as well as the extent of their control over the Purdue board and Purdue.

297. By 2014, the Sacklers knew that state attorneys general were investigating Purdue, commencing actions against the company, and that settlements and/or judgments against Purdue would become a cost of doing business for Purdue. Despite this knowledge, the Sackler Defendants continued to vote to have Purdue pay the Sackler Families significant distributions and send money to offshore companies. And Purdue continued to forecast hundreds of millions of distributions of Purdue's profits to the Sackler Families.

298. Despite knowing that Purdue faces certain liabilities to the states, including the State of Nevada, Purdue—at the Sackler Defendants' direction—continued to pay the Sackler Defendants hundreds of millions of dollars each year in distributions during the relevant time period for no consideration and in bad faith. As a result of Defendants' unlawful distributions to the Sackler Defendants, assets are no longer available to satisfy Purdue's future creditor, the State of Nevada.

299. According to publicly available information, annual revenue at Purdue averaged about $3 billion, mostly due to OxyContin sales, and Purdue had made more than $35 billion

[50] Amy Baxter, *Billionaire Drugmaker Granted Patent for Opioid Addiction*, Health Exec, Sept. 10, 2018, *available at* https://www.healthexec.com/topics/healthcare-economics/billionaire-drugmaker-granted-patent-addiction.

since releasing OxyContin in 1995.[51] According to publicly available information, Purdue, at the direction of the Sackler-controlled board, paid the Sackler Defendants $4 billion in profits stemming from the sale of Purdue's opioids. In June 2010, Purdue's staff gave the Sacklers an updated 10-year plan for growing Purdue's opioid sales in which the Sacklers stood to receive at least $700 million each year from 2010 through 2020. In December 2014, Purdue's staff told the Sacklers that Purdue would pay their family $163 million in 2014 and projected $350 million in 2015. At board meeting after board meeting, the Sacklers voted to have Purdue pay their families hundreds of millions in Purdue profits from the sale of OxyContin, among other drugs.

300. Purdue has been involved in two decades of litigation for its misconduct vis-à-vis the sale and marketing of OxyContin. Purdue and the Sackler Defendants thus always understood, and were aware of, the catastrophic effect of investigations and lawsuits relating to the opioid litigation. But Purdue's and the Sacklers' business as usual approach means—by Purdue's own recent admission—that Purdue cannot pay what it owes to plaintiffs including the State of Nevada because distributions to Purdue's owners (the Sackler Defendants) continued unabated during the relevant time period.

301. Purdue, at the direction of the Sackler Defendants, inappropriately and illegally conveyed hundreds of millions of dollars of Purdue's profits from opioids to the Sackler Defendants each year during the relevant time period despite Purdue's and the Sacklers' knowledge that they face certain, and significant, liabilities because of the multitude of litigations against Purdue by state attorneys general, including Nevada's Attorney General.

302. No regard was given to Purdue's ability to pay creditors like Nevada, or even negotiate a settlement in good faith, given that hundreds of millions of dollars each year were squandered by distributing those funds to members of the Sackler family.

[51] Ella Nilsen, *AG locked in prolonged battle with drug companies*, Concord Monitor, July 14 2016, *available at* https://www.concordmonitor.com/NH-attorney-general-battle-with-drug-companies-3424021.

303. Now, when faced with reality that Purdue—and the Sacklers—will finally be held accountable commensurate to their misconduct, Purdue has publicly admitted that it cannot pay these liabilities and commenced bankruptcy proceedings on the eve of a landmark jury trial and in the middle of discovery with dozens of state attorneys general, including Nevada.

304. Ultimately, the Sacklers used their ill-gotten wealth to cover up their misconduct with a philanthropic campaign intending to whitewash their decades-long success in profiting at Nevadans' expense.

iii. Endo's misrepresentations regarding addiction risk

305. Endo also falsely represented that addiction is rare in patients who are prescribed opioids.

306. Until April 2012, Endo's website for Opana, *www.opana.com*, stated that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."

307. Upon information and belief, Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER. Endo's training materials for its sales representatives in 2011 also prompted sales representatives to answer "true" to the statement that addiction to opioids is not common.

308. One of the Front Groups with which Endo worked most closely was the American Pain Foundation ("APF"), described more fully below. Endo provided substantial assistance to, and exercised editorial control, over the deceptive and misleading messages that APF conveyed through its National Initiative on Pain Control ("NIPC")[52] and its website

[52] Endo was one of the APF's biggest financial supporters, providing more than half of the $10 million APF received from opioid manufacturers during its lifespan. Endo was the sole funder of NIPC and selected APF to manage NIPC. Internal Endo documents indicate that Endo was responsible for NIPC curriculum development, web posting, and workshops, developed and reviewed NIPC content, and took a substantial role in distributing NIPC and APF materials. Endo projected that it would be able to reach tens of thousands of prescribers nationwide through the distribution of NIPC materials.

www.painknowledge.com, which claimed that "[p]eople who take opioids as prescribed usually do not become addicted."

309. Another Endo website, www.*PainAction.com*, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

310. In a brochure available on *www.painknowledge.com* titled "*Pain: Opioid Facts*," Endo-sponsored NIPC stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted." In numerous patient education pamphlets, Endo repeated this deceptive message.

311. In a patient education pamphlet titled "*Understanding Your Pain: Taking Oral Opioid Analgesics*," Endo answers the hypothetical patient question—"What should I know about opioids and addiction?"—by focusing on explaining what addiction is ("a chronic brain disease") and is not ("Taking opioids for pain relief"). It goes on to explain that "[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction." This publication is still available online.

312. An Endo publication, *Living with Someone with Chronic Pain*, stated, "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website, *www.opana.com*, until at least April 2012.

313. In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on *www.painknowledge.com*, omitted addiction from the "common risks" of opioids, as shown below:

> **As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:**
>
> - Constipation
> - Drowsiness
> - Confusion
> - Nausea
> - Itching
> - Dizziness
> - Shortness of breath
>
> Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

iv. Actavis's misrepresentations regarding addiction risk

314. Through its "Learn More About Customized Pain Control with Kadian," material, Actavis claimed that it is possible to become addicted to morphine-based drugs like Kadian, but that it is "less likely" to happen in those who "have never had an addiction problem." The piece goes on to advise that a need for a "dose adjustment" is the result of tolerance, and "not addiction."

315. Training for Actavis sales representatives deceptively minimizes the risk of addiction by: (i) attributing addiction to "predisposing factors" like family history of addiction or psychiatric disorders; (ii) repeatedly emphasizing the difference between substance dependence and substance abuse; and (iii) using the term pseudoaddiction, which, as described elsewhere, dismisses evidence of addiction as the under-treatment of pain, and dangerously, counsels doctors to respond to its signs with more opioids.

316. Actavis conducted a market study on takeaways from prescribers' interactions with Kadian sales representatives. The study revealed that doctors reported a strong recollection of the sales representatives' discussion of Kadian's supposed low-abuse potential. Actavis' sales representatives' misstatements on the low-abuse potential were considered an important

factor to doctors, and were likely repeated and reinforced to their patients. Additionally, doctors reviewed visual aids that Kadian sales representatives used during the visits, and Actavis noted that doctors who reviewed those visual aids associated Kadian with less abuse and no highs, in comparison to other opioids. Numerous marketing surveys of doctors in 2010 and 2012, for example, confirmed Actavis's messaging about Kadian's purported low addiction potential, and that it had less abuse potential than other similar opioids.

317. A guide for prescribers, published under Actavis's copyright, deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." The guide is copyrighted by Actavis in 2007, before Actavis officially purchased Kadian from Alpharma. These statements convey both that (1) Kadian does not cause euphoria and therefore is less addictive and that (2) Kadian is less prone to tampering and abuse, even though Kadian was not approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

318. In March 2010, the FDA found that Actavis had been distributing promotional materials that "minimize[] the risks associated with Kadian and misleadingly suggest[] that Kadian is safer than has been demonstrated."[53]

v. Mallinckrodt's misrepresentations regarding addiction risk

319. As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through

[53] Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth, LLC (Feb. 18, 2010), https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

unbranded communications distributed through the "C.A.R.E.S. Alliance" it created and led.

320. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." The "C.A.R.E.S. Alliance" itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

321. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!* This book is still available online. The false claims and misrepresentations in this book include the following statements:

- "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."
- "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."
- "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."
- "**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

- "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

322. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse*, which is still available online, Mallinckrodt stated that, "[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated" and cites to a report that concludes that "the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others."

323. Manufacturer Defendants' suggestions that the opioid epidemic is the result of bad patients who manipulate doctors to obtain opioids illicitly helped further their marketing scheme, but those suggestions are at odds with the facts. While there are certainly patients who unlawfully obtain opioids, they are a small minority. For example, patients who "doctor-shop"—i.e., visit multiple prescribers to obtain opioid prescriptions—are responsible for roughly 2% of opioid prescriptions. The epidemic of opioid addiction and abuse is overwhelmingly a problem of false marketing (and unconstrained distribution) of the drugs, not problem patients.

b. Falsehood #2: The false or misleading claims that to the extent there is a risk of addiction, it can be easily identified and managed.

324. While continuing to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted, the Manufacturer Defendants assert that to the extent that *some* patients are at risk of opioid addiction, doctors can effectively identify and manage that risk by using screening tools or questionnaires. In materials they produced, sponsored, or controlled, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for

chronic pain. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance use, mental illness, trauma, or abuse) so that doctors can then more closely monitor those patients. These false and misleading claims were made by all Manufacturer Defendants, examples of which are in the following paragraphs.

325. Purdue shared its *Partners Against Pain* "Pain Management Kit," which contains several screening tools and catalogues of Purdue materials, which included these tools, with prescribers. The website, which directly provides screening tools to prescribers for risk assessments, includes a "[f]our question screener" to purportedly help physicians identify and address possible opioid misuse.[54]

326. Purdue and another manufacturer, Cephalon, sponsored the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which also falsely reassured patients that opioid agreements between doctors and patients can "ensure that you take the opioid as prescribed."

327. Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, a so-called "key opinion leader" (KOL) discussed below, entitled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

328. Purdue sponsored a 2011 CME program 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."

329. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills,

[54] *Risk Assessment Resources*, Prescribe Responsibly, http://www.prescriberesponsibly.com/risk- assessment-resources (last modified July 2, 2015).

and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

330. Endo paid for a 2007 supplement available for continuing education credit in the *Journal of Family Practice* written by a doctor who became a member of Endo's speaker's bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* created by Dr. Webster and linked to Janssen or (b) the *Screener and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts. The *Opioid Risk Tool* was linked to by Endo-supported websites, as well.

331. There are three fundamental flaws in the Manufacturer Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients identified through screening can take opioids long-term without triggering addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

c. <u>Falsehood #3: The false or misleading claims that signs of addictive behavior are "pseudoaddiction," requiring more opioids.</u>

332. The Manufacturer Defendants instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids. Dr. David Haddox, who later became a Senior Medical Director for Purdue, published a study in 1989 coining the term "pseudoaddiction," which he characterized as "the iatrogenic syndrome of abnormal behavior developing as a direct

consequence of inadequate pain management."[55] In other words, people on prescription opioids who exhibited classic signs of addiction—for example, asking for more and higher doses of opioids, self-escalating their doses, or claiming to have lost prescriptions in order to get more opioids—were not addicted, but rather simply suffering from under-treatment of their pain.

333. In the materials and outreach they produced, sponsored, or controlled, Manufacturer Defendants made each of these misrepresentations and omissions, and have never acknowledged, retracted, or corrected them.

334. Purdue, Endo, and Cephalon, sponsored the Federation of State Medical Boards' ("FSMB") *Responsible Opioid Prescribing* (2007), written by Dr. Scott Fishman and discussed in more detail below, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are signs of genuine addiction, are all really signs of "pseudoaddiction." Nevada doctors could obtain CME credit by reading it.

335. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, *www.PartnersAgainstPain.com*, in 2005, and circulated this pamphlet through at least 2007 and on its website through at least 2013. The pamphlet listed conduct including "illicit drug use and deception" that it claimed was not evidence of true addiction but "pseudoaddiction" caused by untreated pain.

336. According to documents provided by a former Purdue detailer, sales representatives were regularly trained and tested on the meaning of pseudoaddiction, implying that sales representatives were directed to, and did, describe pseudoaddiction to prescribers. Purdue's *Pain Management Kit* is another example of a publication used by Purdue's sales force that endorses pseudoaddiction by claiming that "pain-relief seeking behavior can be mistaken for drug-seeking behavior." Upon information and belief, the kit was in use from 2011 through June 2016, or later.

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[55] David E. Weissman & J. David Haddox, *Opioid Pseudoaddiction – An Iatrogenic Syndrome*, 36(3) Pain 363-66 (Mar. 1989), https://www.ncbi.nlm.nih.gov/pubmed/2710565. ("Iatrogenic" describes a condition induced by medical treatment.).

337. Similarly, internal documents show that Endo trained its sales representatives to promote the concept of pseudoaddiction. A training module taught sales representatives that addiction and pseudoaddiction were commonly confused. The module went on to state that "The physician can differentiate addiction from pseudoaddiction by speaking to the patient about his/her pain and increasing the patient's opioid dose to increase pain relief."

338. Endo also sponsored a NIPC CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction and listed "[d]ifferentiation among states of physical dependence, tolerance, pseudoaddiction, and addiction" as an element to be considered in awarding grants to CME providers.

339. Upon information and belief, Endo itself has repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the New York Attorney General, in a 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'"[56] Endo thereafter agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York.

340. Upon information and belief, Endo used the term pseudoaddiction as part of a national marketing effort that, upon information and belief, included the State of Nevada.

341. The CDC Guideline does not and, upon information and belief, never did recommend attempting to provide more opioids to patients exhibiting symptoms of addiction. Dr. Webster admitted that pseudoaddiction "is already something we are debunking as a concept" and became "too much of an excuse to give patients more medication. It led us down a path that caused harm."[57]

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[56] Attorney General of the State of New York, In the Matter of Endo Health Solutions Inc. & Endo Pharmaceuticals Inc., Assurance No.:15-228, Assurance of Discontinuance Under Executive Law Section 63. Subdivision 15 at 7, https://ag.ny.gov/pdfs/Endo_AOD_030116- Fully_Executed.pdf.

[57] John Fauber, "Chronic Pain Fuels Boom in Opioids," *Medpage Today*, (Feb. 19, 2012). https://www.medpagetoday.com/neurology/painmanagement/31254.

d. Falsehood #4: The false or misleading claims that opioid withdrawal can be avoided by tapering.

342. In an effort to underplay the risk and impact of addiction, the Manufacturer Defendants falsely claimed that, while patients become physically dependent on opioids, physical dependence is not the same as addiction and can be easily addressed, if and when pain relief is no longer desired, by gradually tapering patients' dose to avoid withdrawal. Manufacturer Defendants failed to disclose the extremely difficult and painful effects that patients can experience upon ceasing opioid treatment – adverse effects that also make it less likely that patients will be able to stop using the drugs. Manufacturer Defendants also failed to disclose how difficult it is for patients to stop using opioids after they have used them for prolonged periods.

343. A non-credit educational program sponsored by Endo, *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days. However, this claim is at odds with the reported experience of patients addicted to opioids. Most patients who have been taking opioids regularly will, upon stopping treatment, experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others.[58] This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

344. For example, Purdue sponsored the APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

[58] Mayo Clinic, *Tapering off opioids: When and how*, https://www.mayoclinic.org/diseases-conditions/prescription-drug-abuse/in-depth/tapering-off-opioids-when-and-how/art-20386036.

345. To this day, the Manufacturer Defendants have not corrected or retracted their misrepresentations regarding tapering as a solution to opioid withdrawal.

e. Falsehood #5: The false or misleading claims that opioid doses can be increased without limit or greater risks.

346. In materials they produced, sponsored or controlled, Manufacturer Defendants instructed prescribers that they could safely increase a patient's dose to achieve pain relief. Each of the Manufacturer Defendants' claims was deceptive in that it omitted warnings of increased adverse effects that occur at higher doses, effects confirmed by scientific evidence.

347. These misrepresentations were integral to the Manufacturer Defendants' promotion of prescription opioids. As discussed above, patients develop a tolerance to opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose.

348. In a 1996 sales memo regarding OxyContin, for example, a regional manager for Purdue instructed sales representatives to inform physicians that there is "no[] upward limit" for dosing and ask, "if there are any reservations in using a dose of 240mg-320mg of OxyContin."[59]

349. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics:

> It went something like this. "Doctor, what is the highest dose of OxyContin you have ever prescribed?" "20mg Q12h." "Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?" "Okay." "Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?" "I don't

[59] Letter from Windell Fisher, Purdue Regional Manager, to B. Gergely, Purdue Employee (Nov. 7, 1996), http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/ (last updated May 5, 2016) (hereinafter "Letter from Fisher").

> know, maybe." "Doctor, but you do agree that you would at least Rx the 40mg dose, right?" "Yes."
>
> The next week the rep would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin.

350. These misrepresentations were particularly dangerous. As noted above, opioid doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. The recommendation of 320 mg every twelve hours is ten times that.

351. By way of example, in its 2010 Risk Evaluation and Mitigation Strategy ("REMS") for OxyContin, however, Purdue does not address the increased risk of respiratory depression and death from increasing dose, and instead advises prescribers that "dose adjustments may be made every 1-2 days"; "it is most appropriate to increase the q12h dose"; the "total daily dose can usually be increased by 25% to 50%"; and if "significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration."[60]

352. Endo sponsored a website, *www.painknowledge.com*, which claimed that opioid dosages may be increased until "you are on the right dose of medication for your pain," at which point further dose increases would not be required.

353. Endo also published on its website a patient education pamphlet entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked, "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased…You won't 'run out' of pain relief."

354. Purdue, along with another manufacturer, Cephalon, sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that

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[60] Purdue Pharma, L.P., *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P., https://web.archive.org/web/20170215190303/https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf (last modified Nov. 2010).

opioids have "no ceiling dose" and therefore are safer than taking acetaminophen or other non-steroidal anti-inflammatory drugs ("NSAIDs") like ibuprofen.

355. Manufacturer Defendants were aware of the greater dangers high dose opioids posed. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events" and that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." For example, a study of patient data from the Veterans Health Administration published in 2011 found that higher maximum prescribed daily opioid doses were directly associated with a higher risk of opioid overdose deaths.[61]

f. Falsehood #6: The false or misleading claims that long-term opioid use improves functioning.

356. Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Manufacturer Defendants consistently promoted opioids as capable of improving patients' function and quality of life because they viewed these claims as a critical part of their marketing strategies. In recalibrating the risk-benefit analysis for opioids, increasing the perceived benefits of treatment was necessary to overcome its risks.

357. Purdue noted the need to compete with this messaging, despite the lack of data supporting improvement in quality of life with OxyContin treatment:

> Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine . . . .We do not have such data to support OxyContin promotion. . . . In addition, Janssen has been using the "life uninterrupted" message in promotion of Duragesic for non-cancer pain, stressing that Duragesic "helps patients think less about their pain." This is a competitive advantage based on our inability to make any quality of life claims.[62]

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[61] Amy S. B. Bohnert, Ph.D. et al., *Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths*, 305(13) J. of Am. Med. Assoc. 1315, 1315-1321 (Apr. 6, 2011), https://jamanetwork.com/journals/jama/fullarticle/896182.

[62] Meier, *supra* at 281.

358. Despite its acknowledgment that "[w]e do not have such data to support OxyContin promotion," Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association, proclaiming, "There Can Be Life With Relief," and showing a man happily fly- fishing alongside his grandson, implying that OxyContin would help users' function. This ad earned a warning letter from the FDA, which admonished, "It is particularly disturbing that your November ad would tout 'Life With Relief' yet fail to warn that patients can die from taking OxyContin."[63]

359. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients. But the article cited as support for this in fact stated the contrary, noting the absence of long-term studies and concluding, "[f]or functional outcomes, the other analgesics were significantly more effective than were opioids."

360. A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months— that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

361. Similarly, since at least May of 2011, Endo has distributed and made available on its website, *www.opana.com*, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like those of a construction worker or chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

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[63] Chris Adams, *FDA Orders Purdue Pharma to Pull Its OxyContin Ads*, Wall St. J. (Jan. 23, 2003, 12:01am), https://www.wsj.com/articles/SB1043259665976915824.

362. The APF's *Treatment Options: A Guide for People Living with Pain* (2007), sponsored by Purdue and Cephalon, counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in May 2012.

363. Endo's NIPC website *www.painknowledge.com* claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." In addition to "improved function," the website touted improved quality of life as a benefit of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make claims of functional improvement.

364. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

365. Mallinckrodt's website, in a section on responsible use of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[64]

366. The Manufacturer Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long term. The FDA, for years, has made clear through warning letters to manufacturers the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life.[65] Based upon a review of the existing scientific

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[64] Mallinckrodt Pharmaceuticals, *Responsible Use*, http://www.mallinckrodt.com/corporate-responsibility/responsible-use.

[65] The FDA has warned other drugmakers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive

evidence, the CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use."[66]

367. Consistent with the CDC's findings, substantial evidence exists demonstrating that opioid drugs are ineffective for the treatment of chronic pain and worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. The few longer-term studies of opioid use had "consistently poor results," and "several studies have showed that opioids for chronic pain may actually worsen pain and functioning . . ."[67] along with general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.

368. The available evidence indicates opioids may worsen patients' health and pain. Increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization. The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long- term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[68] According to the CDC, "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]."[69]

369. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and

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impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); 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), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities… has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[66] CDC Guideline *supra* at 20.

[67] Thomas R. Frieden and Debra Houry, *Reducing the Risks of Relief – The CDC Opioid- Prescribing Guideline*, New Eng. J. Med., at 1503 (Apr. 21, 2016).

[68] CDC Guideline, *supra* at 2, 18.

[69] Frieden & Houry, *supra*, at 1503.

social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[70] In fact, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.[71] Another study demonstrated that injured workers who received a prescription opioid for more than seven days during the first six weeks after the injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids at all.[72] Moreover, the first randomized clinical trial designed to make head-to-head comparisons between opioids and other kinds of pain medications was recently published on March 6, 2018, in the Journal of the American Medical Association. The study reported that "[t]here was no significant difference in pain-related function between the 2 groups" – those whose pain was treated with opioids and those whose pain was treated with non-opioids, including acetaminophen and NSAIDs like ibuprofen. Accordingly, the study concluded: "Treatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months."

g. Falsehood #7: The false or misleading claims that alternative forms of pain relief pose greater risks than opioids.

370. In materials they produced, sponsored or controlled, the Manufacturer Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over- the-counter acetaminophen or over-the-counter or prescription NSAIDs.

371. For example, in addition to failing to disclose in promotional materials the risks of addiction, overdose, and death, the Manufacturer Defendants routinely ignored the risks of

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[70] Andrea Rubinstein, M.D. *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma- medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747.

[71] Jeffrey Dersh, et al., *Prescription Opioid Dependence Is Associated With Poorer Outcomes In Disabling Spinal Disorders*, 33(20) Spine 2219-27 (Sept. 15, 2008).

[72] Franklin, GM, Stover, BD, Turner, JA, Fulton-Kehoe, D, Wickizer, TM, *Early Opioid Prescription and Subsequent Disability Among Workers With Back Injuries: The Disability Risk Identification Study Cohort*, 33 Spine 199, 201-202.

hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time,"[73] hormonal dysfunction,[74] decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the elderly,[75] neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or with benzodiazepines, which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans suffering from pain.[76]

372. The APF's *Treatment Options: A Guide for People Living with Pain*, sponsored by Purdue and Cephalon, warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdoses, when the figure is closer to 3,200.[77]

373. Endo's NIPC website, *www.painknowledge.com*, contained a flyer called "*Pain: Opioid Therapy*." This publication listed opioids' adverse effects but with significant omissions, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

374. As another example, the Endo-sponsored CME put on by NIPC, *Persistent Pain in the Older Adult*, discussed above, counseled that acetaminophen should be used only short-term and includes five slides on the FDA's restrictions on acetaminophen and its adverse effects, including severe liver injury and anaphylaxis (shock). In contrast, the CME downplays the risk of opioids, claiming opioids have "possibly less potential for abuse than in younger patients," and does not list overdose among the adverse effects. Some of those misrepresentations are described above; others are laid out below.

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[73] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).
[74] H.W. Daniell, *Hypogonadism in Men Consuming Sustained-Action Oral Opioids*, 3(5) J. Pain 377-84 (2001).
[75] *See* Bernhard M. Kuschel, *The Risk of Fall Injury in Relation to Commonly Prescribed Medications Among Older People – a Swedish Case-Control Study*, Eur. J. Pub. H. 527, 527-32 (July 31, 2014).
[76] Karen H. Seal, *Association of Mental Health Disorders With Prescription Opioids and High- Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940-47 (2012).
[77] Robert E. Tarone, et al., *Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies*, 11 Am. J. of Therapeutics 17-25 (2004).

375. In April 2007, Endo sponsored an article aimed at prescribers, published in *Pain Medicine News*, titled "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain."[78] The article asserted:

> Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.[79]

376. To help allay these concerns, Endo emphasized the risks of NSAIDs as an alternative to opioids. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids.

377. Additionally, Purdue and Endo sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

378. As a result of the Manufacturer Defendants' deceptive promotion of opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.[80]

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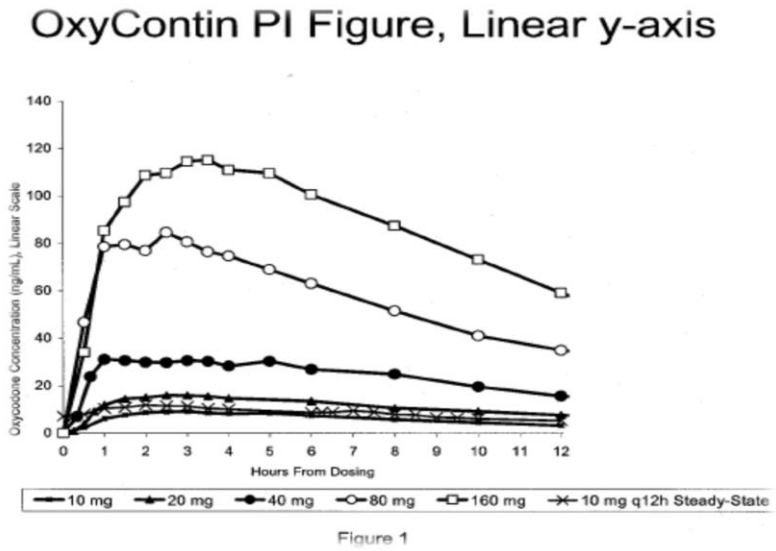
[78] Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, https://www.painmedicinenews.com/download/BtoB_Opana_WM.pdf.
[79] *Id.* at 1.
[80] M. Daubresse, et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care, 870-878 (2013). For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5%

h. Falsehood #8: The false or misleading claims that OxyContin provides twelve hours of pain relief.

379. Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action, making the knowingly false claim that OxyContin would provide 12 hours of pain relief for most patients. As laid out below, Purdue made this claim for two reasons. First, it provides the basis for both Purdue's patent and its market niche, allowing it to both protect and differentiate itself from competitors. Second, it allowed Purdue to imply or state outright that OxyContin had a more even, stable release mechanism that avoided peaks and valleys and therefore the rush that fostered addiction and attracted abusers.

380. Purdue promotes OxyContin as an extended-release opioid, but the oxycodone does not enter the body on a linear rate. OxyContin works by releasing a greater proportion of oxycodone into the body upon administration, and the release gradually tapers, as illustrated in the following chart, which was apparently adapted from Purdue's own sales materials:[81]



of these visits; and referrals to physical therapy remained steady. *See also* J. Mafi, et al., *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am Med. Ass'n Internal Med. 1573, 1573 (2013).

[81] Jim Edwards, "*How Purdue Used Misleading Charts to Hide OxyContin's Addictive Power*," CBS News, September 28, 2011, https://www.cbsnews.com/news/how-purdue-used-misleading- charts-to-hide-oxycontins-addictive-power/; *see also* Jim Edwards, "*Who Signed Off on Purdue's Misleading OxyContin Chart? Judge May Want Answers*," CBS News, January 7, 2010, https://www.cbsnews.com/news/who-signed-off-on-purdues-misleading-oxycontin-chart-judge- may-want-answers/.

381. The reduced release of the drug over time means that the oxycodone no longer provides the same level of pain relief. As a result, in many patients, OxyContin does not last for the twelve hours for which Purdue promotes it—a fact that Purdue has known at all times relevant to this action.

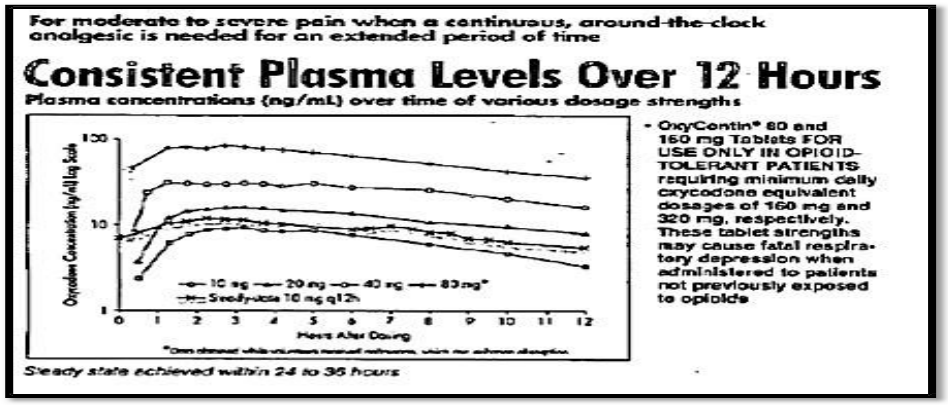
382. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid triggers a powerful psychological response. OxyContin thus behaves more like an immediate release opioid. Second, the initial burst of oxycodone means that there is less of the drug at the end of the dosing period, which results in the drug not lasting for a full twelve hours and precipitates withdrawal symptoms in patients, a phenomenon known as "end of dose" failure. (The FDA found in 2008 that a "substantial number" of chronic pain patients will experience end-of-dose failure with OxyContin.)

383. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—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."[82] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

384. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full twelve hours. Its advertising in 2000 included claims that OxyContin provides "Consistent Plasma Levels Over 12 Hours." That claim was accompanied by a chart, mirroring the chart on the previous page. However, this version of the chart deceptively minimized the

[82] Harriet Ryan, et al., "*'You Want a Description of Hell?' OxyContin's 12-Hour Problem*," Los Angeles Times, May 5, 2016, http://www.latimes.com/projects/oxycontin-part1/ (hereinafter, "*You Want a Description of Hell*").

rate of end-of- dose failure by depicting 10 mg in a way that it appeared to be half of 100 mg in the table's y-axis. That chart, shown below, depicts the same information as the chart above, but does so in a way that makes the absorption rate appear more consistent:



385. Purdue's 12-hour messaging was key to its competitive advantage over short-acting opioids that required patients to wake in the middle of the night to take their pills. Purdue advertisements also emphasized "Q12h" dosing. These include an advertisement in the February 2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. A Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is 'all of the analgesic efficacy of immediate- release oxycodone, with convenient q12h dosing,'" and further that "[t]he convenience of q12h dosing was emphasized as the most important benefit."[83]

386. In keeping with this positioning statement, a Purdue regional manager emphasized in a 1996 sales strategy memo that representatives should "convinc[e] the physician that there is no need" for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and instead the solution is prescribing higher doses."[84] One sales manager instructed her team that anything shorter than 12-hour dosing "needs to be nipped in the bud NOW!!"[85]

[83] Memorandum from Lydia Johnson, Marketing Executive at Purdue, to members of Oxycontin Launch Team (Apr. 4, 1995), http://documents.latimes.com/oxycontin-launch-1995/ (last updated May 5, 2016).
[84] Letter from Fisher, *supra*.
[85] *You Want a Description of Hell*, *supra*.

387. Purdue executives therefore maintained the messaging of twelve-hour dosing even when many reports surfaced that OxyContin did not last twelve hours. Instead of acknowledging a need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills, even though higher dosing carries its own risks, as noted above. It also means that patients will experience higher highs and lower lows, increasing the craving for their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day— which converts to the 90 MME that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[86]

388. The information that OxyContin did not provide pain relief for a full twelve hours was known to Purdue, and Purdue's competitors, but was not disclosed to prescribers. Purdue's knowledge of some pain specialists' tendency to prescribe OxyContin three times per day instead of two was set out in Purdue's internal documents as early as 1999 and is apparent from MedWatch Adverse Event reports for OxyContin.

389. Even Purdue's competitor, Endo, was aware of the problem; Endo attempted to position its Opana ER drug as offering "durable" pain relief, which Endo understood to suggest a contrast to OxyContin. Opana ER advisory board meetings featured pain specialists citing lack of 12-hour dosing as a disadvantage of OxyContin. Endo even ran advertisements for Opana ER referring to "real" 12-hour dosing.

390. Purdue's failure to disclose the prevalence of end-of-dose failure meant that prescribers were misinformed about the advantages of OxyContin in a manner that preserved Purdue's competitive advantage and profits, at the expense of patients, who were placed at greater risk of overdose, addiction, and other adverse effects.

[86] CDC Guideline, *supra*, at 16.

i. Falsehood #9: The false or misleading claims that new formulations of certain opioids successfully deter abuse.

391. Rather than take the widespread opioid abuse as reason to cease their untruthful marketing efforts, Manufacturer Defendant Purdue and Endo seized the epidemic as a competitive opportunity. These companies developed and oversold "abuse-deterrent formulations" ("ADF") opioids as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids as well as an advantage of these expensive branded drugs over other opioids. These Defendants' false and misleading marketing of the benefits of their ADF opioids preserved and expanded their sales while falsely reassuring prescribers, thereby prolonging the opioid epidemic. Other Manufacturer Defendants, including Actavis and Mallinckrodt, also promoted their branded opioids as formulated to be less addictive or less subject to abuse than other opioids.

392. The CDC Guideline confirms that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes." Tom Frieden, the former Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or deaths."

i. Purdue's deceptive marketing of reformulated OxyContin and Hysingla ER

393. Reformulated ADF OxyContin was approved in April 2010. It was not until 2013 that the FDA, in response to a citizen petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations. But in the beginning, the FDA made clear the limited claims that could be made

about ADF, noting that no evidence supported claims that ADF prevented tampering, oral abuse, or overall rates of abuse.

394. It is unlikely a coincidence that reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode Purdue's market share and the price it could charge. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis.

395. Despite its self-proclaimed good intention, Purdue merely incorporated its generally deceptive tactics with respect to ADF. Purdue sales representatives regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue sales representatives:

- claimed that Purdue's ADF opioids prevent tampering and that its ADFs could not be crushed or snorted;
- claimed that Purdue's ADF opioids reduce opioid abuse and diversion;
- asserted or suggested that its ADF opioids are non-addictive or less addictive;
- asserted or suggested that Purdue's ADF opioids are safer than other opioids, could not be abused or tampered with, and were not sought out for diversion; and
- failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

396. If pressed, Purdue acknowledged that perhaps some "extreme" patients might still abuse the drug, but claimed the ADF features protect the majority of patients. These misrepresentations and omissions are misleading and contrary to Purdue's own information and publicly available data.

397. Purdue knew or should have known that reformulated OxyContin is not more tamper-resistant than the original OxyContin and is still regularly tampered with and abused.

398. Purdue's own funded research shows that half of OxyContin abusers continued to abuse OxyContin orally after the reformulation rather than shift to other drugs.

399. In 2009, the FDA noted in permitting ADF labeling that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)". In the 2012 medical office review of Purdue's application to include an abuse-deterrence claim in its label for OxyContin, the FDA noted that the overwhelming majority of deaths linked to OxyContin were associated with oral consumption, and that only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug.

400. The FDA's Director of the Division of Epidemiology stated in September 2015 that no data that she had seen suggested the reformulation of OxyContin "actually made a reduction in abuse," between continued oral abuse, shifts to injection of other drugs (including heroin), and defeat of the ADF mechanism. Even Purdue's own funded research shows that half of OxyContin abusers continued to abuse OxyContin orally after the reformulation rather than shift to other drugs.

401. A 2013 article presented by Purdue employees based on review of data from poison control centers concluded that ADF OxyContin can reduce abuse, but it ignored important negative findings. The study revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids after the reformulation of OxyContin. In short, the article deceptively emphasized the advantages and ignored the disadvantages of ADF OxyContin.

402. Websites and message boards used by drug abusers, such as bluelight.org and reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. Purdue has been aware of these methods of abuse for more than a decade.

403. One-third of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, there was no meaningful reduction in opioid abuse overall, as many users simply shifted to other opioids such as heroin.

404. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated OxyContin product has had a meaningful impact on abuse."[87] Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

405. Despite its own evidence of abuse, and the lack of evidence regarding the benefit of Purdue's ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers. Purdue's recent advertisements in national newspapers also continues to claim its ADF opioids as evidence of its efforts to reduce opioid abuse, continuing to mislead prescribers, patients, payors, and the public about the efficacy of its actions.

ii. Endo's deceptive marketing of reformulated Opana ER

406. As the expiration of its patent exclusivity for Opana ER neared, Endo also made abuse-deterrence a key to its marketing strategy.

407. Opana ER was particularly likely to be tampered with and abused. That is because Opana ER has lower "bioavailability" than other opioids, meaning that the active pharmaceutical ingredient (the "API" or opioid) does not absorb into the bloodstream as rapidly

[87] Jill Hartzler Warner, Assoc. Comm'r for Special Med. Programs, *Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee*; *Notice of Meeting*, 80(103) Fed. Reg. 30686, 30686 (May 29, 2015).

as other opioids when taken orally. Additionally, when swallowed whole, the extended-release mechanism remains intact, so that only 10% of Opana ER's API is released into the patient's bloodstream relative to injection; when it is taken intranasally, that rate increases to 43%. The larger gap between bioavailability when consumed orally versus snorting or injection, the greater the incentive for users to manipulate the drug's means of administration

408. Endo knew by July 2011 that "some newer statistics around abuse and diversion are not favorable to our product."

409. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant.

410. Even prior to its approval, the FDA had advised Endo that it could not market the new Opana ER as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse." In other words, Opana ER was still crushable. Indeed, Endo's own studies dating from 2009 and 2010 showed that Opana ER could be crushed and ground, and, in its correspondence with the FDA, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."

411. Further, a January 4, 2011 FDA Discipline Review letter made clear to Endo that "[t]he totality of these claims and presentations suggest that, as a result of its new formulation, Opana ER offers a therapeutic advantage over the original formulation when this has not been demonstrated by substantial evidence or substantial clinical experience. In addition, these claims misleadingly minimize the risks associated with Opana ER by suggesting that the new formulation's "INTAC" technology confers some form of abuse-deterrence properties when this has not been demonstrated by substantial evidence." The FDA acknowledged that while there is "evidence to support some limited improvement" provided by the new coating, but would not let Endo promote any benefit because "there are several limitations to this data." Also, Endo was required to add language to its label specifically indicating that "Opana ER tablets may be abused by crushing, chewing, snorting, or injecting

the product. These practices will result in less controlled delivery of the opioid and pose a significant risk to the abuser that could result in overdose and death."

412. The FDA expressed similar concerns in nearly identical language in a May 7, 2012 letter to Endo responding to a February 2, 2012 "request . . . for comments on a launch Draft Professional Detail Aid . . . for Opana ER." The FDA's May 2012 letter also includes a full two pages of comments regarding "[o]missions of material facts" from Endo's promotional materials.

413. Endo also consciously chose not to do any post-approval studies. According to internal documents, the company decided, by the time its studies would be done, generics would be on the market and "any advantages for commercials will have disappeared." However, this lack of evidence did not deter Endo from marketing Opana ER as ADF while its commercial window remained open.

414. Nonetheless, in August of 2012, Endo submitted a citizen petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted and that it was resistant injection by syringe. Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse and deterrence), which would prevent generic copies of original Opana ER.

415. Endo then sued the FDA, seeking to force expedited consideration of its citizen petition. The court filings confirmed Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the

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reformulated drug to "promote the public welfare" would be lost.[88] The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."[89]

416. Despite Endo's purported concern with public safety, not only did Endo continue to distribute original, admittedly unsafe Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[90]

417. In its citizen petition, Endo asserted that redesigned Opana ER had "safety advantages." Endo even relied on its rejected assertion that Opana was less crushable to argue that it developed Opana ER for patient safety reasons and that the new formulation would help, for example, "where children unintentionally chew the tablets prior to an accidental ingestion."[91]

418. However, in rejecting the petition in a 2013 decision, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when subjected to . . . cutting, grinding, or chewing." In a 2013 letter, the FDA warned that Opana ER tablets' "extended-release features can be compromised, causing the product to 'dose dump,' when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing."[92] Also troubling, Opana ER can be prepared for snorting using commonly available methods and "readily prepared for injection."[93] The letter discussed "the

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[88] Plf.'s Opp. To Defs.' and Intervenor's Motions to Dismiss and Plf.'s Reply in Supp. of Motion for Prelim. Inj. [ECF No. 23], *Endo Pharms. Inc. v. U.S. Food and Drug Admin., et al.*, No. 1:12-cv-01936, at 20 (D.D.C. Dec. 14, 2012).

[89] Defs.' Resp. to the Court's Nov. 30, 2012 Order [ECF No. 9], *Endo Pharms. Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936, at 6 (D.D.C. Dec. 3, 2012).

[90] *Id.*; Endo News Release (Sept. 6, 2012) [ECF No. 18-4], *Endo Pharms. Inc. v. U.S. Food and Drug Admin., et al.*, No. 1:12-cv-01936 (D.D.C. Dec. 9, 2012) at 81.

[91] Citizen Petition, FDA Docket 2012-8-0895, at 5.

[92] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

[93] *Id.* at 6.

troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection."[94]

419. Meanwhile, in 2012, an internal memorandum to Endo account executives noted that abuse of Opana ER had "increased significantly" in the wake of the purportedly abuse- deterrent formulation. In February 2013, Endo received abuse data regarding Opana ER from Inflexxion, Inc., which gathers information from substance abusers entering treatment and reviews abuse-focused internet discussions, that confirmed continued abuse, particularly by injection.

420. In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500%. Endo's own data, presented in 2014, found between October 2012 and March 2014, 64% of abusers of Opana ER did so by injection, compared with 36% for the old formulation.[95] The transition into injection of Opana ER made the drug even less safe than the original formulation. Injection carries risks of HIV, hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.

421. Publicly, Endo sought to marginalize the problem. On a 2013 call with investors, when asked about an outbreak of TTP in Tennessee from injecting Opana ER, Endo sought to limit its import by assigning it to "a very, very distinct area of the country."

422. Despite its knowledge that Opana ER was widely abused and injected, Endo marketed the drug as tamper-resistant and abuse-deterrent. Upon information and belief, based on the company's detailing elsewhere, Endo sales representatives informed doctors that Opana ER was abuse-deterrent, could not be tampered with, and was safe. In addition, sales representatives did not disclose evidence that Opana was easier to abuse intravenously and, if pressed by prescribers, claimed that while outlier patients might find a way to abuse the drug, most would be protected.

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[94] *Id.* at 6, n. 21.

[95] Theresa Cassidy, *The Changing Abuse Ecology: Implications for Evaluating the Abuse Pattern of Extended-Release Oxymorphone and Abuse-Deterrent Opioid Formulations*, Pain Week Abstract 2014, https://www.painweek.org/assets/documents/general/724- painweek2014acceptedabstracts.pdf.

423. A review of national surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential." An internal Endo document also notes that market research showed that, "[l]ow abuse potential continues as the primary factor influencing physicians' anticipated increase in use of Opana ER over the next 6 months."

424. In its written materials, Endo marketed Opana ER as having been designed to be crush-resistant, knowing that this would (falsely) imply that Opana ER actually was crush-resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced "the completion of the company's transition of its Opana ER franchise to the new formulation designed to be crush resistant."

425. The press release further stated that: "We firmly believe that the new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers." The press release described the old formulation of Opana as subject to abuse and misuse but failed to disclose the absence of evidence that reformulated Opana was any better. In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."

426. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." A January 2013 article in Pain Medicine News, based in part on an Endo press release, described Opana ER as "crush-resistant." This article was posted on the *Pain Medicine News* website, which was accessible to patients and prescribers.

427. Endo, upon information and belief, targeted particular geographies for the redesigned Opana ER where abuse was most rampant, including Nevada.

428. In March 2017, because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and TTP, an FDA advisory committee recommended that Opana be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017.

Endo announced on July 6, 2017 that it would agree to stop marketing and selling Opana ER. However, by this point the damage had been done. Even then, Endo continued to insist, falsely, that it "has taken significant steps over the years to combat misuse and abuse."

iii. Manufacturer Defendants' misrepresentations regarding abuse deterrence

429. A guide for prescribers under Actavis's copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide declares that "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and "KADIAN may be less likely to be abused by health care providers and illicit users" because of its "[s]low onset of action." Kadian, however, was not approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

430. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt's promotional materials stated that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving."[96] One member of the FDA's Controlled Substance Staff, however, noted in 2010 that hydromorphone has "a high abuse potential comparable to oxycodone" and further stated that "we predict that Exalgo will have high levels of abuse and diversion."[97]

431. With respect to Xartemis XR, Mallinckrodt's promotional materials stated that "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."[98] In anticipation

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[96] Mallinckrodt Press Release, *FDA Approves Mallinckrodt's EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain* (Aug. 27, 2012), http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159.

[97] 2010 Meeting Materials, Anesthetic and Analgesic Drug Products Advisory Committee, at 157-58, FDA, excerpt available at https://www.markey.senate.gov/imo/media/doc/2016-02-19-Markey-ADF-Opioid-timeline.pdf.

[98] Mallinckrodt, *Responsible Use of Opioid Pain Medications* (Mar. 7, 2014).

of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."[99]

432. While Manufacturer Defendants promote patented technology as the solution to opioid abuse and addiction, none of their "technology" addresses the most common form of abuse—oral ingestion—and their statements regarding abuse-deterrent formulations give the misleading impression that these reformulated opioids can be prescribed safely.

433. In sum, each of the nine categories of misrepresentations discussed above regarding the use of opioids to treat chronic pain was deceptive and unconscionable. The misrepresentations were material, false, and misleading, as well as unsupported by or contrary to the scientific evidence. In addition, the misrepresentations and omissions set forth above and elsewhere in this Complaint are misleading and contrary to the Manufacturing Defendants' product labels.

2. The Manufacturer Defendants Disseminated Their Misleading Messages About Opioids Through Multiple Channels

434. The Manufacturer Defendants' false marketing campaign not only targeted the medical community who had to treat chronic pain, but also patients who experience chronic pain.

435. The Manufacturer Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1) "Front Groups" with the appearance of independence from the Manufacturer Defendants; (2) Key Opinion Leaders or "KOLs", that is, doctors who were paid by the Manufacturer Defendants to promote their pro-opioid message; (3) CME programs controlled and/or funded by the Manufacturer Defendants; (4) branded advertising; (5)

[99] Samantha Liss, *Mallinckrodt Banks on New Painkillers for Sales*, St. Louis Bus. J. l (Dec. 30, 2013), http://argentcapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/.

unbranded advertising; (6) publications; (7) direct, targeted communications with prescribers by sales representatives or "detailers"; and (8) speakers bureaus and programs.

a. The Manufacturer Defendants Directed Front Groups to Deceptively Promote Opioid Use.

436. Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Manufacturer Defendants exerted influence and effective control over the messaging by these groups by providing major funding directly to them, as well as through KOLs who served on their boards. These "Front Groups" put out patient education materials, treatment guidelines and CMEs that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks.[100] Manufacturer Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of their own constituencies.

437. "Patient advocacy organizations and professional societies like the Front Groups 'play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.'"[101] "Even small organizations— with 'their large numbers and credibility with policymakers and the public'— have 'extensive influence in specific disease areas.' Larger organizations with extensive funding and outreach capabilities 'likely have a substantial effect on policies relevant to their industry sponsors.'"[102] Indeed, the U.S. Senate's report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, which arose out of a 2017 Senate investigation and, drawing on disclosures from Purdue and other opioid manufacturers, "provides the first comprehensive snapshot of the financial connections

[100] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members' Office, (February 12, 2018), https://www.hsdl.org/?view&did=808171 at 3 ("*Fueling an Epidemic*"), at 3.
[101] *Id.* at 2.
[102] *Id.*

between opioid manufacturers and advocacy groups and professional societies operating in the area of opioids policy,"[103] and found that the Manufacturer Defendants gave millions of dollars in contributions to various Front Groups.[104]

438. The Manufacturer Defendants also "made substantial payments to individual group executives, staff members, board members, and advisory board members" affiliated with the Front Groups subject to the Senate Committee's study.[105]

439. As the Senate *Fueling an Epidemic* Report found, the Front Groups "amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain."[106] They also "lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for over prescription and misbranding."[107]

440. The Manufacturer Defendants took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that Manufacturer Defendants were consistently in control of their content. By funding, directing, editing, approving, and distributing these materials, Manufacturer Defendants exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and through the Front groups, with each other to deceptively promote the use of opioids for the treatment of chronic pain.

i. American Pain Foundation

441. The most prominent of the Front Groups was the American Pain Foundation ("APF"). While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from defendants Purdue, Endo, and other manufacturers. APF received more than $10 million

[103] *Id.* at 1.
[104] *Id.* at 1, 3.
[105] *Id.* at 10.
[106] *Id.* at 12.
[107] *Id.*

in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Endo, and others to avoid using its line of credit. Endo was APF's largest donor and provided more than half of its $10 million in funding from 2007 to 2012.

442. For example, APF published a guide sponsored by Purdue and another opioid manufacturer titled *Treatment Options: A Guide for People Living with Pain* and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide, which is still available online within the state of Nevada, contains multiple misrepresentations regarding opioid use which are discussed below.

443. APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website, *www.painknowledge.com*. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including a series of "dinner dialogues." But it was Endo that substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo's control of NIPC was such that Endo listed it as one of its "professional education initiative[s]" in a plan Endo submitted to the FDA. Yet, Endo's involvement in NIPC was nowhere disclosed on the website pages describing NIPC or *www.painknowledge.org*. Endo estimated it would reach 60,000 prescribers through NIPC.

444. APF was often called upon to provide "patient representatives" for the Manufacturer Defendants' promotional activities, including for Purdue's "Partners Against Pain" and Janssen's "Let's Talk Pain." Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients. As Purdue told APF in 2001, the basis of a grant to the organization was Purdue's desire to strategically align its investments in nonprofit organizations that share its business interests.

445. In practice, APF operated in close collaboration with Manufacturer Defendants, submitting grant proposals seeking to fund activities and publications suggested by Manufacturer Defendants and assisting in marketing projects for Manufacturer Defendants.

446. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a "Master Consulting Services" Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF's funding) for any reason. Even for projects not produced during the terms of this Agreement, the Agreement demonstrates APF's lack of independence and APF's willingness to harness itself to Purdue's control and commercial interests, which would have carried across all of APF's work.

447. APF's Board of Directors was largely comprised of doctors who were on the Manufacturer Defendants' payrolls, either as consultants or speakers at medical events. The close relationship between APF and the Manufacturer Defendants demonstrates APF's clear lack of independence in its finances, management, and mission, and its willingness to allow Manufacturer Defendants to control its activities and messages. This close relationship also supports a reasonable inference that each Manufacturer Defendant that worked with it was able to exercise editorial control over its publications—even when Manufacturer Defendants' messages contradicted APF's internal conclusions. For example, a roundtable convened by APF and funded by Endo also acknowledged the lack of evidence to support chronic opioid therapy. APF's formal summary of the meeting notes concluded that: "[An] important barrier[] to appropriate opioid management [is] the lack of confirmatory data about the long-term safety and efficacy of opioids in non-cancer chronic pain, amid cumulative clinical evidence."

448. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately." Without support from Manufacturer Defendants, to whom APF could no longer be helpful, APF was no longer financially viable.

ii. American Academy of Pain Medicine and the American Pain Society

449. The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[108] The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Model Guidelines for Use of Controlled Substances for the Treatment of Pain issued by the Federation of State Medical Boards (see below), was published on the AAPM's website.

450. Since 1998, the Federation of State Medical Boards has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies."

451. AAPM's corporate council includes Purdue, Endo, Janssen, Depomed, Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Dr.

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[108] The Use of Opioids for the Treatment of Chronic Pain, *APS & AAPM (1997),* http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf *(as viewed August 18, 2017).*

Scott Fishman (2005), Dr. Perry G. Fine (2011), and Dr. Lynn R. Webster (2013), all of whose connections to the opioid manufacturers are well-documented as set forth elsewhere in this Complaint.

452. Fishman, who also served as a KOL for Manufacturer Defendants, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[109]

453. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations.

454. AAPM describes the annual event as an "exclusive venue" for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Manufacturer Defendant Purdue, Endo, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at one conference alone.

455. AAPM's staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

456. With the assistance, prompting, involvement, and funding of Manufacturer Defendants, AAPM and APS issued their own treatment guidelines in 2009 ("2009 Guidelines"), and continued to recommend the use of opioids to treat chronic pain. Fourteen of

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[109] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at http://www.medscape.org/viewarticle/500829.

the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received support from Defendants Endo, Janssen, Teva, and Purdue. Of these individuals, six received support from Purdue, eight from Teva, nine from Janssen, and ten from Endo.

457. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

458. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

459. The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated during the relevant time period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Manufacturer Defendants promoted opioids, whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these types of guidelines. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices."[110]

460. The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain, and upon information and belief, the 2009 Guidelines were created just for that purpose.

[110] 2016 CDC Guideline at 2.

461. The Manufacturer Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the 2009 Guidelines, or their financial backing of the authors of the 2009 Guidelines.

iii. The Federation of State Medical Boards

462. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

463. The FSMB finances opioid- and pain-specific programs through grants from Manufacturer Defendants.

464. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies." The 1998 Guidelines that the pharmaceutical companies helped author taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option.

465. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in Nevada.

466. *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Purdue and Endo. The publication also received support from the American Pain Foundation and the American Academy of Pain Medicine. The publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed to state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as "the leading continuing medical

education (CME) activity for prescribers of opioid medications." Nevada doctors could read the book to obtain CME credit. This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.[111]

467. The Manufacturer Defendants relied on the 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

iv. The Alliance for Patient Access

468. Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization that styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[112] It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.[113] As of June 2017, the APA listed 30 "Associate Members and Financial Supporters." The list includes Janssen, Endo, Mallinckrodt, and Purdue.

469. APA's board members have also directly received substantial funding from pharmaceutical companies.[114] For instance, board vice president Dr. Srinivas Nalamachu, who

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[111] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* 8-9 (Waterford Life Sciences 2007).
[112] *About AfPA*, The Alliance for Patient Access, http://allianceforpatientaccess.org/about-afpa (last visited Apr. 25, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.
[113] Mary Chris Jaklevic, *Alliance for Patient Access Uses Journalists and Politicians to Push Big Pharma's Agenda*, Health News Review (Oct. 2, 2017), https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists- politicians-push-big-pharmas-agenda/ (hereinafter "Jaklevic, *Non-Profit Alliance for Patient Access*").
[114] All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's Dollars for Docs database, https://projects.propublica.org/docdollars/.

practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids' side effects, including from Defendants Endo and Purdue. Other board members include Dr. Robert A. Yapundich from North Carolina, who received $215,000 from 2013 through 2015 from pharmaceutical companies, including payments by Defendant Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies, including Defendants Endo and Mallinckrodt; Dr. Howard Hoffberg from Maryland, who received $153,000 between 2013 and 2015 from pharmaceutical companies, including Defendants Endo, Purdue, and Mallinckrodt; and Dr. Robin K. Dore from California, who received $700,000 between 2013 and 2015 from pharmaceutical companies.

470. Among its activities, APA issued a "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[115] Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

> Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.
>
> * * *
>
> In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover,

[115] Pain Therapy Access Physicians Working Group, *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse, Institute for Patient Access* (Dec. 2013), http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna- cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.

> threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . .
>
> We cannot merely assume that these programs will reduce prescription pain medication use and abuse.[116]

471. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.[117]

472. In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication:

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non- pain specialty areas often look down on those who specialize in pain management – a situation fueled by the numerous regulations and fines that surround prescription pain medications.[118]

473. In conclusion, the white paper states that "[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs."[119]

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[116] *Id.* at 4-5.
[117] *Id.* at 5-6.
[118] *Id.* at 6.
[119] *Id.* at 7.

474. The APA also issues "Patient Access Champion" financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a $7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients' access to Medicare and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they appear to be given to provide cover to and reward members of Congress who have supported the APA's agenda.[120]

475. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the "suspicious orders" provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 USC §801 *et seq.* ("CSA" or "Controlled Substances Act"). The AAPM is also a signatory to this letter. An internal U.S. Department of Justice ("DOJ") memo stated that the proposed bill "could actually result in increased diversion, abuse, and public health and safety consequences"[121] and, according to DEA chief administrative law judge John J. Mulrooney ("Mulrooney"), the law would make it "all but logically impossible" to prosecute manufacturers and distributors, like the defendants here, in the federal courts.[122] The bill passed both houses of Congress and was signed into law in 2016.

v. The U.S. Pain Foundation

476. The U.S. Pain Foundation ("USPF") was another Front Group with systematic connections and interpersonal relationships with the Manufacturer Defendants. The USPF was one of the largest recipients of contributions from the Manufacturer Defendants, collecting more than $3 million in payments between 2012 and 2017 from Purdue, and others.[123] The USPF was also a critical component of the Manufacturer Defendants' lobbying efforts to reduce the limits on over-prescription. The USPF advertises its ties to the Manufacturer

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[120] Jaklevic, *Non-profit Alliance for Patient Access*, *supra*.
[121] Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS News (Oct. 17, 2017), https://www.cbsnews.com/news/ ex-dea-agent-opioid-crisis-fueled-bydrug-industry-and-congress/.
[122] John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marquette L. Rev., 333, 346 (2017).
[123] Fueling an Epidemic, *supra*.

Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (i.e. J&J), and Mallinckrodt as "Platinum," "Gold," and "Basic" corporate members.[124] Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

vi. American Geriatrics Society

477. The American Geriatrics Society ("AGS") was another Front Group with systematic connections and interpersonal relationships with the Manufacturer Defendants. The AGS was a large recipient of contributions from the Manufacturer Defendants, including Endo, Janssen, and Purdue. AGS contracted with Endo, Janssen, and Purdue to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter "2002 AGS Guidelines") and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*,[125] hereinafter "2009 AGS Guidelines"). According to news reports, AGS has received at least $344,000 in funding from opioid manufacturers since 2009.[126] AGS's complicity in the common purpose with the Manufacturer Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive upfront funding from drug companies, which would suggest drug company influence, but would instead, accept commercial support to disseminate pro-opioid publications.

478. The 2009 AGS Guidelines recommended that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy." The panel made "strong recommendations" in this regard despite "low quality of evidence" and concluded that the risk

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[124] *Id*. at 12; Transparency, U.S. Pain Foundation, https://uspainfoundation.org/transparency/ (last visited on March 9, 2018).

[125] *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331, 1339, 1342 (2009), available at https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf (last visited Apr. 25, 2018).

[126] John Fauber & Ellen Gabler, "Narcotic Painkiller Use Booming Among Elderly," *Milwaukee J. Sentinel*, May 30, 2012, https://medpagetoday.com/geriatrics/painmanagement/32967.

of addiction is manageable for patients, even with a prior history of drug abuse.[127] These Guidelines further stated that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." These recommendations and statements are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited as many as 1,833 times in Google Scholar (which allows users to search scholarly publications that would be have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.

479. Representatives of the Manufacturer Defendants, often during informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

480. Members of the AGS Board of Directors were doctors on the Manufacturer Defendants' payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs also served in leadership positions within the AGS.

b. <u>The Manufacturer Defendants Paid Key Opinion Leaders to Deceptively Promote Opioid Use.</u>

481. To falsely promote their opioids, the Manufacturer Defendants paid and cultivated a select circle of doctors who were chosen and sponsored by the Manufacturer Defendants for their supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Manufacturer Defendants' well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception that science and respected medical professionals favored the broader use of opioids. These doctors include Dr. Russell Portenoy, Dr. Lynn Webster, Dr. Perry Fine, and Dr. Scott Fishman, as set forth below.

482. Although these KOLs were funded by the Manufacturer Defendants, the KOLs were used extensively to present the appearance that unbiased and reliable medical research

[127] 2009 AGS Guidelines at 1342.

supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.

483. As the Manufacturer Defendants' false marketing scheme picked up steam, these pro-opioid KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and they were placed on boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs.

484. Through use of their KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, the Manufacturer Defendants were able to exert control of each of these modalities through which doctors receive their information.

485. In return for their pro-opioid advocacy, the Manufacturer Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. For example, Dr. Webster and Dr. Fine have received funding from Endo and Purdue.

486. The Manufacturer Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Manufacturer Defendants' agenda. The Manufacturer Defendants also kept close tabs on the content of the materials published by these KOLs. And, of course, the Manufacturer Defendants kept these KOLs well-funded to enable them to push the Manufacturer Defendants' deceptive message out to the medical community.

487. Once the Manufacturer Defendants identified and funded KOLs and those KOLs began to publish "scientific" papers supporting the Manufacturer Defendants' false position that opioids were safe and effective for treatment of chronic pain, the Manufacturer Defendants poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies or articles by their KOLs to drive prescription of opioids for chronic pain. The Manufacturer Defendants cited to, distributed, and marketed these studies and articles by their KOLs as if they were independent medical literature so that it would be

well-received by the medical community. These studies and articles were available to and were intended to reach doctors in Nevada. By contrast, the Manufacturer Defendants did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of chronic opioid therapy.[128]

488. In their promotion of the use of opioids to treat chronic pain, the Manufacturer Defendants' KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and the Manufacturer Defendants.

i. Dr. Russell Portenoy

489. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."[129]

490. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

> *The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs.* This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. *Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and*

[128] *See, e.g.*, Volkow & McLellan, *supra; see also* Matthew Miller, *et al.*, *Prescription Opioid Duration of Action and the Risk of Unintentional Overdose Among Patients Receiving Opioid Therapy*, JAMA Intern Med 2015; 175(4): 608-615.

[129] R. Portenoy & K. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986).

> *the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*[130]

According to Dr. Portenoy, the foregoing problems could constitute "compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain."[131]

491. Despite having taken this position on long-term opioid treatment, Dr. Portenoy soon became a spokesperson for Purdue and other Manufacturer Defendants, promoting the use of prescription opioids and minimizing their risks. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, co-founder of Physicians for Responsible Opioid Prescribing, described him "lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: 'Docs have been letting patients suffer; nobody really gets addicted; it's been studied.'"[132]

492. As one organizer of CME seminars who worked with Portenoy and Purdue pointed out, "had Portenoy not had Purdue's money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue's millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified.[133] Dr. Portenoy's publications and other materials were available to and were intended to reach doctors in Nevada.

493. Dr. Portenoy was also a critical component of the Manufacturer Defendants' control over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.

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[130] Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).
[131] *Id.*
[132] Sam Quinones, *Dreamland: The True Tale of America's Opiate Epidemic* 314 (Bloomsbury Press 2015).
[133] *Id.* at 136.

494. In recent years, some of the Manufacturer Defendants' KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature.[134] Dr. Portenoy has now admitted that he minimized the risks of opioids, and that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[135] He mused, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . . ."[136]

495. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and left real evidence behind:

> I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. *In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind*.[137]

496. Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: "It was pseudoscience. I guess I'm going to always have to live with that one."[138]

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[134] *See, e.g.*, John Fauber, *Painkiller Boom Fueled by Networking*, Journal Sentinel (Feb. 18, 2012), http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by- networking-dp3p2rn-139609053.html/ (reporting that a key Endo KOL acknowledged that opioid marketing went too far).

[135] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal https://www.wsj.com/articles/SB10001424127887324478304578173342657044604. (Last updated Dec. 17, 2012 11:36 AM).

[136] *Id.*

[137] [143]Harrison Jacobs, *This 1-Paragraph Letter May Have Launched the Opioid Epidemic*, AOL (May 26, 2016), https://www.aol.com/article/2016/05/26/letter-may-have-launched-opioid- epidemic/21384408/; Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be.

[138] Meier, *supra*, at 277.

ii. Dr. Lynn Webster

497. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was President of AAPM in 2013 and remains a current board member. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo's special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Endo and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly $2 million from Cephalon alone).

498. Dr. Webster created and promoted the *Opioid Risk Tool*, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's *Opioid Risk Tool* ("ORT") appear on, or are linked to, websites run by Endo and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors in Nevada.[139]

499. Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Manufacturer Defendants' promotional messages, Dr. Webster apparently believed the solution to patients' tolerance or addictive behaviors was more opioids, and he prescribed staggering quantities of pills.

[139] *See* Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

500. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the "[i]nterim results of this study suggest that [fentanyl effervescent buccal tablets are] safe and well-tolerated in patients with chronic pain and [breakthrough pain]."

iii. *Dr. Perry Fine*

501. Dr. Perry Fine's ties to the Manufacturer Defendants have been well-documented. He has authored articles and testified in court cases and before state and federal committees, and he, too, has argued against legislation restricting high-dose opioid prescription for non-cancer patients. He has served on Purdue's advisory board, participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS-AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was also on the board of directors of APF.[140]

502. Multiple videos feature Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death.

503. He has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments he received as required by his employer, the University of Utah—telling the University that he had received under $5,000 in

[140] Scott M. Fishman, MD, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306 (13) JAMA 1445 (Sept. 20, 2011), https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true. (hereinafter, "Fishman").

2010 from J&J for providing "education" services, but J&J's website states that the company paid him $32,017 for consulting, promotional talks, meals, and travel that year.[141]

504. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, in which they downplayed the risks of opioid treatment, such as respiratory depression and addiction:

> At clinically appropriate doses, . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.
>
> Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (i.e., for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.[142]

505. Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled "Optimizing Opioid Therapy," he sets forth a "Guideline for Chronic Opioid Therapy" discussing "opioid rotation" (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches over a person's "lifetime" to manage pain.[143] He states that the "goal is to improve effectiveness which is different from efficacy and safety." Rather, for chronic pain patients, effectiveness "is a balance of therapeutic good and adverse events *over the course of years*." The program assumes that opioids are appropriate treatment over a "protracted period of time," even over a patient's entire "lifetime." Fine even suggests that opioids can be used to treat sleep apnea. He further states that the associated risks of addiction and abuse can be managed

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[141] Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 9:14 AM), https://www.propublica.org/article/two-leaders- in-pain-treatment-have-long-ties-to-drug-industry (hereinafter, "Weber").

[142] Perry G. Fine, MD & Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia* 20 and 34, McGraw-Hill Companies (2004), at 20, 34. http://www.thblack.com/links/RSD/OpioidHandbook.pdf.

[143] Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

by doctors and evaluated with "tools," but leaves that for "a whole other lecture."[144] Dr. Fine's articles and educational talks were available to and were intended to reach doctors in Nevada.

iv. Dr. Scott Fishman

506. Dr. Scott Fishman is a physician whose ties to the opioid drug industry are legion. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received "market rate honoraria." As discussed below, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Manufacturer Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."[145]

507. Dr. Fishman authored a physician's guide on the use of opioids to treat chronic pain titled *Responsible Opioid Prescribing* in 2007, which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

508. In 2012, Dr. Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created:

> Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it's critical to remember that the problem of unrelieved pain remains as urgent as ever.[146]

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[144] *Id.*

[145] Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306(13) JAMA 1445 (2011); Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 2:14 PM), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug- industry.

[146] Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians*, 10-11 (Waterford Life Sciences 2d ed. 2012).

509. The updated guide still assures that "[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins."[147] Nevada doctors could read the guide to obtain CME credit.

510. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: "I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical coper' and an addict."[148] The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction." These physician's guides were available to and were intended to reach doctors in Nevada.

c. The Manufacturer Defendants Disseminated Their Misrepresentations Through Continuing Medical Education Programs.

511. Now that the Manufacturer Defendants had both a group of physician promoters and had built a false body of "literature," Manufacturer Defendants needed to make sure their false marketing message was widely distributed.

512. One way the Manufacturer Defendants aggressively distributed their false message was through thousands of CME courses.

513. A CME is a professional education program provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations' conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

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[147] *Id.*

[148] Scott M. Fishman, *Listening to Pain: A Clinician's Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).

514. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for the Manufacturer Defendants' opioid reeducation effort. As one target, Manufacturer Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Manufacturer Defendants' deceptions.

515. The Manufacturer Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects. In order to conduct such CMEs in the State of Nevada, the Manufacturer Defendants had to make the same misrepresentations regarding their opioid products to the State agencies. Because of these misrepresentations and deceptive marketing, these CMEs were available to and were intended to reach doctors in Nevada.

516. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo, and Teva. The FSMB website described it as the "leading continuing medical education (CME) activity for prescribers of opioid medications." Endo sales representatives distributed copies of *Responsible Opioid Prescribing* with a special introductory letter from Dr. Scott Fishman.

517. In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

518. The American Medical Association ("AMA") recognized the impropriety that pharmaceutical company-funded CMEs creates; stating that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen

possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."[149]

519. Physicians, including those who practice or practiced in Nevada, attended or reviewed CMEs sponsored by the Manufacturer Defendants during the relevant time period and were misled by them.

520. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, the Manufacturer Defendants could expect instructors to deliver messages favorable to them, as these organizations were dependent on the Manufacturer Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Manufacturer Defendant-driven content in these CMEs had a direct and immediate effect on Nevada prescribers' views on opioids. Producers of CMEs and the Manufacturer Defendants both measure the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

d. The Manufacturer Defendants Used "Branded" Advertising to Promote Their Products to Doctors and Consumers.

521. The Manufacturer Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs, including within the state of Nevada. The Manufacturer Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain* and *Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical Association*. The Manufacturer Defendants collectively spent more than $14 million on the medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011 total includes $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

[149] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011), at 1.

522. The Manufacturer Defendants also targeted Nevada consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient specifically requests it.[150] They also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.[151] Endo's research, for example, also found that such communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. The Manufacturer Defendants increasingly took their opioid sales campaigns directly to consumers, including through patient-focused "education and support" materials in the form of pamphlets, videos, or other publications that patients could view in their physician's office.

e. The Manufacturer Defendants Used "Unbranded" Advertising to Promote Opioid Use for Chronic Pain Without FDA Review.

523. The Manufacturer Defendants also aggressively promoted opioids in Nevada through "unbranded advertising" to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as "disease awareness"—encouraging consumers to "talk to your doctor" about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product's limits and risks. In contrast, a pharmaceutical company's "branded" advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA Guidance on pharmaceutical advertising refers to as "fair balance." Branded advertising is also subject to FDA review for consistency with the drug's FDA-approved label. Through unbranded materials, the Marketing Defendants expanded the

[150] In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay et al., *Effects of Patient Medication Requests on Physician Prescribing Behavior, Results of a Factorial Experiment* 52(2) Med. Care 294-99 (April 2014).

[151] *Id.*

overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.

524. By funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their "core messages" via their own "detailers" (an industry term for sales representatives) and speaker programs, the Manufacturer Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, CME programs, and medical conferences and seminars. To this end, the Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

525. The Manufacturer Defendants marketed opioids in Nevada through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to, and typically is not reviewed by, the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, the Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

526. Many of the Manufacturer Defendants utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue's pain-management website, *www.inthefaceofpain.com*. The website contained testimonials from several dozen "advocates," including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue paid the advocates hundreds of thousands of dollars and never publicly disclosed those payments.

f. The Manufacturer Defendants Funded, Edited, and Distributed Publications that Supported Their Misrepresentations.

527. The Manufacturer Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and

(c) was likely to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals rather than treatment goals and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

528. To accomplish their goal, the Manufacturer Defendants—sometimes through third- party consultants and/or Front Groups—commissioned, edited, and arranged for the placement of favorable articles in academic journals, including journals distributed in Nevada.

529. The Manufacturer Defendants' plans for these materials did not originate in the departments with the organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in the Manufacturer Defendants' marketing departments.

530. The Manufacturer Defendants made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Manufacturer Defendants knew that the articles distorted the significance or meaning of the underlying study, as with the Porter & Jick letter. The Manufacturer Defendants also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence. Posters are preliminary, unpublished, non-peer reviewed reports that are intended to be turned into peer- reviewed academic papers, but sometimes do not.

531. The Manufacturer Defendants published or commissioned deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised

concerns about chronic opioid therapy. These publications were available to and were intended to reach doctors in Nevada.

g. The Manufacturer Defendants Used Detailing to Directly Disseminate Their Misrepresentations to Prescribers.

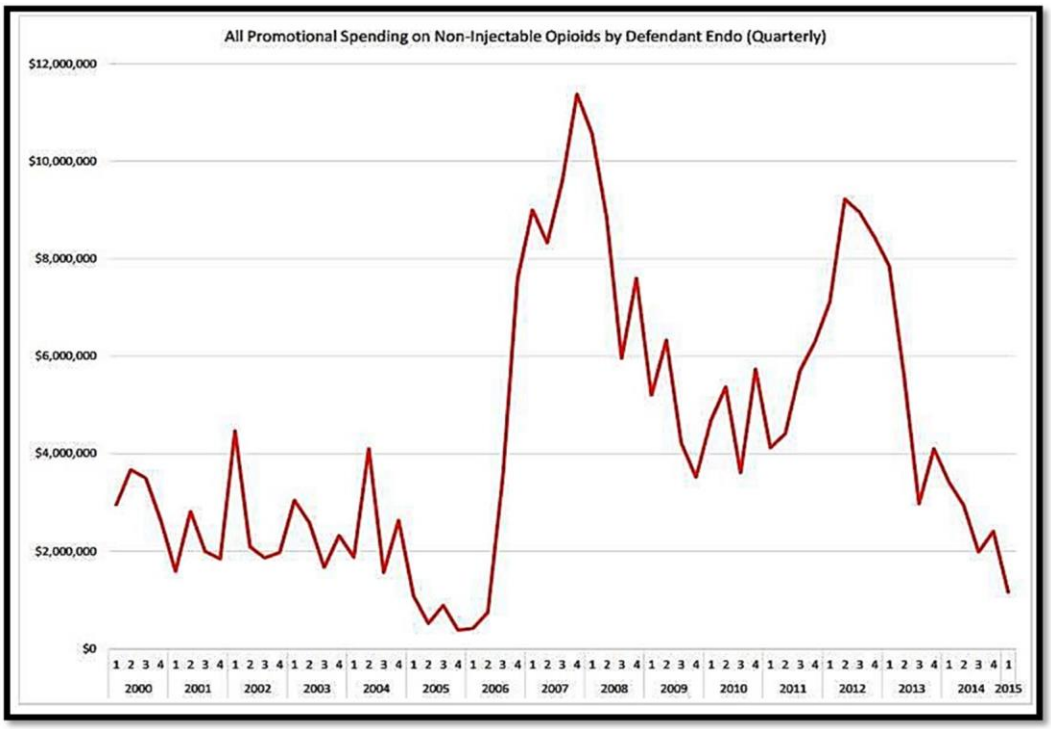
532. The Manufacturer Defendants' sales representatives executed carefully crafted marketing tactics, developed at the highest rungs of their corporate ladders, to reach targeted doctors in Nevada with centrally orchestrated messages. The Manufacturer Defendants' sales representatives also distributed third-party marketing material to their target audience that was deceptive.

533. Each Manufacturer Defendant promoted opioids through sales representatives (also called "detailers") and, upon information and belief, small group speaker programs to reach out to individual prescribers. By establishing close relationships with doctors, the Manufacturer Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain.

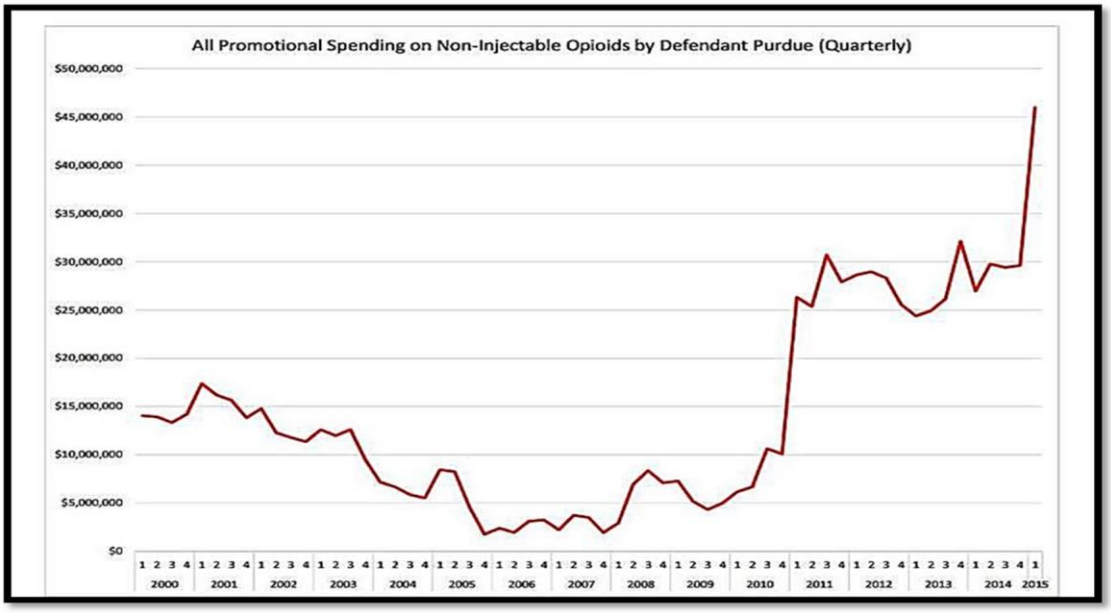
534. In accordance with common industry practice, the Manufacturer Defendants purchase and closely analyze prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management and analytics corporation started by Arthur Sackler. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors, including doctors in Nevada, and disseminated the misinformation and materials described above.

535. Manufacturer Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Manufacturer Defendants spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Manufacturer Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $13 million by Teva, and $10 million by Endo.

536. Endo's quarterly spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):



537. Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation, but then spiked to above $25 million in 2011 (for a total of $110 million that year), and continues to rise, as shown below:



h. Manufacturer Defendants Used Speakers' Bureaus and Programs to Spread Their Deceptive Messages.

538. In addition to making sales calls, Manufacturer Defendants' detailers also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Manufacturer Defendants. These speaker programs and associated speaker trainings serve three purposes: they provide an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; they qualify and/or vet doctors to be selected for a forum in which the Manufacturer Defendants can further market directly to the speaker himself or herself; and they provide an opportunity for Manufacturer Defendants to market to the speaker's peers. The Manufacturer Defendants grade their speakers, and make the offer of future opportunities contingent upon, speaking performance, post-program sales, and product usage. Purdue, Endo, and Mallinckrodt each made thousands of payments to physicians nationwide, for activities including participating on speakers' bureaus, providing consulting services, and other services.

3. The Manufacturer Defendants Targeted Vulnerable Populations.

539. The Manufacturer Defendants specifically targeted their marketing at two vulnerable populations—the elderly and veterans.

540. Elderly patients taking opioids have been found to be exposed to elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression, which occur more frequently in elderly patients.

541. The Manufacturer Defendants promoted the notion—without adequate scientific foundation—that the elderly are particularly unlikely to become addicted to opioids. The AAPM's and APS 2009 Guidelines, for example, which Purdue, Janssen, and Endo publicized, described the risk of addiction as "*exceedingly low* in older patients with no current or past history of substance abuse." (emphasis added). As another example, an Endo-sponsored CME put on by NIPC, *Persistent Pain in the Older Adult*, taught that prescribing opioids to older patients carried "possibly less potential for abuse than in younger patients." Contrary to these assertions, however, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.[152]

542. Similarly, Endo targeted marketing of Opana ER towards patients over 55 years old. Such documents show Endo treated Medicare Part D patients among the "most valuable customer segments." However, in 2013, one pharmaceutical benefits management company recommended against the use of Opana ER for elderly patients and unequivocally concluded: "[f]or patients 65 and older these medications are not safe, so consult your doctor."

543. According to a study published in the 2013 *Journal of American Medicine*, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental

[152] Kate M. Dunn, PhD et al., *Opioid Prescriptions for Chronic Pain and Overdose*, Ann Intern Med. 2010 Jan. 19; 152(2):85-92, https://www.ncbi.nlm.nih.gov/pubmed/20083827.

injuries. A 2008 survey showed that prescription drug misuse among military personnel doubled from 2002 to 2005, and then nearly tripled again over the next three years.[153] Veterans are twice as likely as non-veterans to die from an opioid overdose.[154]

544. Yet, the Manufacturer Defendants deliberately targeted veterans with deceptive marketing. For example, a 2009 publication sponsored by Purdue and Endo was written as a personal narrative of one veteran but was in fact another vehicle for opioid promotion. Called *Exit Wounds*, the publication describes opioids as "underused" and the "gold standard of pain medications" while failing to disclose significant risks of opioid use, including the risks of fatal interactions with benzodiazepines. *Exit Wounds* was distributed within Nevada. According to a VA Office of Inspector General Report, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines, despite the increased danger of respiratory depression from the two drugs together.

545. Opioid prescriptions have dramatically increased for veterans and the elderly. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59. And in 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills—four times as many as they did in 2001.

4. The Manufacturer Defendants' Scheme Succeeded, Creating a Public Health Epidemic.

a. Manufacturer Defendants Dramatically Expanded Opioid Prescribing and Use.

546. The Manufacturer Defendants necessarily expected a return on the enormous investment they made in their deceptive marketing scheme, and worked to measure and expand their success. Their own documents show that they knew they were influencing prescribers and

[153] National Institute on Drug Abuse, *Substance Abuse in the Military*, Revised March 2013, https://www.drugabuse.gov/publications/drugfacts/substance-abuse-in-military.

[154] Barbara Goldberg, "Opioid abuse crisis takes heavy toll on U.S. veterans," *Reuters*, November 10, 2017, https://www.reuters.com/article/us-usa-veterans-opioids/opioid-abuse- crisis-takes-heavy-toll-on-u-s-veterans-idUSKBN1DA1B2.

increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse.

547. Endo, for example directed the majority of its marketing budget to sales representatives—with good results: 84% of its prescriptions were from the doctors they detailed. Moreover, as of 2008, cancer and post-operative pain accounted for only 10% of Opana ER's uses; virtually all of Endo's opioid sales—and profits—were from a market that did not exist ten years earlier. Internal emails from Endo staff attributed increases in Opana ER sales to the aggressiveness and persistence of sales representatives. Similarly, according to an internal Janssen training document, sales representatives were told that sales calls and call intensity have high correlation to sales.

548. Upon information and belief, each of the Manufacturer Defendants tracked the impact of their marketing efforts to measure their impact in changing doctors' perceptions and prescribing of their drugs. They purchased prescribing and survey data that allowed them to closely monitor these trends, and they did actively monitor them. For instance, they monitored doctors' prescribing before and after detailing visits, at various levels of detailing intensity, and before and after speaker programs. Manufacturer Defendants continued and, in many cases, expanded and refined their aggressive and deceptive marketing for one reason: it worked. As described in this Complaint, both in specific instances and more generally, Manufacturer Defendants' marketing changed prescribers' willingness to prescribe opioids, led them to prescribe more of their opioids, and persuaded them to continue prescribing opioids or to switch to supposedly "safer" abuse-deterrent ("ADF") opioids.

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549. This success would have come as no surprise. Drug company marketing materially impacts doctors' prescribing behavior.[155] The effects of sales calls on prescribers' behavior is well documented in the literature, including a 2017 study that found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers.[156] The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study examined four practices, including visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in both prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

550. Manufacturer Defendants spent millions of dollars to market their drugs to prescribers and patients nationwide, including in Nevada, and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.[157] These results are

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[155] *See, e.g.*, P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); *see also* A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

[156] Larkin et al, *Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317(17) J. of Am. Med. Assoc. 1785-1795 (May 2, 2017), https://jamanetwork.com/journals/jama/fullarticle/2623607. 305(13).

[157] Research Letter, Prescription Drug Abuse: A National Survey of Primary Care Physicians, JAMA Intern. Med. (Dec. 8, 2014), E1-E3.

directly due to the Manufacturer Defendants' fraudulent marketing campaign and repeated misrepresentations.

551. Thus, both independent studies and Manufacturer Defendants' own tracking confirm that Manufacturer Defendants' deceptive marketing scheme dramatically increased their sales, including sales within Nevada.

b. Manufacturer Defendants' Deception in Expanding Their Market Created and Fueled the Opioid Epidemic.

552. Independent research demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[158] It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.[159]

553. 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. The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[160]

554. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses."[161] Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses.[162] For these reasons, the CDC concluded that efforts to reign in the prescribing of opioids for chronic

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[158] Theodore J. Cicero et al., *Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16.8 Pharmacopidemiology and Drug Safety, 827-40 (2007).

[159] Anna Lembke, M.D., *Why Doctors Prescribe Opioids to Known Opioid Abusers*, New Eng. J. Med. 2012; 367:1580-1581 (Oct. 25, 2012), https://www.nejm.org/doi/full/10.1056/NEJMp1208498.

[160] Robert M. Califf, M.D., et al., *A Proactive Response to Prescription Opioid Abuse*, New Eng. J. Med., http://www.nejm.org/doi/full/10.1056/NEJMsr1601307.

[161] Rose A. Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000- 2014*, January 1, 2016, https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.

[162] Olfson, et al., *Service Use Preceding Opioid-Related Fatality*, Am J. Psychiatry 2018 Jun 1; 175(6):538-544.

pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[163]

555. The Manufacturer Defendants' scheme was and continues to be resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain— has become a commonplace, and often first-line, treatment. The Manufacturer Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC, opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. The prescribing rate in Nevada rose during this time, from 87.7 prescriptions per 100 residents in 2006 to 100.3 in 2010.[164] Nevada's death rate from drug overdose grew dramatically in lockstep with Defendants' increasing sale and distribution of opioid drugs.[165] In 2015, more than 650,000 opioid prescriptions were dispensed in the U.S. every day on average. While previously a small minority of opioid sales, today between 80% and 90% of opioids dispensed (measured by weight) are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

F. Opioid Manufacturers Worked with the Same Consulting Company to Increase Prescription Opioid Sales.

556. The Manufacturer Defendants, particularly Purdue, Mallinckrodt, Johnson, Endo, and Actavis, did not develop and implement their marketing schemes entirely on their own. They each entered into agreements with the same Consulting Company, which created and implemented marketing schemes for the opioid manufacturers.

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[163] Rudd et al., *supra*.

[164] CDC, U.S. State Prescribing Rates, 2006 and 2011 maps for Nevada, https://www.cdc.gov/drugoverdose/maps/rxstate2015.html.

[165] Haeyoun Park & Matthew Bloch, *How the Epidemic of Drug Overdose Deaths Ripples Across America*, N.Y. Times, Jan. 18, 2016, https://www.nytimes.com/interactive/2016/01/07/us/drug- overdose-deaths-in-the-us.html.

557. The consulting services the Manufacturer Defendants received went beyond simply developing ideas or plans to boost opioid sales. It involved detailed data studies and physician studies to target those prescribers likely to write more opioid prescriptions and to target sales in specific ZIP codes where diversion, opioid abuse disorder, and opioid overdoses were especially high. This information allowed the Manufacturer Defendants to dramatically increase their opioid sales and profits, while communities were devastated by increasing numbers of opioid overdose deaths.

558. The plans developed by the Consulting Company and implemented by opioid manufacturers were designed to increase the quantity of opioid prescriptions to a higher number of people for a longer duration of the prescriptions.

559. Over 1.6 billion opioid dosage units were distributed into Nevada from 2006 to 2012. In 2011 alone, 268,988,901 opioid dosage units were shipped into Nevada, which is Nevada's highest amount for a single year. The Manufacturer Defendants who worked with the Consulting Company manufactured 38.5% of all dosage units distributed in Nevada from 2006 to 2012.

560. The Consulting Company worked so closely with the Manufacturer Defendants that they developed a close relationship wherein at times they worked day-to-day with the Manufacturer Defendants.

561. Due to confidentiality provisions in proposals and contracts, the public was unaware of the relationship between the Manufacturer Defendants and the Consulting Company. The working agreements were kept concealed from the public. These companies worked together, in secret, to increase the quantities of opioids in Nevada.

562. The Manufacturer Defendants not only turned to the Consulting Company for marketing schemes to increase opioid sales, but they also turned to the Consulting Company for assistance in building trust and improving their reputations. For example, Purdue needed to improve its reputation after its 2007 guilty plea related to the misrepresentations it made regarding OxyContin. The Consulting Company provided its consulting services and, as a

result, Purdue sold even more opioids into targeted markets with documented histories of opioid diversion, opioid abuse, and opioid overdose deaths.

563. This reputation and brand building was necessary for all of the Manufacturer Defendants as the opioid epidemic became increasingly publicized and questions arose regarding the safety and efficacy of prescription opioids.

564. After the guilty pleas entered by Purdue's parent company and executives in 2007, the FDA began asking opioid manufacturers to develop Risk Evaluation and Mitigation Strategies ("REMS"), which are plans for assessing and mitigating the risk posed by prescription opioids. The FDA's requirements for a REMS could vary by opioid manufacturer, but generally required training and certification for prescribers and dispensing pharmacies, as well as recording and maintaining physician-patient agreements. The FDA REMS requirements had the potential to drastically reduce Manufacturer Defendants' sales and profits, leading them to engage the Consulting Company to assist in placating the FDA while simultaneously increasing opioid sales. The Consulting Company believed it would benefit manufacturers of Class II opioids to band together to ward off the strict treatment from the FDA.

565. The Consulting Company was successful in organizing the manufacturers in banding together against the FDA's "elements to assure safe use," which included training and certification of prescribers, training and certification of dispensing pharmacies, and the recording and maintenance of physician-patient agreements. The FDA, after being pressured by the group of opioid manufacturers, did not require the "elements to assure safe use," which was a substantial victory for the opioid manufacturers orchestrated by the Consulting Company.

566. Ultimately, each Manufacturer Defendant wanted its opioid products to perform well on the market without roadblocks and penalties from the FDA. In order to do so, they needed consulting services to reframe their messaging to the FDA and other regulatory agencies and refocus their marketing to target the prescribers in the areas that were hardest hit by opioid diversion, abuse, and overdose deaths.

567. The Consulting Company developed marketing schemes to combat the FDA requirements, including paying doctors for information regarding how they treated patients, their attitudes towards prescribing opioids, and their reactions to messages being developed to promote opioids. This information was then used to develop physician segments and test messaging that would be used for future opioid products, including Purdue's new formulation of OxyContin. Different messaging was developed for different physician segments. The ultimate goal of this messaging for Purdue's OxyContin was to start more opioid naïve patients on OxyContin, move extended-release patients to OxyContin, move existing OxyContin patients on to higher doses, and prolong the amount of time patients took OxyContin.

568. The marketing and scheming was not limited to Purdue. J&J, Endo, Mallinckrodt, and Actavis, all worked with the same firm to increase the sale of their prescription opioid products. Though the nuances to the scheme was slightly different from manufacturer to manufacturer, the goal was the same, to target specific physicians to prescribe more, to more people for a longer duration. The Consulting Company developed a granular approach to target the physicians that were opioid friendly in order to drive up their prescription numbers, and the opioid manufacturers implemented the plans. They targeted areas with already well documented opioid diversion, abuse, and death problems to increase opioid sales. They also identified segments of the population most likely to abuse opioids – i.e. men in their 30s and 40s with chronic pain.

569. The Consulting Company also turned to the idea of "abuse-deterrent" formulas, touting the myth that these new formulations were somehow safer, less habit forming, and better for long-term use. None of that information was based in truth, but it was created to address the fears and concerns of physicians and patients.

570. The marketing schemes developed by the Consulting Company and implemented by the opioid manufacturers worked. Sales of prescription opioids grew and remained high even as more information came to light regarding the dangers of those drugs. These opioid manufacturers had record sales in Nevada in 2011, the same year that Nevada

received the highest dosage units of opioids and also had its highest rate of opioid overdose deaths.

571. All the while, these Manufacturer Defendants had the benefit of information the Consulting Company obtained through its work for the FDA and other government agencies who were working to combat the opioid crisis.

572. Together, the Manufacturer Defendants, implemented marketing schemes developed for them by the same Consulting Company, and fueled the opioid market and the opioid epidemic.

G. Defendants Throughout the Supply Chain Deliberately Disregarded Their Duties to Maintain Effective Controls to Prevent Diversion and to Identify, Report, and Take Steps to Halt Suspicious Orders.

573. Through their systematic and deceptive marketing schemes, the Manufacturer Defendants created a vastly and dangerously larger market for opioids both in Nevada and nationwide. All of the Defendants, including the Distributor Defendants, compounded this harm by facilitating the supply of far more opioids than could have been justified to serve that market. The failure of the Defendants to maintain effective controls and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious breached both their State statutory and common law duties.

574. For over a decade, as the Manufacturer Defendants increased the demand for opioids, all the Defendants, including the Distributor Defendants, aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

575. Both the Manufacturer Defendants and the Distributor Defendants have several responsibilities under Nevada law with respect to control of the supply chain of opioids. First, they must set up a system to prevent diversion, including excessive volume and other suspicious orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All suspicious orders must be reported to relevant enforcement authorities and the Nevada Board of Pharmacy. Further, they must also stop shipment of any order which is flagged as suspicious and should only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.

1. All Defendants Have a Duty to Provide Effective Controls and Procedures to Guard Against Theft and Diversion, and to Report Suspicious Orders and Not to Ship Those Orders Unless Due Diligence Disproves Their Suspicions.

576. Multiple sources, including Nevada statutes and regulations, impose duties on the Manufacturer Defendants and the Distributor Defendants to provide effective controls and procedures to guard against theft and diversion of opioid drugs. Multiple sources also impose duties on all the Defendants to report suspicious orders and to not ship such orders unless due diligence disproves those suspicions.

577. Under the common law, all Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By flooding the State with more opioids than could be used for legitimate medical purposes, by failing to provide effective controls and procedures against theft and diversion, and by filling and failing to report orders that they knew or should have known were likely being diverted for illicit uses, Defendants breached that duty and both created and failed to prevent a foreseeable risk of harm.

578. Each of the Defendants assumed a duty, when speaking publicly about opioids and their efforts to combat diversion, to speak accurately and truthfully.

579. The Manufacturer Defendants and Distributor Defendants also had multiple duties under Nevada statutes and regulations. Opioids are Schedule II controlled substances. NAC § 453.520. As such, opioids are defined as substances that pose a high potential for abuse that may lead to severe psychological or physical dependence. NRS § 453.176.

580. Under Nevada law, each of the Defendants was required to be registered through the Nevada Board of Pharmacy. NAC § 453.110; NRS § 639.070.

581. The Nevada Board of Pharmacy governs the licensing of wholesale drug distributors in this state. NRS § 639.070. *See also* NRS §§ 639.009; 639.0085; 639.012; 639.0155; 639.016; 639.233 (including manufacturers, repackagers, chain drug warehouses, wholesale drug warehouses, and retail pharmacies within the scope of the Nevada wholesale distributing regulations). Wholesalers and wholesale distributors are subject to additional licensing requirements. NRS §§ 639.500 – 639.515.

582. As registrants, each of the Defendants was required to maintain effective controls and procedures to guard against theft and diversion (*see* NAC §§ 453.400, 435.410; NRS §§ 639.500 – 639.515, 639.585) and to operate in compliance with all applicable federal, state and local laws and regulations. *See* NRS §§ 639.510. Defendants violated their obligations and breached their duties under Nevada law.

583. Specifically, under Nevada law, it is "[u]nlawful to manufacture, engage in wholesale distribution, compound, sell or dispense or permit to be manufactured, distributed at wholesale, compounded, sold or dispensed, any drug, poison, medicine or chemical," without first complying with the regulations adopted by the Nevada Board of Pharmacy. NRS § 639.100.

584. Under Nevada law, each of the Defendants was required to provide effective controls and procedures to guard against the theft and diversion of opioid drugs. *See* NAC § 453.400 ("[a]ll applicants and registrants shall establish and maintain effective controls and procedures to prevent or guard against theft and misuse of controlled substances").

585. In addition, the Nevada Board of Pharmacy has the power to regulate the "means of recordkeeping and storage, handling, sanitation and security of drugs" including those drugs "stored for the purpose of wholesale distribution." NRS § 639.070.

586. The Nevada Controlled Substances Act and Administrative Code incorporate by reference relevant federal laws and regulations. *See, e.g.*, NAC §§ 453.100; 453.120; 453.220; 453.410. In fact, wholesalers are defined by 21 CFR § 205.3(g) as an entity that "supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law." NRS § 639.016. Additionally, it is grounds for suspension or revocation of a license or registration to violate "any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs." NRS § 639.210(11).

587. Under Nevada law, it is unlawful for a person who is licensed to engage in wholesale distribution to fail to "deliver to another person a complete and accurate statement of prior sales for a prescription drug, if such a statement is required, before selling or otherwise transferring the drug to that person." NRS § 639.550(1). Additionally, it is unlawful for a wholesaler to fail to "acquire a complete and accurate statement of prior sales for a prescription drug, if such a statement is required, before obtaining the drug from another person." NRS § 639.550(2). Furthermore, Nevada law requires wholesalers, manufacturers, and their employees to adopt and abide by a marketing code of conduct, enforce policies regarding investigation into compliance and corrective actions, and submit and report certain information to the Board. NRS § 639.570.

588. Both Manufacturer Defendants and Distributor Defendants have violated their duties under the Nevada Controlled Substances Act and the Nevada Administrative Code. *See, e.g.*, NRS §§ 639.100, 639.210, 639.550, 639.570; NAC §§ 453.110, 453.400, 435.410.

589. Defendants violated their duties as licensed wholesale distributors by selling huge quantities of opioids that were diverted from their lawful, medical purpose, thus causing an opioid and heroin addiction and overdose epidemic in this State.

590. A reasonable manufacturer or distributor of a Schedule II substance would be on notice of suspicious orders such as orders of an unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. These criteria are disjunctive and are not all-inclusive. For example, 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. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

591. To be clear, the Manufacturer Defendants were required to comply with the same licensing and permitting requirements as the Distributor Defendants. *See* NRS § 639.233 (requiring manufacturers and distributors to register with the Nevada Board of Pharmacy); NRS § 639.570 (requiring manufacturers and distributors to adopt a marketing code of conduct and requiring annual audits to monitor compliance); NRS § 639.288 (requiring manufacturers and distributors to comply with state laws in handling, selling, possessing, or dealing such drugs).

592. The same legal duties to prevent diversion and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under Nevada law. *See, e.g.,* NAC § 453.400; NRS §§ 639.233, 639.570. Like the Distributor Defendants, the Manufacturer Defendants also breached these duties.

593. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the

distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

594. In sum, all Defendants have many responsibilities under Nevada law related to controlling the supply chain of opioids. They must set up a system to prevent diversion, including identifying excessive volume and other suspicious orders by reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All suspicious orders or noncompliance with a marketing code of conduct must be reported to relevant enforcement authorities.

595. State statutes and regulations reflect a standard of conduct and care below which reasonably prudent manufacturers and distributors would not fall. Together, these laws and industry guidelines make clear that Distributor and Manufacturer Defendants alike possess and are expected to possess specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the supply chain is not properly controlled.

596. Further, these laws and industry guidelines make clear that the Distributor Defendants and Manufacturer Defendants alike have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

597. Since their inception, Distributor Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products

and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, Distributor Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For example, Distributor Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Distributor Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Distributor Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

598. Manufacturer Defendants also have specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors' offices and pharmacies, and from their purchase of data from commercial sources, such as IMS Health (now IQVIA). Their extensive boots-on-the-ground sales forces allow Manufacturer Defendants to observe the signs of suspicious prescribing and dispensing discussed elsewhere in the Complaint—lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few. In addition, Manufacturer Defendants regularly mined data, including, upon information and belief, chargeback data, that allowed them to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusually high dose prescribing that would have alerted them, independent of their sales representatives, to suspicious prescribing. These information points gave Manufacturer Defendants all the insight into prescribing and dispensing conduct they would have needed to prevent diversion and fulfill their obligations under Nevada and related laws.

599. Defendants have a duty to, and are expected to, be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.

600. Each of the Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Nevada.

601. Thus, each Defendant owes a duty under Nevada law to monitor and detect suspicious orders of prescription opioids.

602. Each Defendant owes a duty under Nevada law to investigate and refuse suspicious orders of prescription opioids.

603. Each Defendant owes a duty under Nevada law to report suspicious orders of prescription opioids, including suspicious orders originating outside Nevada that would likely result in distribution of Defendants' opioids into Nevada .

604. Each Defendant owes a duty under Nevada law to prevent the diversion of prescription opioids into illicit markets in Nevada.

605. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

606. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in Nevada and the damages caused thereby.

607. Defendants breached these duties by failing to: (a) control the supply chain; (b) maintain effective controls, procedures and security to prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of serious overuse of opioids.

2. Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders.

608. The reason for the reporting rules is to create a "closed" system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified

approach to narcotic and dangerous drug control. Both because distributors handle large volumes of controlled substances, and because they are uniquely positioned based on their knowledge of their customers and orders, distributors are supposed to act as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market. Because of this role, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses as it did here.

609. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

610. Recently, Mallinckrodt, a prescription opioid manufacturer, admitted in a settlement with DEA that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA." Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product." Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[166]

611. Trade organizations to which Defendants belong have acknowledged that wholesale distributors have been responsible for reporting suspicious orders for more than 40 years. The Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), a trade association of pharmaceutical distributors

[166] Administrative Memorandum of Agreement, available at https://www.justice.gov/usao-edmi/press-release/file/986026/download.

to which Distributor Defendants belong, has long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society." Guidelines established by the HDA also explain that distributors, "[a]t the center of a sophisticated supply chain . . . are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[167]

612. The DEA also repeatedly reminded the Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. Each of the Distributor Defendants attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion

613. The DEA advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances that they are "one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant

[167] Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[168] The DEA's September 27, 2006 letter also expressly reminded them that registrants, in addition to reporting suspicious orders, have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[169] The same letter warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[170]

614. The DEA sent another letter to Defendants on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[171] The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[172]

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[168] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), *filed in Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

[169] *Id.* at 2.

[170] *Id.*

[171] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

[172] *Id.*

3. Defendants Worked Together to Inflate the Quotas of Opioids They Could Distribute.

615. Finding it impossible to legally achieve their ever-increasing sales ambitions, Defendants engaged in the common purpose of increasing the supply of opioids through deceptive means, thereby falsely increasing the quotas that governed the manufacture and distribution of their prescription opioids.

616. Wholesale distributors such as the Distributor Defendants had close financial relationships with both Manufacturer Defendants and customers, for whom they provide a broad range of value-added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their dispensing customers and would be difficult and costly for the dispenser to reproduce. For example, "[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock." *Fed. Trade Comm'n v. Cardinal Health, Inc*., 12 F. Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers." Wholesalers typically also offer marketing programs, patient services, and other software to assist their dispensing customers.

617. Distributor Defendants had financial incentives from the Manufacturer Defendants to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders or using any effective controls to prevent diversion. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

618. The Manufacturer Defendants engaged in the practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The *Washington Post* has described the practice as industry-wide, and the HDA includes a "Contracts and Chargebacks Working Group," suggesting a standard practice. Further, in a recent settlement with the DEA, Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors)." The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants," meaning pharmacies or other dispensaries, such as hospitals. Manufacturer Defendants buy data from pharmacies as well. This exchange of information, upon information and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well.

619. The contractual relationships among the Defendants also include vault security programs. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opioids. The manufacturers negotiated agreements whereby the Manufacturer Defendants installed security vaults for the Distributor Defendants in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

620. In addition, Defendants worked together to achieve their common purpose through trade or other organizations, such as the Pain Care Forum ("PCF") and the HDA.

621. The PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding, including the Front Groups described in this Complaint. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

622. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[173] Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[174]

623. Rather than abide by these public safety statutes, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[175]

624. The Defendants who stood to profit from expanded prescription opioid use are members of and/or participants in the PCF. In 2012, membership and participating organizations included Endo, Purdue, and Actavis.[176] Each of the Manufacturer Defendants worked together through the PCF. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a

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[173] Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity, https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller- echochamber-shaped-policy-amid-drug-epidemic. (Last Updated Dec. 15, 2016, 9:09 AM) (emphasis added).

[174] *Id.*

[175] *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-slowed-enforcement-while-the-opioid- epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; *see also* Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea- enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had- no-leadership-in-wv-amid-flood-of-pain-pills-.

[176] Mallinckrodt became an active member of the PCF sometime after 2012.

minimum, through their trade organization, the HDA.[177] The Distributor Defendants participated directly in the PCF as well.

625. Additionally, the HDA led to the formation of interpersonal relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants, including Actavis, Endo, Purdue, and Mallinckrodt, were members of the HDA. The HDA and each of the Distributor Defendants eagerly sought the active membership and participation of the Manufacturer Defendants by advocating for the many benefits of members, including "strengthen[ing] . . . alliances."[178]

626. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[179] Clearly, the HDA and the Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and "alliances" between the Manufacturer Defendants and Distributor Defendants.

627. The application for manufacturer membership in the HDA further indicates the level of connection among the Defendants and the level of insight that they had into each other's businesses.[180] For example, the manufacturer membership application must be signed by

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[177] PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings- Schedule-amp.pdf. The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. *Executive Committee*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/executive-committee (last accessed Apr. 25, 2018).

[178] *Manufacturer Membership*, Healthcare Distribution Alliance, https://healthcaredistribution.org/about/membership/manufacturer (last accessed Apr. 25, 2018).

[179] *Id.*

[180] *Manufacturer Membership Application*, Healthcare Distribution Alliance,

a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

628. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their "most recent year end net sales" through wholesale distributors, including the Distributor Defendants AmerisourceBergen, Anda, Inc., Cardinal Health, McKesson, and their subsidiaries.

629. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Manufacturer Defendants and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

630. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[181] The conferences also gave the Manufacturer Defendants and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[182] The HDA and its conferences were and continue to be significant opportunities for the Manufacturer Defendants and Distributor Defendants to interact at a high-level of leadership. It is clear that the Manufacturer Defendants have embraced this opportunity by attending and sponsoring these events.[183]

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https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-application.ashx?la=en.

[181] *Business and Leadership Conference – Information for Manufacturers*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-business-and- leadership-conference/blc-for-manufacturers.

[182] *Id.*

[183] *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-distribution-management-conference.

631. After becoming members of HDA, Defendants were eligible to participate on councils, committees, task forces and working groups, including:

1. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."

2. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributor and manufacturer members.

3. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributor and manufacturer members.

4. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.

5. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.

632. The Distributor Defendants and Manufacturer Defendants also participated, through the HDA, in webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship

notices, and invoices.[184] For example, on April 27, 2011, the HDA offered a webinar to "accurately and effectively exchange business transactions between distributors and manufacturers…." The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell prescription opioids.

633. Taken together, the interaction and length of the relationships between and among the Manufacturer Defendants and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly-knit industry. The Manufacturer Defendants and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids in the state of Nevada and nationwide.

634. The HDA and the PCF are but two examples of these overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants were in communication and cooperating with each other during the relevant time period.

635. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances* (the "Industry Compliance Guidelines") regarding diversion. As the HDA (then the HDMA) explained in an amicus brief, the Industry Compliance Guidelines were the result of "[a] committee of HDMA members contribut[ing] to the development of this publication" beginning in late 2007.[185]

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[184] *Webinar Leveraging EDI: Order-to-Cash Transactions CD Box Set*, Healthcare Distribution Alliance, (Apr. 27, 2011), https://www.healthcaredistribution.org/resources/webinar-leveraging- edi.

[185] *See* Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. of Justice*, No. 12- 5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *5.

636. This statement by the HDA and the Industry Compliance Guidelines themselves support the allegation that Defendants utilized the HDA to form agreements about their approach to their duties under controlled substances laws. As John M. Gray, President/CEO of the HDA stated in April 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Here, it is apparent that all of the Defendants, working together, found the same balance – an overwhelming pattern and practice of failing to identify, report or halt suspicious orders and failure to prevent diversion, all the while obscuring naked profit motives with opaque concerns about drug "access."

637. The Defendants' scheme involved a decision-making structure driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the state and federal government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and to identify, report or halt suspicious orders or report them to any appropriate agencies.

638. The Defendants worked together to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Marketing and Distributor Defendants did this through their participation in the PCF and HDA.

639. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas, and Procurement Quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease the production quotas for prescription opioids due to diversion of suspicious orders.

640. The Defendants also had reciprocal obligations to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other's compliance with their reporting obligations.

641. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure the continued appearance of consistency in their dealings with DEA.

642. The desired appearance of consistency was achieved. As described below, none of the Defendants reported suspicious orders as required by law, and the flow of opioids continued unimpeded.

4. Defendants Kept Careful Track of Prescribing Data and Knew About Diversion and Suspicious Orders and Prescribers.

643. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor and Marketing Defendants but has not been disclosed to the public.

644. Publicly available information confirms that the Manufacturer Defendants and Distributor Defendants funneled far more opioids into communities across the United States than could have been expected to serve legitimate medical use and ignored other red flags of suspicious orders. This information, along with the information known only to the Manufacturer Defendants and Distributor Defendants, would have alerted them to likely signs of diversion and potentially suspicious orders of opioids.

645. This information includes the following facts:

1. Distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

2. Manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;

3. Manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion, as described elsewhere in this Complaint;

4. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and

5. Manufacturer Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

646. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids – even the artificially wider market for chronic pain.

647. At all relevant times, the Defendants were in possession of national, regional, state, and local prescriber-and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies, including but not limited to: IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the "Data Vendors").

648. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[186] The "know your customer" questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

649. Defendants purchased nationwide, regional, state, and local prescriber- and patient- level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors' information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.[187]

650. IMS Health, for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.[188]

651. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple physicians,

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[186] *Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances*, Drug Enforcement Admin. Diversion Control Div., https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr., Kathleen H. Dooley, Esq. *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC (Oct. 2010), https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

[187] A Verispan representative testified that the Supply Chain Defendants use the prescribing information to "drive market share." *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 661712, *9-10 (Feb. 22, 2011).

[188] Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How We Turned a Mountain of Data into a Few Information-Rich Molehills*, (accessed on February 15, 2018), http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&type=pdf, Figure 2 at p.3.

organized by territory, regarding competing drugs, and analyzed the market share of those drugs.[189]

652. This information allowed the Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.[190]

653. Defendants were, therefore, collectively aware of the suspicious orders that flowed daily from their manufacturing and distribution facilities because Defendants have made it part of their collective business to know where those orders went and to whom.

654. Defendants refused to maintain effective controls to prevent diversion, and refused to identify, investigate and report suspicious orders to the DEA or the Nevada Board of Pharmacy when they became aware of the same, despite their actual knowledge of drug diversion rings. For instance, as described in detail below, Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[191] and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include seventy-six (76) actions involving orders to show cause and forty-one (41) actions involving immediate suspension orders, all for failure to report suspicious orders.[192]

655. In fact, Manufacturer and Distributor Defendants internalized illegal diversion as an expected and foreseeable result of their business and incorporated those expectations into their business planning.

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[189] Joint Appendix in *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 705207, *467-471 (Feb. 22, 2011).

[190] In *Sorrell*, expert Eugene "Mick" Kolassa testified, on behalf of the Data Vendor, that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id.*; *see also* Joint Appendix in *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *204 (Feb. 22, 2011).

[191] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

[192] *Id.*

656. Sales representatives were also aware that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

> Actions have consequences – so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

657. Moreover, Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, Dr. Rand, operated a pill mill in Reno, Nevada, an activity for which he has been indicted, charged, and sentenced. Additionally, as discussed, *supra*, Dr. Steven Holper in Clark County, Nevada, has been indicted on charges related to the excessive Subsys prescriptions he has written to patients.

658. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this is an organized drug ring[.]"[193] She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report."[194] This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after

[193] Harriet Ryan et al., *More Than 1 million OxyContin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, LOS ANGELES TIMES (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2//.
[194] *Id.*

the clinic was shut down in 2010 to inform the authorities. This was a pattern and practice in the medical community of which Purdue was familiar and about which it did nothing.

659. As to Actavis, a Kadian prescriber guide discusses abuse potential of Kadian. It is full of disclaimers that Actavis has not done any studies on the topic and that the guide is "only intended to assist you in forming your own conclusion." However, the guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) "KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." The guide is copyrighted by Actavis in 2007, before Actavis officially purchased Kadian from Alpharma.

660. Defendants' obligations to maintain effective controls against diversion and to report suspicious prescribing ran head on into their marketing strategy. Defendants did identify doctors who were their most prolific prescribers, not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement, nor to report those doctors who drove Defendants' sales.

661. Defendants purchased data from IMS Health (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own and competitors' sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high frequency detailing visits.

662. For example, at a national sales meeting presentation in 2011, Actavis pressed its sales representatives to focus on its high prescribers: "To meet and exceed our quota, we must continue to get Kadian scripts from our loyalists. MCOs will continue to manage the pain products more closely. We MUST have new patient starts or we will fall back into 'the big leak'. We need to fill the bucket faster than it leaks." "The selling message should reflect the

opportunity and prescribing preferences of each account. High Kadian Writers / Protect and Grow / Grow = New Patient Starts and Conversions." In an example of how new patients plus a high-volume physician can impact performance: "102% of quota was achieved by just one high volume physician initiating Kadian on 2-3 new patients per week."

663. This focus on marketing to the highest prescribers had two impacts. First, it demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids. But instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

664. Whenever examples of opioid diversion and abuse have drawn media attention, Purdue and other Manufacturer Defendants have consistently blamed "bad actors." For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was "fooled" by the doctor: "The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us."[195]

665. But given the closeness with which Defendants monitored prescribing patterns through IMS Health data, it is highly improbable that they were "fooled." In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino's clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Indeed, a Purdue executive referred to Purdue's tracking system and database as a "gold mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.[196]

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[195] Meier, *supra*, at 179.

[196] Harriet Ryan et al., *More Than 1 million OxyContin Pills Ended Up in the Hands of Criminals and Addicts, supra.*

666. As discussed below, Endo knew that Opana ER was being widely abused. Yet, as the New York Attorney General investigation into Endo revealed, Endo sales representatives were not aware that they had a duty to report suspicious activity and were not trained on the company's policies or duties to report suspicious activity. Worse, Endo paid bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal prescribing.

667. Sales representatives making in-person visits to such clinics were likewise not fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives alike, Manufacturer Defendants and their employees turned a collective blind eye, allowing certain clinics to dispense staggering quantities of potent opioids and feigning surprise when the most egregious examples eventually made the nightly news.

5. Defendants Failed to Report Suspicious Orders or Otherwise Act to Prevent Diversion.

668. As discussed above, Defendants failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into communities in Nevada and across America. Despite the notice described above, and in disregard of their duties, Defendants continued to pump massive quantities of opioids despite their obligations to control the supply, prevent diversion, report, and take steps to halt suspicious orders.

669. Governmental agencies and regulators have confirmed (and in some cases, Defendants have admitted) that Defendants did not meet their obligations and engaged in especially blatant wrongdoing.

670. For example, on January 5, 2017, McKesson entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150 million civil penalty for, inter alia, failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Santa Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA. McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the]

DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."

671. McKesson further admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the

CSA and the CSA's implementing regulations, 21 CFR Part 1300 et seq., at the McKesson Distribution Centers." Due to these violations, McKesson agreed to a partial suspension of its authority to distribute controlled substances from certain of its facilities some of which, investigators found "were supplying pharmacies that sold to criminal drug rings."

672. Additionally, Defendant CVS Pharmacy, Inc. owned and/or operated, more than 9,800 pharmacies in the United States. Collectively CVS pharmacies made Defendant CVS Pharmacy, Inc. one of the largest customers of McKesson.

673. Using the economic leverage resulting from being one of its largest customers, Defendant CVS Pharmacy, Inc. negligently and/or purposefully limited the ability of McKesson to fulfill its regulatory and statutory responsibilities to prevent diversion and monitor suspicious orders of controlled substances placed by CVS pharmacies.

674. Beginning in 2008, with the implementation of the McKesson Controlled Substance Monitoring Program (CSMP), CVS represented to McKesson as follows:

- That it had a controlled substance monitoring program;
- That it possessed a dedicated Regulatory Control/Compliance resource that was responsible for monitoring pharmacy purchases of controlled substances;
- That its pharmacy management regularly reviews pharmacy purchases of controlled substances;
- That it possessed the process and tools used to monitor controlled substance purchases made by individual pharmacies.

675. Specifically, CVS represented the existence of a more comprehensive "Viper" regulatory program that it claimed the "DEA is very well aware of." The Viper program was further represented to be a monitoring program. Don Walker, Senior Vice President of Distribution at McKesson, felt comfortable allowing opioid threshold increases by McKesson, without CVS explanation, because of McKesson's understanding that "CVS is also co-managing on their side with Viper and their regulatory team."

676. As a result of the misrepresentations made by CVS with respect to the existence of a controlled substance monitoring program, McKesson gave its "proxy" to CVS headquarters to perform due diligence investigations of potentially suspicious orders and individual CVS pharmacies that were ordering excessive amounts of prescription opioids. McKesson inquiries concerning suspicious orders and activities of individual CVS pharmacies were made to Defendant CVS Pharmacy, Inc. and not to individual CVS pharmacies. McKesson negligently relied upon the due diligence efforts and findings of CVS in its decisions to ship opioids to CVS pharmacies. Additionally, prescription opioid thresholds for CVS pharmacies were increased by McKesson without input or explanation from CVS, again relying upon CVS representations of internal regulatory controls. McKesson stated in 2012 that "the assumption is made that they have done their due diligence."

677. Contrary to the representations of CVS, Viper was not a monitoring program. CVS's 30(b)(6) witness Mark Vernazza admitted at deposition that Viper "was not deemed an SOM report." Viper was no more than a theft report that provided no ability to evaluate specific orders of controlled substances placed by CVS pharmacies to McKesson. In reality, CVS had no policies, procedures or programs to monitor prescription opioid orders placed by its pharmacies to McKesson or any other outside vendor until 2014.

678. When McKesson sought to fulfill its responsibilities, efforts to monitor CVS pharmacies were resisted by CVS as early as 2008. In 2008 and 2010 CVS refused to provide McKesson sales or dispensing information for individual stores in order to establish accurate opioid thresholds. In March of 2012, Don Walker, the Senior Vice President of Distribution at McKesson and Tom McDonald, Director of Regulatory Affairs, met with CVS. At that

meeting, CVS was requested to provide information with regard to "cash sales ratio per store." Don Walker of McKesson acknowledged that this was "important information" to have to identify diversion. CVS refused to provide this information. Mr. Walker described this as a "business decision" on the part of CVS.

679. At the same meeting described above, McKesson requested that CVS provide it with "mechanisms for the review of prescribing doctors". Mr. Walker testified that this information was requested in an attempt to "improve our abilities to monitor all of our retail national account pharmacies". McKesson did not have such information relating to CVS at this point in time. According to Mr. Walker, the DEA, as early as 2006, had identified prescribing doctors as a focus of monitoring. CVS again refused to provide this information.

680. At the March 2012 meeting described above, McKesson additionally requested that CVS provide them with "the ratio of prescriptions per doctor." Prior to 2012, McKesson had not been provided such information. CVS again refused to provide such information.

681. At the March 2012 meeting described above, McKesson requested that CVS provide them with a "rate of growth of each store, year over year." McKesson had no such information prior to this meeting and CVS refused to provide it at that time. Again, CVS indicated that such information was "proprietary."

682. As a result of its misrepresentations, affirmative acceptance, and refusals outlined above, although CVS knew the importance of the data and responsibility for the monitoring of prescription opioid orders distributed from McKesson to CVS Pharmacies throughout the United States including Nevada and Plaintiff's communities specifically, CVS failed to make reasonable efforts to maintain effective controls against diversion of controlled substances and to monitor suspicious orders of controlled substances placed by CVS pharmacies to McKesson.

683. Similarly, in 2017, the Department of Justice fined Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The government alleged that "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled

substances—orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."

684. On December 23, 2016, Cardinal Health agreed to pay the United States $44 million to resolve allegations that it violated the Controlled Substances Act in Maryland, Florida and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA. In the settlement agreement, Cardinal Health admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

a. "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 CFR §1301.74(b)";

b. "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 CFR §1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 USC §842(a)(5)"; and

c. "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 USC §828 and 21 CFR Part 1305."

685. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws as well as for the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These quantities alone are sufficient to show that the Defendants failed to control the supply chain or

to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for $16 million to the state; Cardinal Health settled for $20 million.

686. Upon information and belief, AmeriSourceBergen, Cardinal Health, and McKesson, are three (3) of the largest distributors in the State of Nevada, resulting in excessive shipments of opioids into Nevada's communities.

687. Thus, it is the various governmental agencies who have alleged or found—and the Defendants themselves who have admitted—that the Defendants, acting in disregard of their duties, pumped massive quantities of opioids into communities around the country despite their obligations to control the supply, prevent diversions, and report and take steps to halt suspicious orders.

688. The sheer volume of prescription opioids distributed to pharmacies in the State of Nevada is excessive for the medical need of the community and facially suspicious.[197] Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[198]

689. Not only did Defendants fail to maintain effective controls to prevent diversion of controlled substances, they invested time, research, and funds to ensure the supply would be large enough for the excessive demand. Upon information and belief, J&J created and supplied a more potent strand of poppy that ultimately propped up the excessive, illegitimate, and harmful demand of opioids across the nation and in the State of Nevada, specifically.

690. The State is of the information and belief that the Defendants failed to report "suspicious orders" originating from Nevada to the DEA, the Nevada Department of Public Safety, and/or the Nevada Board of Pharmacy as they were required to do under Nevada law.

691. The Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Nevada.

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[197] *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-02 (Sept. 15, 2015) (1.47 million dosage units of oxycodone to Nevada customers in 2009, 2.8 million dosage units of oxycodone. To Nevada customers in 2010, and 192,000 doses to Nevada customers in 2011.

[198] *Id.* (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,316, 62,322 (2012)).

692. The Defendants illegally promoted the sale of dangerous and harmful drugs, in violation of the Nevada Controlled Substances Act, §§ 453.005 to 453.730, by supplying suspicious orders for opiates to retail pharmacies, hospitals, and other health care facilities throughout the State of Nevada that the Defendants knew were suspicious, including orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

693. The laws at issue here, and cited above, are public safety laws.

694. The Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

695. The Distributor Defendants' violations of public safety statutes constitute prima facie evidence of negligence under Nevada law.

696. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.[199]

697. The Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates originating from Nevada.

698. The Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful. They refuse to abide by the duties imposed by law which are required to maintain a Nevada license to distribute prescription opiates.

699. The Defendants have misrepresented their compliance with Nevada law, both to the public and to Nevada state regulators.

700. The Defendants enabled the supply of prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

[199] *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

701. The Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into Nevada and into areas surrounding Nevada from which opioids were illicitly diverted into Nevada.

6. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement.

702. To protect their registered distributor status with *inter alia* the Nevada Board of Pharmacy, Defendants undertook efforts to fraudulently assure the public that they were complying with their obligations under licensing regulations. Through such statements, Defendants attempted to assure the public they were working to curb the opioid epidemic.

703. When a manufacturer or distributor does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting and without maintaining effective controls against diversion by those involved in the supply chain, law enforcement may be delayed in taking action – or may not know to take action at all. Indeed, this notice to law enforcement is the very essence of what the suspicious order reporting requirements are all about.

704. After being caught for failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future," including specific measures delineated in a "Compliance Addendum" to the Settlement. Yet, in 2017, McKesson paid $150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson

had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written promises not to do so.

705. More generally, the Distributor Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: "We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing 'the right thing' serves everyone." Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription-controlled medications that do not meet [its] strict criteria." Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

706. Along the same lines, Defendant McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process," creating the impression that McKesson uses this tracking to help prevent diversion. Defendant McKesson has also publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."

707. Defendant AmerisourceBergen, too, has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances." A company

spokeswoman also provided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients."

708. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Defendants, through their trade associations, the HDMA (now HDA) and the National Association of Chain Drugstores ("NACDS"), filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements.[200]

1. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

2. "Distributors 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."

709. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed, falsely, that their conduct was in compliance with those obligations.

710. Defendant Mallinckrodt similarly claims to be "committed. . . to fighting opioid misuse and abuse," and further asserts that: "In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances . . . ."

711. Other Manufacturer Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its

[200] Brief for HDMA and NACDS, *Masters Pharms., Inc. v. U.S. Drug Enf't Admin.,* Case No 15- 1335, 2016 WL 1321983, (D.C. Cir. April 4, 2016) at *3-4, *25.